



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL
Directorate C - Public Health and Risk Assessment
C7 – Risk assessment

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EXPLANATIONS FOR THE CHANGES IN THE SCHER MANDATE ON FLUORIDE FOLLOWING THE PUBLIC CONSULTATION ON THE WORKING MANDATE

This note sets out the rationale for the modifications made to the 'working mandate' destined for its Scientific Committee on Health and Environment Risks (SCHER) titled : *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 the most common fluoridating agents including silicofluorides (e.g. (hydro)fluorosilicic acid, sodium silicofluoride, disodium hexafluorosilicate or hexafluorosilicic acid) in drinking water fluoridation* following a public consultation conducted between 17 March 2009 and 8 April 2009.

Introduction

In line with its procedures on Stakeholder Dialogue of the Commission non food Scientific Committees published on 15 September 2007, the Health and Consumers Directorate General of the European Commission, conducted a public consultation on the above 'working mandate' between 17 March 2009 and 8 April 2009. At the same time, a call for the submission of information was also conducted between 17 March 2009 and 26 April 2009. The 'working mandate' and background note put out in the consultation and the revised final mandate containing the track changes are found in the following link (link to be inserted).

Results/Participation

The Commission received a total of 97 comments to the working mandate. Whilst most comments arrived by the 8 April 2009 deadline, a number of comments were received after the deadline and as late as 24 April 2009. All comments were considered for their pertinence on the subject regardless of their submission date. In addition, in line with the rules of procedures of the Commission Scientific Committees¹, the SCHER working group has also commented on the working mandate. In introducing changes to the mandate, efforts were made to thematically group comments and introduce all possible pertinent changes.

Modifications to the Mandate

The working mandate has been modified to take into account all pertinent comments that were submitted and were within the competences of the Scientific Committees and respected

¹ http://ec.europa.eu/health/ph_risk/documents/ev_20040907_rd01_en.pdf

the clear separation between risk assessment and risk management that underpins the Scientific Advisory structure of the European Commission. Comments on policy, risk management, legal clarification and status, were not considered as although pertinent to the subject matter are outside the competences of the Scientific Committees. Detailed explanations of the changes to the working mandate are provided below. The numbering of paragraph and lines in the explanations below correspond to the sections of the 'working mandate' which was submitted to the public consultation.

Changes to the working mandate and background document

1. Title: The phrase '*after 2005*' in line 1 has been deleted in light of comments received that pertinent evidence before 2005 that was not considered in previous scientific reviews should also be considered. The phrase '*the most common drinking water fluoridating agents including..*', in line 4, has been added to the title in response to comments to enlarge the scope to include all fluoridating agents which may be used rather than limiting the focus of the consultation on fluorosilicates. The phrase '*in drinking water fluoridation*' in line 8 has been deleted as being redundant.

2. First paragraph, lines 1-2: phrase '*it is beneficial*' has been modified to '*it is considered to be beneficial*' in response to comments suggesting a less absolute way to reflect on the available scientific evidence and debate on the subject.

3. Second paragraph, lines 1-2 and line 4: the phrases '*While no one doubts the beneficial effects of fluoride*' in line 1 has been deleted and '*excessive intake of fluoride*' has been replaced by '*fluoride intake*' in lines 2 and 4 in response to comments suggesting a less absolute way to reflect on the available scientific evidence and debate on the subject.

4. Second paragraph, line 6: phrase '*developing brain and other tissues*, has been added to the phrase '*Systemic effects following prolonged or high exposure to fluoride have also been reported and more recently effects on the thyroid...*' after comments and publications were received pointing to those effects.

5. Second paragraph, lines 7 and 8: phrase '*more recently but have not been properly documented*' at the end of the sentence has been deleted as being redundant.

6. Third paragraph, lines 3-6: the phrase '*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*' has been replaced by the entire paragraph 4 of the 'working mandate' which has been spilt into two sentences to improve readability as follows: '*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*'. *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 change was in light of comments to avoid pre-empting conclusive statements in the background and to improve the readability and the logical flow of the text.

7. Third paragraph, line 8: After the modifications described under point 6 above, this has now become the first sentence of the fourth paragraph starting with '*Exposure assessment was conducted...*'

8. Third paragraph, line 8: Format of references of EFSA opinions was corrected and the phrase '*and 2008, on calcium fluoride and sodium monofluorophosphate as sources of fluoride*' was added for completeness.

9. Fifth paragraph, first sentence (lines 1-3): Changed from the original and has become a stand alone paragraph: '*The potential for negative health effects that may result from excessive intake have put in question the practice of intentional water fluoridation in some parts of the European Union and elsewhere (USA).*' to '*There is a continuous controversy over the benefit of fluoride and, in particular, the practice of intentional water fluoridation in tooth decay prevention. This has led several countries to discontinue the practice of intentional water fluoridation while others continue to maintain it and in some cases expand it.*' The changes were in order to present a factual and neutral account of the present situation after scientific argumentation and evidence received both in favour and against water fluoridation.

