

HUMAN HEALTH RISKS ASSOCIATED WITH THE MASS FLUORIDATION OF THE PUBLIC DRINKING WATER SUPPLY

ALLIANCE FOR NATURAL HEALTH RESPONSE TO:

Second public call for the submission of new information or data on the hazard profile, health effects, and human exposure to fluoride and information and data on the health risks that may be associated with the use of most common drinking water fluoridation agents like silicofluorides (e.g. (hydro)fluorosilicic acid, sodium silicofluoride).

Call notification:

http://ec.europa.eu/health/ph risk/committees/04 scher/scher call info 05 en. htm

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The following comments are made by the Alliance for Natural Health, a non-governmental organisation comprised of scientists, doctors, other health practitioners and consumers seeking to develop and promote more sustainable systems of healthcare based around nature. More details about the ANH can be found at our website: www.anhcampaign.org.

With regard to the call by the SCHER for scientific information concerning the risks associated with fluoridation, we argue that the scientific justifications by governments promoting mass artificial fluoridation (typically in the range 0.8-1.2 mg F/L), namely Ireland and the UK, are flawed. If risk/benefit evaluation of mass drinking water fluoridation is to be undertaken, it must include evaluation of all other options for reducing dental caries, including those that include and exclude the use of fluoridated products.

Our comments are set out in numbered sections, each providing a component of the logic that demonstrates the scientifically invalid and public health endangering nature of mass fluoridation. Key references are given to support each point.

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1. Any new assessment of risk of drinking water fluoridation has to be seen in the context of other risk assessments undertaken, particularly that undertaken by the Scientific Committee on Food (SCF) or the European Food Safety Authority (EFSA).

The Tolerable Intake Levels established by the EFSA (2005) are as follows:

- 1.5 mg/day for children aged 1-3 years
- 2.5 mg/day for children aged 4-8 years
- 5 mg/day for children aged 9-15 years
- 7 mg/day for children over 15 years and adults

Key reference:

EFSA, 2005. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride. *The EFSA Journal* 192, 1-65.

2. Identification of vulnerable groups

There is general agreement among risk assessors and scientists, as well within the dental and medical professions, that children represent the primary vulnerable group.

In particular there is now good evidence to suggest that the most critical ages for fluoride exposure in relation to the development of enamel fluorosis, which in turn may create conditions that exacerbates dental caries, are 15 - 30 months of age, with slight differences between males and females.

Key references:

Browne D, Whelton H, O'Mullane D. Fluoride metabolism and fluorosis. *J Dent.* 2005; 33(3): 177-86.

Alvarez JA, Rezende KM, Marocho SM, Alves FB, Celiberti P, Ciamponi AL. Dental fluorosis: exposure, prevention and management. *Med Oral Patol Oral Cir Bucal*. 2009; 14(2): E103-7.

3. Impact of the most sensitive risk, namely dental fluorosis

There is also no dispute as to the fact that dental fluorosis is the most sensitive risk factor. However, peculiarly, among government authorities that promote drinking water fluoridation, there is a widespread, yet scientifically

unjustified view, that dental fluorosis is merely a cosmetic or aesthetic problem and that no other adverse effects are associated with it. This view is irrational since it is well known that even slight pitting of the enamel associated with moderate fluorosis creates increased accumulation of bacteria or food particles which exacerbate dental caries. Given that the treatment regime that is intended to treat or prevent dental caries may actually increase its risk, levels of fluoride exposure which give rise to dental fluorosis should not be tolerated because they are outweighed by a risk which is rarely considered.

French researchers have recently identified, via *in vitro* study, the likely mechanism for the impact of low-levels of fluoride on symptoms of dental fluorosis, relating to the effects of fluoride to fluoride-sensitive genes which "may impair the formation of the extracellular matrix and influence cell communication" in odontoblasts (tooth forming cells) in babies.

Based on such a mechanism, it is reasonable to assume that other genes may also be impacted adversely. Faced with this evidence, it would in any event be irresponsible to assume that all genes are insensitive to the levels of fluoride to which all persons in the population are exposed should the public drinking water supply be fluoridated.

Key reference:

Wurtz T, Houari S, Mauro N, MacDougall M, Peters H, Berdal A. Fluoride at non-toxic dose affects odontoblast gene expression in vitro. *Toxicology*. 2008; 249(1): 26-34. Epub 2008 Apr 25.

The effect of fluoride on odontoblasts was shown previously by other workers in China and the UK.

