European Food Safety Authority

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TECHNICAL REPORT

Outcome of a public consultation on the Draft Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on Dietary Reference Values for fluoride[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Food Safety Authority (EFSA) carried out a public consultation to receive input from the scientific community and all interested parties on the Draft Scientific Opinion on Dietary Reference Values (DRVs) for fluoride, prepared by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) and endorsed by the Panel for public consultation at its Plenary meeting on 20 March 2013. The written public consultation for this document was open from 2 May 2013 to 14 June 2013 (9:00 am). EFSA received comments from six interested parties. EFSA and its NDA Panel wish to thank all stakeholders for their contributions. The current report summarises the outcome of the public consultation, and includes a brief summary of the comments received and how the comments were addressed. The NDA Panel prepared an updated version of the Scientific Opinion on Dietary Reference Values for fluoride taking into account the questions/comments received. This Opinion was discussed and adopted at the NDA Plenary meeting on 11 July 2013, and is published in the EFSA Journal.

KEY WORDS

fluoride, Dietary Reference Value, Adequate Intake, public consultation

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TABLE OF CONTENTS

BACKGROUND

Scientific advice on nutrient intakes is important as the basis of Community action in the field of nutrition; for example, such advice has in the past been used as the basis of nutrition labelling. The Scientific Committee for Food report on nutrient and energy intakes for the European Community dates from 1993.

In 2005, the European Commission asked EFSA to review and if necessary update such advice to ensure that Community action in the area of nutrition is underpinned by the latest scientific advice. To this end, EFSA has been requested to consider the existing Population Reference Intakes for nutrients and certain other dietary components.

The Scientific Opinion on general principles for deriving and applying Dietary Reference Values, and the Scientific Opinions on Dietary Reference Values for water, for fats and for carbohydrates and dietary fibre were published in 2010. The Scientific Opinions on Dietary Reference Values for protein and for energy were published in 2012 and 2013, respectively. The public consultations on the draft Opinions on Dietary Reference Values for fluoride and for molybdenum were launched at about the same time and were the first consultations for Draft Opinions on Dietary Reference Values for micronutrients.

TERMS OF REFERENCE

In line with EFSA's policy on openness and transparency, and in order for EFSA to receive comments from the scientific community and stakeholders, EFSA shall release the Draft Scientific Opinion on Dietary Reference Values for fluoride for public consultation. The comments resulting from the public consultation shall be published in a technical report.

Before its adoption by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel), the Draft Scientific Opinion on Dietary Reference Values for fluoride needs to be revised, taking into account the comments received during the public consultation.

CONSIDERATION

1. Introduction

Upon request from the European Commission and following previously published Scientific Opinions on Dietary Reference Values for water, fats, carbohydrates and dietary fibre, protein, and energy, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) developed a Draft Scientific Opinion on Dietary Reference Values for fluoride. In line with EFSA's policy on openness and transparency, and in order for EFSA to receive comments on its work from the scientific community and stakeholders, EFSA engages in public consultations on key issues. Accordingly, the Draft Scientific Opinion was published on EFSA's website for comments (2 May 2013 to 14 June 2013, 9:00 am[4]) (see Appendix A). The NDA Panel prepared an updated version of the Scientific Opinion, taking into account the comments received. The updated Scientific Opinion was discussed and adopted at the NDA Plenary meeting on 11 July 2013, and is published in the EFSA Journal (EFSA NDA Panel). EFSA is committed to publishing the comments received during the public consultation, as well as a short report on the outcome of the consultation.

2. Screening and evaluation of comments received

2.1. Comments received

EFSA received 68 comments from six interested parties. Three were from (non-profit) Non-Governmental Organisations dedicated to promoting natural approaches to healthcare or to campaigns for non-fluoridated water and for increasing awareness about the toxicity of fluoride compounds, and three were submitted by individuals in a personal capacity. A summary of the comments is given below, and all written comments received are listed in Appendix B. The numerous comments related to policy or risk management aspects were considered to be outside the scope of the consultation, and are not covered in this report.

2.2. Nature of specific comments

The main issues raised in the comments received are summarised below. The NDA Panel has reviewed all comments carefully and has updated the Scientific Opinion on Dietary Reference Values for fluoride accordingly. The updated Scientific Opinion is published in the EFSA Journal[4].

2.2.1. Functions and health consequences of fluoride

Comments received

- The inverse relationship between fluoride intake and dental caries and the beneficial effect of fluoride on dental health was questioned. Publication bias was suggested as one reason that led to the establishment of this association.
- It was hypothesised and repeatedly mentioned that the caries-preventive effect may be due to vitamin D and not to fluoride, and that scientific studies evaluating the effect of fluoridation measures have usually not accounted for UV-B exposure.
- It was stated that the lower prevalence of caries is due to a delay in tooth eruption caused by fluoride (in water), and consequently to a lower exposure time to a cariogenic environment rather than to fluoride *per se*; it was also stated that this confounder has mostly not been taken into account in scientific studies.

[4] The foreseen closure date of the public consultation was 13 June 2013. However, on 13 June 2013 it was impossible to submit comments between noon and 5:30 pm due to technical problems. Therefore, the time for submitting comments was extended until 14 June 2014, 9:00 am.

- It was stated that fluoride acts as a cytoplasmic poison and that fluoridation leads to cytoplasmic disturbances and impairment of cytoplasmic functional efficiency denoted as "subclinical". It was suggested that the section on physiology and metabolism of fluoride be changed accordingly.
- Differences in naturally occurring fluorides and synthetic fluorides were pointed out, for example with respect to pharmacokinetic profiles and absorption efficiency. It was stated that these differences have not always been taken into account when assessing the effects of fluoridation.
- It was repeatedly stated that the use of fluoride to prevent dental caries refers to medicinal use of fluoride, as the fluoride salts used for caries prevention are not considered products for which an exemption has been granted, i.e. foods, food supplements, cosmetics or medical devices, and that the permission for use of sodium fluoride and calcium fluoride in food supplements was erroneously granted by the EC.
- It was stated that the water fluoride concentration associated with beneficial effects is lower (i.e. 0.3 ppm and not 1.0 ppm) than given in the draft opinion and that no further reductions in caries prevalence are observed with higher concentrations.

Panel consideration of comments received

- The person submitting the comment did not provide evidence for publication bias. The NDA Panel disagrees with the comment on selection bias in performing its task. Pertinent studies were selected from the available publications with regard to quality of study design, study execution, processing of data and reporting. No peer-reviewed scientific publications were submitted that would alter statements in the Opinion; for example, one report (Ziegelbecker and Ziegelbecker, 1993) that showed no or inverse associations between fluoride content of drinking water and DMFT scores of children did not take into account any confounding parameters.
- EFSA's NDA Panel agrees, and has stated in the Opinion, that dental health is determined by many factors besides fluoride. Vitamin D, either from the diet or from endogenous synthesis, may be one of them. However, a potential association between higher sunlight exposure and lower caries prevalence does not detract from the possibility of separate mechanisms involving, among others, fluoride.
- EFSA's NDA Panel agrees that the assessment of occurrence and severity of caries should take into account the time between eruption of the tooth and the appearance of carious lesions. However, there is only limited evidence for a delay in eruption of permanent teeth in children from areas with fluoridated water (1.0 ppm) compared to areas with non-fluoridated water (0.2 ppm) (Künzel, 1976; Virtanen et al., 1994; Leroy et al., 2003), and it has not been quantified. Moreover, a delay in eruption (if it exists) might indicate a beneficial effect of fluoride in preventing caries in primary teeth. Delayed tooth eruption could affect caries scoring for different age groups (NRC, 2006). There is a secular trend for later tooth eruption, a sex effect and geographical differences. The reported differences of less than a year are, however, unlikely to be responsible for decreases in caries prevalence of permanent teeth associated with fluoride, considering the biological variation of age at eruption. One study (Komarek et al., 2005) performed a Bayesian survival analysis to examine the effect of fluoride intake on the time to caries development in the permanent premolars in children between 7 and 12 years of age. This analysis is based on data from 4 468 Flemish schoolchildren examined yearly for tooth health over a period of six years. In this study, a positive effect of fluoride was only found for mandibular teeth of boys. However, fluoride exposure was not assessed. Instead, children were classified as presenting with or without dental fluorosis (diagnostic criterium white spots on at least two permanent maxillary incisors during the fourth or during both the fifth and sixth examination) with 10.8 % of children affected. This analysis does not permit conclusions on a dose-response relationship because too many assumptions were made.
- This Opinion is not intended as an assessment of fluoride toxicology, in line with the Terms of Reference; therefore, some mechanisms of toxicity are only very briefly mentioned in Section

2.2.4.2. More details are given in the Opinion on the Tolerable Upper Intake Level (UL) of fluoride (EFSA, 2005).

- Absorption of different fluoride compounds occurring in food is described in Section 2.3.1. of the Opinion. The Panel concluded that the available data are insufficient for absorption of fluoride to be taken into account in setting an Adequate Intake (AI).
- The suggested misclassification in European food law of fluoride as a food constituent is not in the remit of the NDA Panel, but see Section 2.2.4. of this Technical Report.
- The NDA Panel has assessed caries risk in relation to total fluoride intake and not particularly the association between fluoride concentration in drinking water and caries risk.