10. Fifth paragraph, second sentence (line 3 and onwards) : It has now become a stand alone paragraph containing the original text with the following modifications after comments and evidence were received to possible toxicity/adverse health effects of the fluoridating agents themselves: '*...have pointed to scientific evidence showing that the health and environmental risks of the most common fluoridating agents, silicofluorides (e.g. (hydro)fluorosilicic acid, sodium silicofluoride, disodium hexafluorosilicate or hexafluorosilicic acid) have not been properly assessed and point to evidence that these chemicals in drinking water may cause adverse effects to the health of humans and exert possible exacerbating effects on fluoride disposition in bone.*

11. Terms of reference, general: The questions have been rearranged and renumbered for clarity following a number of comments that pointed to confusion between the question on fluoride and the one on fluoridating agents. Hence question 1 now concerns the evaluation of fluoride and includes a number of sub-questions to help orient the work of the SCHER whereas question 2 concerns the assessment of fluoridating agents. Finally, the phrase '*for Scientific Committees*' has been deleted as being redundant.

Introduction : It has been simplified by stating simply what the SCHER is asked to do

Question 1 : The sentence '*Taking into consideration the SCCP opinion of 20.09.05 on the safety of fluorine compounds in oral hygiene products, the EFSA NDA opinion of 22.02.2005 on the Tolerable Upper Intake Level of Fluoride, and the EFSA CONTAM panel opinion of 22.06.05,*' has been moved here as a general introduction to question 1, rather than to the entire mandate as it was before in the 'working mandate'

Question 1, part a): The sentence '*In particular the Committee should consider evidence that has become available after 2005 but also evidence produced before and which was not considered by the SCCP and EFSA panels at the time*' has been added following comments pointing to evidence available before 2005 which was not referenced in the SCCP and EFSA opinions and hence may not have been considered by them.

Question 1, part b, line 1: The first sentence, '*If supported by information that has become available in the public domain since 2005 concerning the exposure of humans to fluoride from all sources*' has been deleted since comments were supportive of the need for an integrated assessment.

Question 1, part c: This has now been split in two parts. Part a) remains unchanged as in the working mandate. Part B ' *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*' has been added following comments that certain exposure situations/uses of fluoride are more efficient in preventing tooth decay than others and hence there is merit for the SCHER to examine and rank the evidence in terms of efficiency.

Comments for which no changes could be made

In addition to the comments received which resulted in the above changes, the following comments were received which were outside the scope of the mandate itself and/or the competences of the SCHER and hence could not be addressed by modifications in the mandate. The key comments in that category are summarised below and brief explanations are provided as to the reasons they were not considered.

1. Comments requesting that the SCHER should decide for or against intentional water fluoridation

These comments concern risk management (policy) decisions and as such are outside the competences of the Commission Advisory Structure and Scientific Committees which operate under a clear separation between risk assessment and risk management. Hence those comments were not considered but scientific documentation and input that accompanied them was.

2. Fluoridation agents should be considered and assessed as medicines under the Directive 2001/83/EC (Medicinal Products Directive) or as food under Regulation 178/2002/EC

These comments concern the legal status of the fluoridating agents and hence are outside the competences of the SCHER and were not considered for this mandate. The questions on the legal status of fluoridating agents have been addressed by the Commission on previous occasions² in response to questions from the European Parliament.

3. Comments doubting the appropriateness of SCHER to conduct an integrated risk assessment.

The SCHER one of the few European Union Scientific bodies able by virtue of its composition, competence, and experience in reviewing the integrated assessments conducted under the Existing Substances Regulation (793/93/EEC) to conduct integrated risk assessments on chemicals with multiple uses and resulting exposures to humans and to the environment. Hence, it is appropriate that it is commissioned by the European Commission to conduct this assessment. As it is a non food Scientific Committee, it will rely heavily on the expertise of European Food Safety Authority (EFSA) for the food related (including bottled mineral water) aspects of the issue. This cooperation has already been agreed by the European Commission Health and Consumers Directorate General and EFSA.

4. As a matter of urgency in light of the potential adverse health effects, the fluoride assessment should be conducted under the Rapid Advise provisions of the Commission

² Answers given by Commissioners M. Kyprianou, S. Dimas, A. Vassiliou and G. Verheughen to European Parliament questions 3036/06, 2889/07, 5436/07, 5458/07, 3410/08 by the Honourable K. Sinnott (Ireland) and 4184/07 by the Honourable G. Ford (United Kingdom)

Decision (2008/721/EC) establishing the European Commission Scientific Advisory Structure

Article 2, point 3 of the Commission Decision (2008/721/EC) establishing the Commission Scientific Advisory Structure stipulates that the Commission may request the Scientific Committees for rapid advice 'concerning specific risks in case of urgent needs'. These provisions are essentially intended to provide the European Commission with rapid scientific advice in cases of new or emerging urgent health or environmental risks. The issue of fluoride has been debated scientifically for a good number of years, has been evaluated by a number of scientific bodies on several occasions, is underpinned by a substantial body of scientific evidence, and therefore requires a careful in depth analysis and proper consideration of all available evidence. For those reasons, the European Commission has decided to request a comprehensive analysis of the state of the scientific evidence on fluoride and the fluoridating agents.