Key references:

Liu H, Wang Q, Zhu F, Luo PP, Liu TL, Wei XL. [Effect of fluorosis on the expression of basic fibroblast growth factor in rat incisors]. *Zhonghua Kou Qiang Yi Xue Za Zhi.* 2007; 42(4): 242-4. Chinese.

Moseley R, Waddington RJ, Sloan AJ, Smith AJ, Hall RC, Embery G. The influence of fluoride exposure on dentin mineralization using an in vitro organ culture model. *Calcif Tissue Int.* 2003; 73(5): 470-5.

4. Determination of the threshold concentration of fluoride in drinking water over which dental fluorosis becomes significant

Established evidence suggests that fluorosis (of at least mild severity) will develop in a significant proportion of the population in areas where the fluoride content of drinking water exceeds 0.7 mg/L.

Key references:

Bottenberg P, Declerck D, Ghidey W, Bogaerts K, Vanobbergen J, Martens L. Prevalence and determinants of enamel fluorosis in Flemish schoolchildren. *Caries Res.* 2004; 38(1): 20-8.

Ekanayake L, van der Hoek W. Prevalence and distribution of enamel defects and dental caries in a region with different concentrations of fluoride in drinking water in Sri Lanka. *Int Dent J.* 2003; 53(4): 243-8.

Yang J, Long Y, Shen Y. The optimal concentration of drinking water in eastern Guangdong. *Hua Xi Kou Qiang Yi Xue Za Zhi*. 2001; 19(1): 38-40.

Wondwossen F, Astrom AN, Bjorvatn K, Bardsen A. The relationship between dental caries and dental fluorosis in areas with moderate- and high-fluoride drinking water in Ethiopia. *Community Dent Oral Epidemiol*. 2004;32 (5): 337-44.

NB. Such evidence is further supported by the pre-2005 North-South Survey in Ireland which demonstrated that 39% of 15-year-olds presented with some degree of dental fluorosis.

Key reference:

Whelton H, Crowley E, O'Mullane D, Cronin M, Kelleher V. Children's oral health in Ireland 2002: preliminary results. A North-South survey coordinated by the Oral Health Services Research Centre, University College Cork. Dublin, Department of Health and Children, Dublin. 2003. 60 pp (specifically p. 36). See:

http://www.dohc.ie/publications/pdf/coral.pdf?direct=1

A systematic review carried out by York University concluded that dental fluorosis would occur in 48% (95% CI 40 to 57) of the population at when water is fluoridated at the level fo 1 mg / L.

Key reference:

McDonagh M, Whiting P, Bradley M et al. (2000) Fluoridation of Drinking Water: a systematic review of its efficacy and safety. CRD Report (18). NHS Centre for Reviews and Dissemination, York, UK. ISBN 1 900640 16 3

5. Determination of the mean or maximal dose to which the most vulnerable sub-population is exposed in fluoridated areas.

The volume of drinking water recommended for a 12-month-old child is 1.3 L.

Key reference:

Institute of Medicine of the National Academies. *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride and Sulfate* (2004). Washington DC: The National Academies Press. http://books.nap.edu/catalog/10925.html.

Therefore, assuming artificial fluoridation occurs at 1 mg F/L, a 12-month-old child, amongst the most vulnerable members of society, would be exposed to 1.3 mg of fluoride, almost twice the threshold deemed to give rise to dental fluorosis.

Based on this fact alone, mass fluoridation of the water supply exposes infants to significant risks and therefore should not be considered as an acceptable and beneficial health measure.

6. Evaluation of total exposure

There are inadequate high-quality data to determine total exposure of fluoride from all sources in different parts of Europe. As such, it is essential that a large safety margin is built-in between the Tolerable Intake Level and the highest mean intakes that might be consumed in fluoridated water.

The issue of the importance of total exposure to fluoride in the evaluation of risk was raised as being of crucial importance in the York Review.

Exposure to fluoride in toothpaste and dental care products in its own right, irrespective of exposure to drinking water, may expose children in particular to significant risks.

Key references:

Ismail AI, Hasson H. Fluoride supplements, dental caries and fluorosis: a systematic review. *J Am Dent Assoc.* 2008; 139(11): 1457-68.

Meyer-Lueckel H, Bitter K, Hopfenmuller W, Paris S. Reexamination of Caries and Fluorosis Experience of Children in an Area of Jamaica with Relatively High Fluorosis Prevalence. *Caries Res.* 2009; 43(4): 250-253.