It was considered that no change in the Scientific Opinion was needed on the basis of these comments.

2.2.2. Topical fluoride application vs. fluoride ingestion, especially via fluoridated water

Comments received

- It was stated that in children the caries-protective effect of fluoride is seen after topical application, but that there is no benefit from oral fluoride intake.
- With reference to the report by SCHER (2010) it was stated that water fluoridation does not provide dental health benefits over topical fluoride application. It was also stated that caries control should be via "clinically tested fluoride vehicles" (i.e. presumably fluoride varnishes). The importance of regular dental hygiene, dental examinations and other measures for caries prevention (e.g. screening for *Streptococcus mutans* counts in pregnant women in Scandinavian countries) was mentioned. It was mentioned that caries prevalence has declined irrespective of water fluoridation and that water fluoridation measures are no longer cost-effective.

Panel consideration of comments received

- In its opinion on DRVs for fluoride, the AI is for intake from all sources. There is no recommendation for a specific fluoride source (e.g. topical fluoride application or fluoride intake via certain foods). The effects of fluoride intake from supplements on caries risk are assessed in the systematic reviews of Tubert-Jeannin et al. (2011) and Espelid (2009) in Section 5.2.1.2. of the Opinion.
- It is already mentioned in the Opinion that caries development is multifactorial (Section 5.2.1.) and that fluoride application is one of several factors which contribute to dental health. The assessment or comparison of different public health measures (such as water fluoridation), and of dental health care in particular circumstances, is outside the remit of this Scientific Opinion.

It was considered that no change in the Scientific Opinion was needed on the basis of these comments.

2.2.3. Health consequences of excess

Comments received

- It was suggested that more information on the effects of fluoride on the brain, especially during its development, be added.
- It was pointed out that fluoride had other adverse effects besides those on teeth and bone, particularly on the endocrine system.
- Disagreement was expressed with the classification of dental fluorosis as being of cosmetic significance, except for severe dental fluorosis. It was stated that moderate fluorosis creates increased accumulation of bacteria or food particles which may exacerbate dental caries.

- It was pointed out that the association of fluoride intake with fracture risk may be different in "normally aged bone" and in "osteoporotic" bone. It was stated that water fluoridation significantly increases fractures.

Panel consideration of comments received

- Since the publication in 2005 of the Opinion on the UL for fluoride, more information has become available on a potential unfavourable association between fluoride exposure and neurodevelopment, particularly cognitive function. In a recent systematic review and meta-analysis of 27 eligible observational studies which compared IQs or related function measurements of subjects highly exposed to fluoride to subjects living in areas with low fluoride exposure, and which provided mean outcome measures and indicators of variance (standard error or 95 % confidence intervals, CIs) and the number of participants, the authors found in a random-effects model an inverse relationship between fluoride exposure (high versus low fluoride group) and IQ scores with a standardised weighted mean difference of -0.45 (95 % CI -0.56, -0.34; I^2 77.6 %) when all studies were pooled. When studies were excluded from the calculation because of heterogeneity, the difference became smaller. The relative risk of having a low (≤ 69) or marginal (70-79) IQ score on the Chinese version of the Combined Raven's Test on high exposure to fluoride compared to low exposure was 1.75 (95 % CI 1.16, 2.65). It was somewhat higher when data from studies using other tests were included (Choi et al., 2012). This review has methodological limitations by being based on 25 studies from China and on two studies from Iran, from which only one provides data on total dietary fluoride intake, whilst 21 indicate the drinking water fluoride concentrations, four indicate only "low" and "high" without giving numbers (in three of these "high" is defined by the prevalence of dental fluorosis), and in two fluoride exposure is due to coal burning. The fluoride concentration in drinking water varies in the "high" exposure groups from 0.88 to 11.5 mg/L, whilst in the "low" exposure group the fluoride concentration in water varies between 0.18 and 2.35 mg/L. The latter concentration is higher than the 1.5 mg/L permitted in the EU for water intended for human consumption (Council Directive 98/83/EC[5]). This review does not allow a dose-response relationship to be established, and therefore does not contribute to the setting of a Dietary Reference Value (DRV). In addition, seven of the studies did not take into account either low iodine status or water contamination with arsenic. Other contaminations are not mentioned or excluded, nor is information available regarding nutritional status or sociodemographic data, particularly education of the parents.
- This Opinion on DRVs for fluoride is not intended to repeat the assessment of toxicity, but briefly describes the adverse effects of excessive fluoride intake from all sources on the dental system and on the bone system. In Sections 3.1. and 3.2. of the Scientific Opinion on the UL of fluoride (EFSA, 2005) fluoride toxicity in animals and humans is discussed in detail based on the then available data. The inconclusiveness of available data for carcinogenic, genotoxic and reproductive effects of fluoride in humans remains unchanged. Fluoride was also reported to affect human thyroid function. However, in most studies on this relationship, iodine and selenium were not considered, and they are both required for normal thyroid hormone production. For other adverse effects on the endocrine system, see NRC (2006), pages 189-224.
- The Panel states in lines 360-361 of the Opinion that "Very mild forms of dental fluorosis are of aesthetic concern only" and does not mention moderate forms.
- The Panel is not aware of any study that has differentiated between the fracture risk of "normally aged bone" and of osteoporotic bone. In Section 3.2.2.2. of the Opinion on the UL of fluoride (EFSA, 2005), fracture risk of bones in association with fluoride doses administered for prevention or treatment of osteoporosis is discussed.

It was considered that no change in the Scientific Opinion was needed on the basis of these comments.

[5] Directive 98/83/EC of the European Council of 3 November 1998 on the quality of water intended for human consumption, OJ L 330, 5.12.1998, p. 32.

2.2.4. Setting a DRV for fluoride

Comments received

- Disagreement was expressed with the fact that a DRV for fluoride is proposed, because, according to some comments, fluoride is not an essential nutrient, there are no signs of fluoride deficiency, fluoride is a biotoxic element, and the association between fluoride and caries development is unclear.
- It was stated that there is no benefit of systemic or topical fluoride application in adolescents and adults, and that a DRV should not be set for these groups.
- It was pointed out that the proposed DRV cannot be considered safe for the entire population including vulnerable groups such as patients with thyroid disease or those with end-stage renal disease.

Panel consideration of comments received

- Fluoride is naturally occurring in water and foods. It is a nutrient according to the definition in Article 2, 2(2) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on food. Fluoride is therefore included in the Terms of Reference provided by the European Commission to EFSA. EFSA's NDA Panel has provided DRVs for other non-essential nutrients like carbohydrates. DRVs include the Average Requirement (AR), Population Reference Intake (PRI), AI in cases where no AR can be determined, Reference Intake range for macronutrients (RI), and UL. Based on the nature of the nutrient and on available data, EFSA's NDA Panel decides which DRV can be set. For a non-essential nutrient like fluoride no requirement can be defined. Because of beneficial effects with respect to decreasing the risk of caries, the NDA Panel has defined an AI in its Opinion on DRVs for fluoride, and because of recognised adverse effects due to too high fluoride intakes, in 2005 EFSA has defined a UL. EFSA's NDA Panel is aware that the margin between the AI for fluoride of 3.4 and 2.9 mg/day for men and women, respectively, and the UL of 7 mg/day for adults is narrow, but it is the dose that determines whether a nutrient has physiological and/or nutritional effects or adverse effects. The case of fluoride is unusual insofar as the AI has to take account of non-dietary sources of fluoride like dental hygiene products.
- It is stated in the Opinion that the effects of fluoride on caries incidence and prevalence are predominantly assessed in children and adolescents. However, in a meta-analysis the effectiveness of oral (including via water) and topical fluoride application in adults above the age of 20 years and above the age of 40 years was found to be positive based on studies published after or during the 1980s. Using a random-effects model estimating the absolute difference in annual caries increment or the relative risk ratio, the summary difference in annual caries increment for any fluoride exposure (i.e. via fluoride-containing toothpaste, gel, varnish or rinse, or fluoridated water) was 0.29 coronal surfaces (95 % CI 0.16, 0.42) and 0.22 root surfaces (95 % CI 0.08, 0.37), compared to not-exposed adults. For water fluoridation, the prevented fraction was 27 % (95 % CI 19 %, 34 %) (Griffin et al., 2007). This study is already mentioned in Section 5.2.1.2. of the Scientific Opinion. In older adults (n = 160, 58-84 years of age), a randomised controlled trial of 15 months' duration assessed the effect of fluoride applied in milk on dental root caries. The numbers of root caries index reversals (i.e. higher numbers of inactive caries lesions and lower numbers of more severe active lesions than at baseline) were significantly ($p < 0.05$) higher in the fluoride intervention groups than in the placebo group. In the intervention groups, but not in the placebo group, electric resistance measurements at the carious lesions increased ($p < 0.05$), indicating that remineralisation had occurred (Petersson et al., 2011). The mechanisms of action on dental health described for fluoride should apply similarly in children and in adults (see Section 2.2.1. of the Scientific Opinion).
- The Scientific Opinion is targeted at the general healthy population but not at diseased populations such as subjects with thyroid disease or those with end-stage renal disease.

It was considered that no change in the Scientific Opinion was needed on the basis of these comments, except for the additional mentioning of the study by Griffin et al. (2007) in Section 5.2.1.1. and the addition of a description of the study by Petersson et al. (2011) in Section 5.2.1.2. of the Opinion.

REFERENCES

Choi AL, Sun G, Zhang Y and Grandjean P, 2012. Developmental fluoride neurotoxicity: a systematic review and meta-analysis. Environmental Health Perspectives, 120, 1362-1368.

EFSA (European Food Safety Authority), 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 2005, 192, 1-65. doi:10.2903/j.efsa.2005.2192

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific opinion on Dietary Reference Values for fluoride. EFSA Journal 2013;11(8):3332, 47 pp. doi:10.2903/j.efsa.2013.3332

Espelid I, 2009. Caries preventive effect of fluoride in milk, salt and tablets: a literature review. European Archives of Paediatric Dentistry, 10, 149-156.

Griffin SO, Regnier E, Griffin PM and Huntley V, 2007. Effectiveness of fluoride in preventing caries in adults. Journal of Dental Research, 86, 410-415.

Komarek A, Lesaffre E, Harkanen T, Declerck D and Virtanen JI, 2005. A Bayesian analysis of multivariate doubly-interval-censored dental data. Biostatistics, 6, 145-155.

Künzel VW, 1976. [Cross-sectional comparison of the median eruption time for permanent teeth in children from fluoride poor and optimally fluoridated areas]. Stomatologie der DDR, 5, 310-321.

Leroy R, Bogaerts K, Lesaffre E and Declerck D, 2003. The effect of fluorides and caries in primary teeth on permanent tooth emergence. Community Dentistry and Oral Epidemiology, 31, 463-470.

NRC (National Research Council), 2006. Fluoride in drinking water: a scientific review of EPA's standards. Committee on Fluoride in Drinking Water. Board on Environmental Studies and Toxicology. Division on Earth and Life Studies. National Academies Press, Washington DC, USA, 508 pp.

Petersson LG, Magnusson K, Hakestam U, Baigi A and Twetman S, 2011. Reversal of primary root caries lesions after daily intake of milk supplemented with fluoride and probiotic lactobacilli in older adults. Acta Odontologica Scandinavica, 69, 321-327.

SCHER (Scientific Committee on Health and Environmental Risks of the European Commission), 2010. SCHER pre-consultation opinion on critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water. 18 May 2010. 55 pp.

Tubert-Jeannin S, Auclair C, Amsallem E, Tramini P, Gerbaud L, Ruffieux C, Schulte AG, Koch MJ, Rege-Walther M and Ismail A, 2011. Fluoride supplements (tablets, drops, lozenges or chewing gums) for preventing dental caries in children. Cochrane Database of Systematic Reviews. 12, CD007592, 80 pp.

Virtanen JI, Bloigu RS and Larmas MA, 1994. Timing of eruption of permanent teeth: standard Finnish patient documents. Community Dentistry and Oral Epidemiology, 22, 286-288.

Ziegelbecker R and Ziegelbecker R, 1993. WHO data on dental caries and natural water fluoride levels. Fluoride, 26, 263-266.

APPENDICES

APPENDIX A. EXPLANATORY TEXT FOR THE PUBLIC CONSULTATION ON THE DRAFT SCIENTIFIC OPINION ON DIETARY REFERENCE VALUES FOR FLUORIDE

EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) has launched an open consultation on the draft scientific opinion on dietary reference values for fluoride. This document proposes dietary reference values for fluoride for adults, infants and children, pregnant and lactating women.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders, EFSA has launched a public consultation on the draft document developed by the NDA Panel of EFSA.

Interested parties are invited to submit written comments by 13 June 2013. Please use exclusively the electronic template provided with the documents to submit comments and refer to the line and page numbers. Please note that comments submitted by e-mail or by post cannot be taken into account and that a submission will not be considered if it is:

- submitted after the deadline set out in the call
- presented in any form other than what is provided for in the instructions and template
- not related to the contents of the document
- contains complaints against institutions, personal accusations, irrelevant or offensive statements or material
- is related to policy or risk management aspects, which is out of the scope of EFSA's activity.

EFSA will assess all comments from interested parties which are submitted in line with the criteria above. The comments will be further considered by the relevant EFSA Panel and taken into consideration if found to be relevant.

All comments submitted will be published. Comments submitted by individuals in a personal capacity will be presented anonymously. Comments submitted formally on behalf of an organisation will appear with the name of the organisation.

APPENDIX B. FULL LIST OF COMMENTS RECEIVED ON THE DRAFT SCIENTIFIC OPINION OF THE EFSA PANEL ON DIETETIC PRODUCTS, NUTRITION, AND ALLERGIES (NDA) ON THE DIETARY REFERENCE VALUES FOR FLUORIDE

This list contains the comments submitted to EFSA via the public consultation held from 02 May 2013 to 14 June 2013 (9 am). Comments submitted by individuals in a personal capacity are presented anonymously. Comments submitted formally on behalf of an organisation appear with the name of the organisation.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Anonymous	1. Introduction	Lines 209 to 217: 1. The introduction is incomplete: It doesn't contain the EFSA NDA's assessment of a Tolerable Upper Intake Level for fluoride (document "Opinion of the Scientific Panel on Dietetic, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride (Request No EFSA-Q-2003-018) (adopted on 22 February 2005)" which is by far too high to protect people, as demonstrated in Rudolf Ziegelbecker senior's submission to EFSA of Feb. 2006. It doesn't contain the EU Commission's SCHER committee's opinion of 2011 (http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_139.pdf) "Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water" which investigated the effects of fluoride in water. Among the results: "Systemic exposure to fluoride through drinking water is associated with an increased risk of dental and bone fluorosis in a dose-response manner without a detectable threshold." and "Scientific evidence for the protective effect of topical fluoride application is strong, while the respective data for systemic application via drinking water are less convincing". Personal comment: Indeed, SCHER's ONLY (SINGLE) seemingly impressive proof for a protective effect of fluoride in water is HEAVILY CONFOUNDED by the KNOWN CARIESTATICUM VITAMIN D from the SUN's UVB radiation. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3219170/, http://www.landesbioscience.com/journals/29/article/15841/, a paper which proves that in the U.S. vitamin D acts at least by far more caries protecting than water fluoridation).The UVB map and the fluoride-in-water-map of Denmark, where SCHER's example comes from, are evidently "linearly dependent" (="overlapping"; they seem almost identical for a non-scientific eye). Therefore SCHER's only impressive example for a caries-protective effect might be largely due to solar