The World Health Organization (1984) has indicated that fluoride consumption from tea and herbal infusions alone can lead to skeletal fluorosis, a form of fluorosis that is of even greater public health concern than dental fluorosis.

Key reference:

Malinowska E, Inkielewicz I, Czarnowski W, Szefer P. Assessment of fluoride concentration and daily intake by human from tea and herbal infusions. *Food Chem Toxicol.* 2008; 46(3): 1055-61.

7. Delivering optimum levels of fluoride via drinking water

There is little scientific basis to the widely held view, common among government authorities which promote drinking water fluoridation, that "optimal" intake levels of fluoride are between 0.05 and 0.07 mg fluoride per kilogram of body weight (mg F/kg bw). Higher quality studies demonstrate that levels of intake *at or below* 0.05 mg F/kg bw are required if both fluorosis and dental caries are to be avoided. In other words, existing recommended ranges, that would be commonly achieved, or exceeded, if water is fluoridated at the level of 1 mg/L, are in excess of the levels that are likely to be optimal.

Furthermore, high variation in fluoride intake both as a result of variations in drinking water consumption, as well as from variations in consumption of fluoride from other sources, means that the concept of delivery of optimal levels in drinking water is scientifically invalid.

Key reference:

Warren JJ, Levy SM, Broffitt B, Cavanaugh JE, Kanellis MJ, Weber-Gasparoni K. Considerations on Optimal Fluoride Intake Using Dental Fluorosis and Dental Caries Outcomes - A Longitudinal Study. *J Public Health Dent*. 2008 Nov 21 [ahead of print].

8. Bioavailability of synthetic vs natural fluorides, under varying circumstances (e.g. water hardness)

The comparative bioavailability of artificial and natural fluorides are not adequately understood, although existing evidence suggests that artificial fluorides, such as fluorosilicic acid, are even more bioavailable than naturally occurring forms, such as calcium fluoride. Given that artificial fluorides are likely to be almost completely absorbed by the body, their risk at a given dosage is likely to be considerably greater than caused from chronic ingestion of natural fluorides. However, many studies on natural fluorides have been used in risk assessments evaluating the feasibility of intentional fluoridation when these are not directly relevant and will understate risk owing to the typically lower bioavailability of naturally-occurring fluorides.

Key references:

World Health Organization (2002) *Fluorides. Environmental Health Criteria* 227. World Health Organisation, Geneva.

Maguire A, Zohouri FV, Mathers JC, Steen IN, Hindmarch PN, Moynihan PJ. Bioavailability of fluoride in drinking water: a human experimental study. *J Dent Res.* 2005; 84(11): 989-93.

Conclusions

Since there is no safety margin (and often an overlap) between those levels required to significantly reduce the risk of dental caries in children and exposures that may result in dental fluorosis or other adverse effects, including some which may not yet have been elucidated, there is no justifiable scientific basis to consider the population-wide medication of the water supply with fluoride. Alternative strategies of fluoride delivery, which allow more specific targeting and dosing should be considered in place of fluoridation, as well as non-fluoride related dental care strategies, such as methods of improved dental hygiene and reduced sugar consumption.

There is considerable scientific uncertainty in much of the scientific data used in risk assessments by government authorities that have found ways of justifying their decision to support mass fluoridation of drinking water. Such risk assessments fail to take into account the usual, precautionary-based methods of handling public health risks, which typically involve using large uncertainty factors (greater than or equal to 10) applied to the Lowest Observable Adverse Effect Levels. If such methods are used, the maximum level proposed for fluoridation of drinking water would be less than one-tenth of the levels at which water is typically artificially fluoridated in the UK and Ireland (e.g. <0.1 mg/L instead of 1 mg/L).

It is apparent that there are definite and considerable risks associated with mass fluoridation of the water supply. These risks are greatest for young infants, but the effects of long-term, lifelong exposure are yet to be determined. The risks associated with mass fluoridation of the public water supply are unpredictable particularly given the difficulty in controlling the dosage of fluoride (mg F / kg bw), itself dependent on the level of fluoride present in drinking water, the amount of drinking water consumed and the body weight of the consumer. In addition, there is some risk of accidental overexposure through human or mechanical error associated with fluoride metering into the water supply.

On the above grounds, there is no adequate scientific basis for acceptance of mass fluoridation of the public drinking water supply with artificial fluorides.