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		UVB, not to fluoride. The author and his father gathered independent data from the WHO Geneva headquarter. All of the countries do NOT show any caries reduction by fluoride in water, rather an increase (http://www.fluorideresearch.org/264/files/FJ1993_v26_n4_p237-298.pdf - see pages 263-266) A re-look at this publication shows that in these countries (Spain, Malta, Sri Lanka, Greece) will get sufficient vitamin D and that in Hungary (like in Denmark) the seeming fluoride effect at very low fluoride-concentration in water can be possibly explained by differences in UVB, like in Denmark. A general association between sunshine, clouds, rain and fluoride in the water is at least imaginable to researchers. If this hypothesis holds, all fluoridation data worldwide would have to be revised since no fluoridation study except W.B. Grant's accounts for sunshine and vitamin D as a confounder. There's even a second hint in favour of this hypothesis: Dean's famous 21 cities study of 1941/42 is an extreme "flash photograph" since, as my father demonstrated from data gathered for the whole USA, partly by the same team, only 8 years earlier (1933/34) and which included the same cities: Caries findings in the same cities were – in average – about 2 times lower(!) only 8 years earlier – a clear proof that low fluoride in water cannot be the CAUSE for the high caries findings at low fluoride concentrations. This analysis is available only by email from me. 2. I miss the sentence that under the premisis of no or a doubtable caries protecting effect the NDA panel would not have any reason for establishing or confirming an AI for fluoride in nutrition. References at appropriate position within the text!
National Pure Water Association Ltd	1. Introduction	No sound evidence exists for an association between regularly internalised fluoride from all sources - but primarily from drinking water - and any reliable caries-preventive effect. The NDA Panel and other bodies evidently still rely on data published by Dean (1942) which was used by McLure to derive an 'optimal' dietary intake rate of 0.05mg/kg/day for children, guided by the erroneous belief that the mechanism of enamel protection against caries required teeth to take up F^- while enamel was being laid down by the ameloblasts. This is precisely the time span for the creation of dental fluorosis, whose prevalence and severity are essentially linear functions of F^- intake levels while enamel is laid down. Ziegelbecker's (1981) comprehensive datasets showed clearly that below 2 ppm there was no relationship between F^- in drinking water and caries rates, and that at higher F^- levels caries rates were increasing. Dean had admitted under oath that he had carefully selected the datapoints of his published graph showing minimum caries experience with 1-2 ppm F^- naturally in US water supplies. Warren (2009) concluded that, based on individual F^- intakes up to 4 years, deriving any 'optimal' intake rate was 'problematic' - there being such wide intake ranges from zero upwards in individual children and

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		relatively little differences in average intake rates between those with dental fluorosis and/or caries experience and those without. Osmunson (2007) has provided graphs showing no relationship between water fluoridation and US caries experience, but a clear inverse relationship between net dental expenditure and caries experience irrespective of fluoridation status. There is sound experimental and clinical justification for supplementing oral F^- levels regularly in order to reinforce outermost enamel resistance to caries but the great majority of dentists are well aware that the inevitable accompanying F^- internalisation should be minimised as effectively as possible. This supports the use of modern fluoride varnishes to control childhood caries as effectively and safely as possible. Both dental fluorosis and bone/tendon mineralisation disturbances occur in proportion to F intake rates down to much lower levels than quoted here where diet is poor and the cytoplasmic toxicity effects of F^- are inevitably intensified. Adequate nutritional intakes are indeed vital for optimal health, including protection against disease, and against toxic substances that can undermine normal cytoplasmic functions. These observations clearly undermine the entire rationale behind the present NDA Panel draft opinion.
Fluoride Action Network	1. Introduction	The EFSA Panel on Diebetic Products, Nutrition and Allergies has proposed establishing a dietary reference value (DRV) for fluoride of 0.05 mg/kg/day. This proposal should be rejected for 5 reasons. (We have included the first 2 of these reasons here, and will include the remaining 3 reasons in subsequent submissions). 1) Fluoride Is Not an Essential Nutrient: The EFSA Panel report recognizes that fluoride is “not an essential nutrient” and that there is “no average [fluoride] requirement for the performance of essential physiological functions.” (p. 27). 2) Fluoride’s Alleged Dental Benefits Do Not Require Ingestion: The EFSA Panel claims that a DRV is appropriate because of fluoride’s alleged dental benefits. This rationale, however, makes little sense because it is now known that fluoride’s predominant benefit for children’s oral health comes from topical contact, not ingestion. (NRC 2006; Fejerskov 2004; Zimmer 2003; CDC 2001; Featherstone 2000). Fluoride’s anti-caries effect during childhood, therefore, does not require that any fluoride be swallowed. The situation is even clearer for adolescents and adults, since the teeth in these populations are fully formed and thus no longer capable of receiving any

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		benefit from systemic fluoride incorporation. Since adult teeth cannot benefit from ingesting fluoride, and since fluoride provides no known benefits any other tissue in the body besides the teeth, there is no reason at all to set a DRV for adults. As the EFSA Panel notes on page 27, "[f]rom the available data, no beneficial effect of fluoride on bone health can be deduced." [To be continued...]
National Pure Water Association Ltd	2.1. Chemistry	No mention is made here of the fact that fluoride ions are strong complexers of cations in accordance to their charge. This leads to stimulated dissolution into water supplies of many toxic cations e.g. Al3+, Pb2+ radionuclides Ra2+ Sr2+ i.e. fluoridated water picks up additional toxic species, in addition to those already present (As et al) in the impure industrial fluorosilicic acid used to fluoridate. The similarity of F^- and OH- in size and charge (and c.f. HF and H2O) may help to explain why biological systems have not evolved any effective way of providing an effective barrier to keep biochemically disruptive F^- outside themselves in the aqueous environment. They therefore have to rely on efficient excretion and/or sequestration into insoluble matrices to remove this 'ubiquitously biotoxic species' from the cytoplasmic milieu. Bacteria cannot do this effectively; Strep mutans is clearly significantly metabolically compromised as F^- concentrations increase in the immediate environment, and metabolism is restored as they fall. Bacteria have evolved transformations enabling them to function as well as possible if environmental F^- levels remain high. Higher organisms cannot alter themselves to the same extent, but they can respond to environmental threats via epigenetic changes that can compensate as far as possible for loss of function.
Anonymous	2.2. Functions of fluoride	Fluoride is not a necessary nutrient and there is no function or process in the human body that requires fluoride. There is some evidence that fluoride may help in the process of re-enamalisation in the teeth but the evidence is contradictory and it is widely accepted that this action is topical and not systemic – ie ingestion is not necessary. It is rather peculiar therefore, that EFSA, while accepting the non-essential nature of fluoride, should be suggesting an Adequate Intake level. Fluoride is a List ii substance under the Council Directive 80/68/EEC relating to the prevention of discharges of certain toxic, persistent and bio-accumulable substances into groundwater. Fluoride is listed as an undesirable substance in Annex 1 of Directive 80/778/EEC relating to the quality of water intended for human consumption. In a comprehensive hazard identification study undertaken by the U.S. EPA examining 254 pollutants that may cause adverse effects to public health and the environment involving quantatitive risk assessment, including dose response

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		evaluation, exposure assessment and risk characterisation, the pollutant fluoride was identified as one of the top twelve critical
Anonymous	2.2. Functions of fluoride	line 240: "At the beginning of the 20th century…..lower prevalence of caries…": The "lower prevalence of caries" always refers to the same chronological age (in fluoridation statistics). However, if there are less teeth in the mouth which have been exposed to acid attacks for a shorter time, there MUST be less caries even if NOT A SINGLE TOOTH is less prone to caries. This has been proven to be the case at many occasions, especially in the early fluoridation studies which had rashly led to the spreading of water fluoridation: For example, analyses of Short's data plus all of the basic fluoridation trials, by Rudolf Ziegelbecker (sen.) in his early published papers (see e.g. http://www.oehha.org/prop65/public_meetings/052909coms/fluoride/RZiegelbecker.pdf, PDF document Page 49), show a) a tooth eruption delay in the order of 6 months at « recommended » concentration of fluoride in water, b) that tooth eruption delay begins already below 1 ppm F in water, c) a partly INCREASED relative caries INCREASE in the fluoridated children compared to the unfluoridated children with the potential of the fluoridated ones to "overtake" the not fluoridated ones concerning caries. Ask for my father's "Compendium of Summaries" (by email) – I can't find it on the Web in the moment. In my handout which I presented personally to the SCHER committee I demonstrated that a delay of half a year can create PRETENDED caries reductions of up to about 50%, probably one cause of the miraculously high caries reductions in the U.S. fluoridation trials (which also suffer from data selections, together this seems near or beyound the border to scientific fraud). Less exposure time of every tooth which can be found in the mouth AND less teeth yield a "quadratic effect". Nevertheless, almost no dental health/fluoride study does take this major confounder into account! In 2009 I received a presentation from Prof Dr Hardy Limeback, Co-Author of the 2006 NRC report, where he showed from own data, backed by a list of papers from authors finding tooth eruption dealys of up to 2 years (!), that "Lower decay rate in fluoridated areas is an artefact of delayed tooth eruption". The table of relevant papers is available from me.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		In 2008 Komarek et. al. re-aligned the data of a „fluoride and caries reduction“ study with respect to the same tooth age and as a consequence this pretended caries reduction was rendered “not significant”. At the 1987 ISFR conference data from East Germany were presented. The seeming (fluoride-dose-dependent) caries reduction completely vanished after I clearly showed, using the original numbers and the observed delays, that the caries was proportional to exposure integral (teeth * time). The U.S. fellow researcher and dentist John Lee confirmed my statement. Result (consider also my comments on the “Introduction”, please): Since the most important confounders “eruption delay” and “vitamin D from the sun’s UVB” are commonly not taken into account, there is no sound proof today that in real world fluoride causes even only a major part of the caries reduction which are attributed to it. Caries is a stochastic process. Even a simple blinded experiment I did with young students, using to almost identical toothpastes, only one of them additionally fluoridated, and eggs in vinegar, observing gas development: Once one egg was in contact with vinegar before the treatment, showing no “protection” at all by that fluoridated toothpaste, but “better” protection by “water only”. Under similarly variable circumstances in humans a LASTING benefit of a slightly increased fluoride concentration in the saliva etc. cannot be expected.
National Pure Water Association Ltd	2.2. Functions of fluoride	These are essentially to act as a ubiquitous cytoplasmic poison. F^- distributes rapidly into all tissues via blood and tissue fluid after absorption. Net cytotoxicity while F^- is elevated in body fluids must be proportional to plasma concentration - leaving net free intracellular F^- lower as F^- is absorbed onto +ve sites on enzymes et al, thus inhibiting vital cytoplasmic activity. Depending on reversibility of absorption onto intracellular sites as plasma F^- falls after peaking, original cytoplasmic activity may be only partly restored. Renal action (F^- passes into urine) and skeletal absorption (slowly reversible if F^- in plasma remains sufficiently low) act to remove F^-/sequester it so, dependent upon ongoing rates of F^- internalisation and net bone storage, renal action exponentially reduces F^- concentration to an age-related base level - but average plasma level in fluoridated areas was originally shown to be 3 times higher than unfluoridated. It must be true that this 0.5 increase in F^- activity has an ongoing adverse impact on overall cytoplasmic metabolism involving enzymes inhibited by F^-/signalling paths i.e. under fluoridation there is an ongoing deficit in cytoplasmic functional efficiency. The fact that the consequences of this remain subclinical does not mean that ‘the additional F^- uptake promoted by fluoridation can have no adverse health/developmental consequences’ for those exposed. Fluoride-sensitive individuals experience more severe functional impairments than the majority, but all are more or less subtly impacted by the imposition of a fluoridated supply. All exposed to excess fluoride intakes are involved in an uncontrolled lifelong toxicity trial (just as any prescription drug has cumulative untoward effects until it is no longer prescribed).

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
National Pure Water Association Ltd	2.2.1. Dental health and tooth development	Dental fluorosis is caused by fluoride uptake into ameloblasts, inhibiting removal of matrix proteins (i.e. an enzyme inhibition effect) immediately prior to enamelisation. Gaps in deposition of apatite crystals are responsible for enamel opacity, and DF severity corresponds to net enlargement of enamel vacancies. In other words, enamel structure is irreversibly damaged by any excess influx of F^-.
Alliance for Natural Health International	2.2.1. Dental health and tooth development	Line 253-6: "Fluoride uptake from the circulation into the enamel occurs only during tooth formation," becoming incorporated into hydroxyapatite. Absent additional sources of artificial fluoride salts – e.g. those added to water supplies and food, and those found in various oral preparations and topically applied products – this process involves low doses of naturally occurring fluoride. And yet, as line 255-6 says, "Fluoride is not essential for tooth development". Doses of fluoride salts used to reduce the incidence of dental caries far exceed those of naturally occurring fluoride. In this instance, fluoride operates through a variety of mechanisms, e.g. modulating mineralisation of the enamel hydroxyapatite crystal and disrupting the metabolism of certain caries-causing Streptocci. In effect, two separate and distinct pharmacokinetic profiles exist: one, involving very low doses of natural fluoride exclusively during tooth development; and another, involving much higher doses of artificial fluorides. The definition of a medicine in European law (Directive 2001/83/EC, amended by Directive 2004/27/EC) is any substance that is used either to "treat or prevent disease" or one that is used "with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action" (Article 1(2), Directive 2004/27/EC). As such, the use of fluoride to prevent dental caries is obviously a medicinal use of fluoride, and the setting of a DRV in the form of an AI is inappropriate – and outside EFSA's remit. Furthermore, it should be noted that, according to Recital 7 of Directive 2004/27/EC, the only exclusions to EU medicines law are for products that are regarded as "clearly" foods, food supplements, cosmetics or medical devices. Fluoride salts used to prevent dental caries are not covered by the parameters of this exemption. Further, although sodium fluoride and calcium fluoride are permitted in food supplements (Regulation (EC) No. 1170/2009), this is a misclassification on the part of the European Commission. The Directive defines Food supplements as having a nutritional or physiological effect. These fluoride salts do not. In many ways, because of their direct toxicological effect on caries-causing Streptococci, fluoride salts are more suitably regulated by the Biocidal Products Directive (98/8/EC). Lines 277-298: The European Commission's Scientific Committee on Health and Environmental Risks (SCHER) report, entitled 'Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		fluoridating agents of drinking water', has the following to say about the relative benefits of topical and dietary fluoride: "Scientific evidence for the protective effect of topical fluoride application is strong, while the respective data for systemic application via drinking water are less convincing. No obvious advantage appears in favour of water fluoridation as compared with topical application of fluoride...A vast number of clinical studies have confirmed that topical fluoride treatment in the form of fluoridated toothpaste has a significant cariostatic effect...[whereas] the caries preventive effect of systemic fluoride treatment is rather poor...The effect of continued systemic exposure of fluoride from whatever source is questionable once the permanent teeth have erupted." Thus, the Commission's own experts have clearly stated that there are no dental health benefits of fluoridated water over topical fluoride application. Water fluoridation is unnecessary in order for EU citizens to achieve the AI. The status of this science has likely been the main reason why the vast majority of EU Member States have rejected water fluoridation schemes.
National Pure Water Association Ltd	2.2.2. Bone health	Normal bone structure and health are also compromised in proportion to cumulative F^- uptake as capacity for remodelling is progressively impaired, leaving the bone embrittled. This explains higher fracture rates for 'normally aged bone' in fluoridated areas. Osteoporotic (weakened, demineralised) bone may gain some fracture resistance via F^- uptakes before significant embrittlement/ greater fracture susceptibility is observed. So osteoporotic fracture data needs careful interpretation.
Anonymous	2.2.4. Health consequences of deficiency and excess	Luxembourg, June 4th, 2013. Distinguished Madam's and Sir's of the EFSA, Firstly, I wish to thank you for allowing the opportunity for the European public to give their comments on the following draft. Although the proposed Dietary Reference Value for Fluoride is very well documented and well elaborated, I would like to use this opportunity to bring to your attention some scientific case studies, in particular one from Harvard University, that are not mentioned in this proposed draft, which would add significantly to the credibility and accuracy of the draft, and hence provide a more adequate, safe and more weighted evaluation concerning the daily intake levels of Flouride for the European population. Myself being a Neuropsychologist, I was somewhat surprised to discover that under Chapter 2.2.3 Health consequences of

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		deficiency and excess, or any other part of the paper for that matter, no effects are mentioned of fluoride intake to arguably one of the most important organs of all; the brain. As is well established in the psychiatric community Flouride can be effective in battling serious mental health conditions and is therefore also used in many of the strongest anti-depressants & anti-psychotics as; Prozac, Luvox, Paxil, Haldol & Depixol to name just a few, all of which contain Flouride as one of their main active ingredients in battling serious mental health conditions. Considering the wide spread use of these medicines that contain Flouride it surprises me just the more that the present draft does not include a single case study of the effects of Flouride on the brain or mental health. I wish to point your attention to a recent study conducted by the University of Harvard which has linked higher levels of Flouride intake through water to lower IQ levels in Children. http://www.reuters.com/article/2012/07/24/idUS127920+24-Jul-2012+PRN20120724 Furthermore, numerous studies have also come to show that Flouride is absorbed in the brain in an area named the Pineal Gland, where it causes calcification which can during long term exposure impair its functions of regulating Melatonin levels and the production of hormones that have important endocrine functions. Please see any or all of the following small selection of studies for further information on Flouride and the brain. http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowAbstractBuch&ArtikelNr=47443&ProduktNr=227489 http://www.sciencedirect.com/science/article/pii/0165799284901271 http://journals.lww.com/anesthesiology/Abstract/1996/02000/Fluoride_Ion_Toxicity_in_Human_Kidney_Collecting.22.aspx http://208.109.172.241/scher/he-2006.pdf http://www.sciencedirect.com/science/article/pii/0890623894900221 http://meridianenergies.net/the-effect-of-fluoride-on-the-physiology-of-the-pineal-gland/

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		Considering the above mentioned findings, I humbly ask, for the benefit and credibility of the following draft and the overall health of the European population, to have these findings carefully considered, evaluated and include into the draft a section on effects on the brain and consequently have the AI Reference Value of Flouride - especially for children - to be adjusted accordingly. Naturally, incentives for further studies should also be provided and recommended. I thank you for your attention. With my sincerest regards, Anonymous Ps. A note of reception or response on part of the EFSA would more than welcomed.
Alliance for Natural Health International	2.2.4.1. Deficiency	Line 333: "No signs of fluoride deficiency have been identified in humans." Line 339-40: "However, caries is not a fluoride deficiency disease." These lines reinforce the fact that fluoride is not an essential nutrient, and that the use of artificial fluoride salts in water supplies, oral hygiene products and topical applications is a medicinal or biocidal use aimed at preventing dental caries. As such, it is entirely unacceptable to propose a Dietary Reference Value in the form of an Acceptable Intake for fluoride. Reduction of dental caries is the primary stated benefit of fluoride intake. However, the intake–response curve for fluoride, as drawn in 1997 by the Institute of Medicine (IOM) in the USA, appears to exaggerate the benefit of fluoride. A plot of the original data points performed by Verkerk (Toxicology 2010;278:27–38), produced a flat response, whereas the IOM intake–response curve suggests a significant dose response at doses 1 mg/L. Thus, the benefits of fluoride intake may have been exaggerated. The doses of fluoride salts used to reduce the incidence of dental caries are far higher than those at which natural fluoride occurs. In this instance, fluoride operates through a variety of mechanisms, including modulating the mineralisation of the enamel hydroxyapatite crystal and disrupting the metabolism of certain Streptoccus bacteria that cause dental caries. In effect, two separate and distinct pharmacokinetic profiles exist: one, involving very low doses of natural fluoride exclusively during tooth development; and another, involving much higher doses of artificial fluorides.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		The definition of a medicine in European law (Directive 2001/83/EC, amended by Directive 2004/27/EC) is any substance that is used either to "treat or prevent disease" or one that is used "with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action" (Article 1(2), Directive 2004/27/EC). As such, the use of fluoride to prevent dental caries is obviously a medicinal use of fluoride, and as such, the setting of a DRV in the form of an AI is inappropriate – and outside EFSA's remit. Furthermore, it should be noted that, according to Recital 7 of Directive 2004/27/EC, the only exclusions to EU medicines law are for products that are regarded as "clearly" foods, food supplements, cosmetics or medical devices. Fluoride salts used to prevent dental caries are not covered by the parameters of this exemption. Furthermore, although sodium fluoride and calcium fluoride are permitted in food supplements, courtesy of Regulation (EC) No. 1170/2009, this appears to be a misclassification on the part of the European Commission. Food supplements are defined in the Directive as having a nutritional or physiological effect, which these fluoride salts do not. In many ways, because of their direct toxicological effect on caries-causing Streptococci, fluoride salts would be more suitably regulated by the Biocidal Products Directive (98/8/EC).
National Pure Water Association Ltd	2.2.4.1. Deficiency	No possible situation of deficiency exists for a wholly biotoxic species.
Anonymous	2.2.4.2. Excess	Neurotoxicity: The NRC report (2206) identified a number of potential health risks from concentrations of fluoride in water from 0.9ppm – in particular the thyroid. Fluoride has been used clinically in doses from 2.3mg daily to treat hyperthyroidism and there are studies showing thyroid effects of low levels of fluoride – especially in area of low iodine (Idris and Wihardja 2008). As the first stage of examining whether there might be a relationship between water fluoridation and a higher prevalence of hypothyroidism prevalence rates (from general practice) were compared for fluoridated and non-fluoridated Primary Care Trust areas in England, adjusted by percentage population over retirement age. The comparison (as shown in email attachment Peckham 2010) suggests a significant difference. This clearly requires further investigation but suggest that there may be a population effect. This may be particularly critical in relation to sub-clinical hypothyroidism (Wilson et al 2006). Dental fluorosis: In areas with water fluoridation in Eire and the UK there has been a substantial increase in levels of fluorosis. While regular data on the prevalence of dental fluorosis is not collected in either country there have been a

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		number of studies that highlight extensive levels of dental fluorosis in fluoridated areas. Whelton et al (2004) in their review of dental fluorosis concluded that the incidence of fluorosis was increasing and that fluoridated areas had higher levels of fluorosis than non-fluoridated areas. Concern about the wider toxic effects of fluoride have been accepted from the very earliest studies on fluoride in water. Dean was concerned that if levels of dental fluorosis were above 10% the early pilots on water fluoridation should not proceed (REF). Fluorosis is also considered by the WHO as a health problem not an aesthetic one (WHO 2001, 2002). There is a direct linear relationship between levels of fluoride in water supplies and levels of dental fluorosis - with more fluorosis the higher the level of fluoride. It is estimated that fluorosis will occur where ingested fluoride is above 0.03-0.04mg/kg which, if the only source of fluoride is in drinking water, would mean that an average 1 year old (10kgs) will exceed this if drinking more than 0.3/0.4 litres per day and an average 6 year old (22kgs) 0.66-0.88 litres per day. However as studies show children under 5 years old ingest some 30% of their toothpaste and fluoride is also found in prepared foodstuffs from pesticide residues and preparation processes if in areas with water fluoridation (Warren et al 2009). In Newcastle, UK, Tabari et al (2000) found a prevalence of 54% in areas with water fluoridation and 6 times as much moderate to severe fluorosis (according to Dean's scale) than in the non-fluoridated area (3% compared to 0.5%). Hardman and Rock (1989) found a significantly higher prevalence of fluorosis in area with water fluoridation than areas with no fluoridation. Whelton et al (2004) found increased levels of mild to severe dental fluorosis in Eire (7%) where the water is fluoridated, compared to Northern Ireland (0%) where there is no fluoridation. Dental fluorosis is indicative of too much fluoride being ingested (eg Bottenberg et al 2004, Levy et al 2006) With moderate to severe levels of dental fluorosis the tooth enamel can become damaged and the teeth pitted, leading to dental caries (Cunha-Cruz and Nadanovsky 2005, US Agency for Toxic Substances and Disease Registry 2003) Studies have also demonstrated that dental fluorosis is of more than aesthetic concern and for those with brown staining (ie. with mild to severe fluorosis), the condition is viewed as worse than having dental decay (Williams et al 2006). Similar views have been expressed in the USA and Australia (Lawson et al 2008, Spencer et al 1996) and a study in Southern Ireland found that fluorosis gave rise to embarrassment among girls more than boys (Browne et al 2006).
National Pure Water Association Ltd	2.2.4.2. Excess	Children's net F^- intakes have increased significantly since 1942, mainly via ingested fluoride toothpaste, thus exacerbating the extent and severity of dental fluorosis - which is why 'optimal DW fluoride levels' have been reduced in many places e.g. Ireland (0.7 ppm) Hong Kong (0.5 ppm). Far from promoting healthy growth (c.f. Bergmann 1994) premature stillbirth rates in fluoridated parts of West Midlands, United Kingdom, are increased, and the mean degree of fetal growth restriction before death is also increased [WMPI: PCT stillbirth/gestational age data (1995-2002)]

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Anonymous	2.2.4.2. Excess	The complete field of IQ-Lowering is missing here! http://www.fluoridealert.org/studies/brain01/ The IQ reduction (confirmed Harvard in 2012) is DRAMATICAL: 7 IQ points at standard deviation of 15 of the IQ curve, at F levels not much above the "recommended" values. Because of statistical principles even at "recommended" concentrations such a dramatical or similar IQ reduction will occur in SOME individuals. I have received information from scientists that the interaction of fluoride with lead had been demonstrated and aluminium, with the proven effect for Aluminium to cross the blood-brain-barrier and causing ALZHEIMERs which is becoming epidemic now. EFSA SHOULD PROTECT ALL GROUPS OF PEOPLE FROM THIS IQ-THREAT! As a full-time and over-worked teacher with a family and many duties, I'm not able to send all material I got from researchers all over the world on this subject during the last years in a well-ordered manner to EFSA. However, any scientist who follows the developments on fluoride and who realizes how quickly the knowledge about malicious health effects of fluoride is increasing and re-discovered now would NOT DARE to set an "adequate intake" value for fluoride, because of the tremendous potential of harm, the lack of effectiveness reducing tooth decay, while intended to function ONLY as a medicine. I would like to provide you also with the following testimonies of serious health effects at, near or above the "RECOMMENDED" doses of fluoride. EFSA should consider that MANY CASES REMAIN UNREPORTED to the scientific literature due to the consequent denying and underestimating of fluoride's dangers by officials: The CASE of a mother (teacher collegue!), reported to me in an occasional talk: Her young child always got diarrhoea when swallowing the fluoride tablets (still prescribed by some doctors!) and became healthy again when she stopped the fluoride tablets. Later, when she started to brush the teeth of her child, the same effect occurred, and after stopping brushing the teeth with fluoridated toothpaste, the whole health problem went away: "Nobody believes me", however, she said. (All this at a "recommended dosage")!

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		ANOTHER CASE was MY OWN BROTHER who LOST CONSCIOUSNESS when brushing his teeth with fluoridated toothpaste, repeatedly, until my father discovered the cause. I cannot identify scientific studies which report these problems. However, they are real. AS REAL as the DEATH of an about 4 years old boy in Upper Austria in 1976, Daniel Huala, who died from about 150 mg ingested fluoirde despite the doctor's measure of emptying his stomach, while in 2004 an Austrian dentist informed the newspaper that fluoride would be harmless up to 5000 tablets of 1 mg, an underestimation by a factor of 50! AS REAL as the DEATH of a young woman from local fluoride application here in Graz – I was told at the Ludwig Boltzmann Institute for Forensic Imaging that the cause had been an overdosage by a factor of ~10, which – if true – means that there is no adequate safety margin with respect to the recommendations. A recommendation of an adequate intake (AI) or a reference value MUST account for all such cases, in my opinion. Probably the NDA panel also doesn't know part of the published low-dose effects from fluoride in the recommended doses or concentrations, see e.g. the 1st and 3rd link on http://www.fluorideresearch.org/ISFR/files/ISFR.htm and do research among ALL publications because this scientific information is INDEED HIDDEN from many researchers by simply NOT LISTING ONE OF THE MOST IMPORTANT BUT INDUSTRY-INDEPENDENT SOURCES FOR RESEARCH PAPERS ON FLUORIDE BY NOT LISTING the journal "FLUORIDE" in "medline". As a single person I can only alert you of this possibility of doing research
Alliance for Natural Health International	2.2.4.2. Excess	EFSA's usual procedure for assessing nutrient risk is to use the most sensitive adverse effect as the basis for setting upper limits. Conversely, and exclusively in the case of fluoride, EFSA's attitude appears to be that the most common sequela of fluoride exposure, dental fluorosis, is of cosmetic significance unless severe (lines 363-5). 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. An overlap of risks and benefits must be considered for fluoride. According to Verkerk (Toxicology 2010;278:27–38): "Available evidence points to an overlap between risk and benefit for a significant proportion, if not a majority, of the child population if European or US ULs or TULs for fluoride are ingested habitually over a lifetime, especially if this includes

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		infant exposures in excess of 0.1 mg F/kg bw at critical times during tooth eruption and enamel formation...Owing to the likely Gaussian distributions of both the beneficial and adverse effects, it can be predicted...that more susceptible individuals in the population will be affected more severely than the average individual." In Ireland, the 'North South Survey of Children's Oral Health in Ireland (2003) shows that fluorosilicates in drinking water cause every third Irish teenager to demonstrate some degree of dental fluorosis as a result of the fluoridation policy. This has been the case even after the Irish government reduced the added fluoride concentration to 0.7 mg/L. Most health authorities that have evaluated the risks of fluoridation have not distinguished between the different forms of fluoride that have been subject to the various studies. For example, calcium fluoride, the principal form of naturally occurring fluoride in mineral waters, is very poorly absorbed by the body, and most of what is ingested is excreted. Synthetic fluorides, in contrast, such as the hexafluorosilicic acid that is generally added to municipal fluoridation schemes, are almost completely absorbed. Many of the older studies were undertaken using less bioavailable forms of fluoride, such as sodium fluoride.
National Pure Water Association Ltd	2.3. Physiology and metabolism of fluoride	Fluoride ion influxes into cells inevitably lead to proportional impairments of cellular enzymes and cell functions and, especially significantly, F^- can promote endocrine and immune functional impairments [NRC (2006)]. Of special significance, too, is G-protein signalling which is erroneously stimulated whenever AlF3 can bind to the receptor site instead of phosphate. All these and other cytoplasmic disturbances will have their most serious consequences during development (e.g. neurons fail to develop as many connections - leading to brain function impairments) and also when bodily functions (including renal function, where fluoride accumulation damages tubules) decline in old age. F^- invariably promotes ROS damage (oxidative stress) - which accounts for the development of 'non-skeletal fluorosis' prevalent in areas of 'endemic fluorosis'- which is reversed by antioxidants (but not if irreversible hard/connective tissue damage has already occurred). F^- enhanced placental oxidative stress may be involved in the 15% increase in reported preterm delivery sustained in areas under fluoridation in New York State [Hart (20090]. [This is only a brief selection of evidence of the many biochemical disruptions attributable to F^- in body tissues so conveniently ignored by the compilers of the NDA Opinion, which appears to imply that F^- passes freely into and out of cells without disturbing their vital metabolism? Of course F^- cannot be metabolised - but it can inhibit vital metabolic enzymes and thus compromise cytoplasmic metabolism - nor be a substrate for any enzyme since organofluorine bonds are not being formed inside animal cells (c.f. some plants)].

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
National Pure Water Association Ltd	2.3.1. Intestinal absorption	In stomach acid HF is formed and this can damage the stomach lining, leading to poor absorption into the blood of other substances that are vital for proper nutrition (Susheela).
National Pure Water Association Ltd	2.3.3. Distribution to tissues	It should be clearly recognised that F^- can complex with Ca2+ and Mg2+ ions, and that this will alter the distribution of these essential cations inside and outside cytoplasm, and will also lead to higher renal clearance of essential Ca2+ and Mg2+. Although the adult blood-brain barrier may be relatively impermeable to F^- there is evidence that the fetal/neonatal brain may be significantly more susceptible to F^- entry, promoting developmental neurotoxicity and permanently impaired brain function. The FDA were instrumental in getting fluoride supplements in pregnancy discontinued. This may have done far more good than merely preventing a waste of tablets for no improvement in caries resistance.
National Pure Water Association Ltd	2.3.4. Accumulation in the body	The skeleton can safely continue to store small amounts of daily internalised F^-, but the available ecological data based on sufficiently large populations indicates that hip and other torsional fractures are significantly increased in artificially fluoridated areas, with due control for confounding factors. This excessive skeletal embrittlement has traumatic and expensive consequences.
National Pure Water Association Ltd	2.3.5. Elimination	This is the key to successful detoxification.
National Pure Water Association Ltd	2.3.5.1. Kidney	The fact that there is effective ongoing F^- clearance for 4 months of postnatal life might be considered as evidence that although fetal skeletal storage of F^- has been effective in keeping fetal plasma levels low the reduction of this prenatal F^- body burden is now possible - and necessary. Renal functional impairment must lead to raised F^- levels in plasma and tissues, and point up the fact that specific subsets in all human populations are disproportionately susceptible to ongoing and cumulative harm caused by consumption of fluoridated drinking water. Pure - very low fluoride - drinking water sources are optimally able to remove F^- from body tissues.
National Pure Water Association Ltd	2.3.5.2. Faeces	The faecal route may be used to detoxify the body tissues. Ground up serpentine (which is insoluble and adsorbs F^- strongly) can be swallowed for as long as necessary (Teotia).

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
National Pure Water Association Ltd	2.3.5.3. Breast milk	The very low level of F in breast milk is a remarkable physiological adaptation, it may well indicate that neonates may be especially susceptible to F^- toxicity. The neonatal brain is still developing rapidly. Research in this area is vital, and expanding. [It is ironic that this is characterised as 'a minor route of fluoride loss' when it is in fact a route of biotoxic fluoride transfer from mother to infant that appears to have been effectively blocked - for reasons needing clarification]
National Pure Water Association Ltd	2.4. Biomarkers of fluoride intake	Measured free F^- in internal fluids (blood and tissue fluid) represents the amount available to promote biotoxicity, and they should all be kept as low as possible.
National Pure Water Association Ltd	2.4.2. Urine	The daily amounts removed into urine, as with other substances excreted, depend on the extent of renal sufficiency. F^- is known to damage renal tubules and (although this is disputed) indicates that renal function will not be so reliably maintained into increasing old age in a fluoridated area.
National Pure Water Association Ltd	2.4.5. Bone and dentin	Fluoride uptake into dentine, as into bone, causes embrittlement. [Teeth are more likely to break up under the drill when attempts are made to insert a filling. Hartlepool (originally naturally fluoridated to 1.4 ppm) residents therefore lost their eventually carious teeth earlier than elsewhere, despite any and all restraining effects of their water supply on carious lesion propagation].
National Pure Water Association Ltd	2.4.6. Hair	Hair serves to remove F^- from the body.
National Pure Water Association Ltd	2.4.7. Nails	Nails remove fluoride from the body.
National Pure Water Association Ltd	2.4.8. Enamel	Outer enamel also removes some fluoride from oral intakes and in so doing it is consolidated. This represents the single situation in which F^- improves the function of any tissue. The common feature is that biotoxic fluoride is being taken out of the circulation where it is actively harmful via these deposition/excretion processes - all are detoxification routes of greater or lesser significance.
National Pure Water Association Ltd	2.6. Conclusion on biomarkers of fluoride intake and body burden	NDA's conclusion is that contemporary net fluoride intakes can be estimated from 24 hr urine analyses, with certain provisos relating to ongoing individual renal function in relation to amounts retained on hard tissues, but that there are no suitable biomarkers of overall body burden. NDA are understandably reluctant to use intake estimates to establish DRVs in relation to caries incidence.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		An independent conclusion is that, for a body whose proper purpose is to ensure optimal nutritional intakes of all kinds including vitamins and essential minerals, the request to confirm that there are rational grounds for setting a DRV for F^- - a ubiquitously biotoxic inorganic species - in the context of optimising caries control, is seen by them to be an inappropriate use of their expertise, unsupported by viable evidence of any caries benefit obtainable by this route. Only because of the ongoing political basis of support for those whose brief is to advocate fluoridation as an effective means of restricting dental caries across entire populations and all age groups could dental apologists have prevailed upon the NDA to draft this document in its current form. NPWA believes that the only sound, scientifically justifiable policy is to advocate taking realistic steps to restrict ongoing fluoride internalisation from all sources as far as possible, while also recognising that clinically tested fluoride vehicles do have a valid role in controlling/restricting the development of dental caries if used appropriately and safely. This is not what either polluting industries or dental apologists are prepared to hear about fluoride from any scientific authority [Bryson (2006)].
National Pure Water Association Ltd	2.7. Effects of genotypes	The fact that certain gene modifications make for higher susceptibility to harm should alert those who advocate fluoridation to the fact that a due proportion of any human population are likely to be particularly susceptible to specific kinds of fluoride toxicity. Indiscriminate medication of entire human populations takes no account of this.
Anonymous	3. Dietary sources and intake data	Exposure assessment Fluoride exposure in water is calculated by the concentration and volume of water consumed per day. The USA Food and Nutrition Board recommends that adults aged 18 and over should drink 3 litres a day and that 5% of adult males drink in excess of 5 litres a day. Estimates in the Opinion may in fact be too low at 1.3 to 3.8 litres per day for adults and 0.5 to 1.5 litres per day for children. In the UK in the past five years there has been a national campaign to encourage the consumption of water in schools. Someone who consumes 3.8 litres of water a day at 0.7ppm fluoride would get a higher dose of fluoride than someone drinking 2 litres of water with 1.2ppm fluoride. I am not clear where exposure levels for fluoride have been obtained. Assessments of the ingestion of fluoride should also consider total ingestion in areas where water is fluoridated as food processing is undertaken with fluoridated water. It is not possible to accurately ascertain the levels of fluoride ingested in areas where the water is fluoridated. In 1991 the CDC in the USA measured fluoride levels and found that where water is fluoridated at between 0.7ppm and 1.2ppm overall fluoride total fluoride intake for adults was between 1.58 and 6.6mg per day while for children it was between 0.9 and 3.6mg per day with a six fold variation just from water consumption alone (U.S. Public Health Services 1991). In the NRC report estimates of fluoride intake from water fluorides alone at 1ppm ranged from under 1mg/d to 5.36mg/d substantially higher than the PHS 1991 figures sugggesting that in fluoridated areas maximum intakes now exceed 8mg/d. The USA Iowa cohort study

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		found that 90% of 3-month-olds consumed over their recommended 0.01 mg/kg bodyweight/per day daily-fluoride-dose from water, supplements and/or dentifrice (Levy et al 2001). Some babies ingest over 6 mg fluoride daily. Mean intake per unit body weight (bw) was about 0.075 mg F/kg bw through 3 months of age, 0.06 mg F/kg bw at 6 and 9 months, 0.035 mg F/kg bw at 12 and 16 months, and 0.043 mg F/kg bw from 20-36 months meaning that many children exceeded the upper tolerable levels, with percentages greatest during the first 9 months. (Levy et al 2001) Similar findings have been found in later studies (Erdal and Buchanan 2005, Marshall et al 2004, Siew et al 2009). Dietry differences and fluoride levels of foods and beverages vary considerably – note high levels in tea and chicken and in pesticde residues on food. Recent analysis of fluoride exposure in the UK National Diet and Nutrition Survey (Henderson et al 2003) has identified that in the UK 14% of the survey sample, regardless of water fluoride, consumed more than 5 mg fluoride daily and 1.3% more than 10 mg daily - sufficient to cause concern (Mansfield 2008). Between age 6 months and six years the safe intake of fluoride is considered by CoMA to be 0.12mg/kg/day, and in younger infants 0.22mg/kg/day. Small children retain up to 70% of ingested fluoride, making them more vulnerable to the long-term disbenefits of over-consumption (Levy et al 1995, Levy et al 2001, Erdal and Buchanan 2005). In their analysis of fluoride ingestion and dental caries and fluorosis experience Warren et al (2009) highlight the complexity of quantifying fluoride intake in areas where there is widespread water fluoridation and increased availability of fluoride countaining products arguing that assessing children's fluoride intake is virtually impossible and thus rendering a concept of taregt intake useless. The term optimal fluoride intake be dropped from common usage (Warren et al 2009: 115, Burk and Eklund 2005). It is not possible to ascertain dosage levels based on dose concentrations in water. Variability in the amount of water drunk and in sources of fluoride from other sources renders any concentration level in water meaningless. This places those with lower body weights and those that drink more water at particular risk.
National Pure Water Association Ltd	3.1.1. Water	Over 95% of fresh surface water sources contain < 0.25 ppm fluoride - any more suggests source contamination. Ground waters in contact with slowly soluble fluoride minerals are likely to contain significantly more. Such waters should neither be used as drinking water sources, nor bottled.
National Pure Water Association Ltd	3.1.1.1. Fluoride intake from water	It is clear that wherever drinking water is fluoridated, its ongoing consumption normally represents the most significant source of swallowed fluoride. Householders can buy suitable equipment to remove most of the fluoride before consumption, and NPWA recommends that they do so.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
National Pure Water Association Ltd	3.1.2. Food	Most fresh food products normally contain low amounts of fluoride. Those that contain significant amounts have come from environments from which it was not possible to avoid internalising more e.g. the sea (marine fish), and high fluoride soils (tea plants). Fish bones and skin can be avoided - the flesh is not high in fluoride. Tea plants sequester fluoride, but it is significantly extracted by boiling water.
National Pure Water Association Ltd	3.1.3. Infant and follow-on formula	As the developing infant is particularly vulnerable to fluoride toxicity a low maximum level in the prepared drink is necessary. This precludes use of fluoridated water, and powdered infant formula must contain sufficiently low amounts.
National Pure Water Association Ltd	3.1.4. Fluoridated salt	Used as recommended, daily adult fluoride intakes from fluoridised salt are about 5 times lower than adult intakes from fluoridated water. The topical benefits may be greater.
National Pure Water Association Ltd	3.1.5. Fluoride-containing dental products	None should be intended to be swallowed, and due warnings should be obligatory.
National Pure Water Association Ltd	3.2. Intake	No-one should believe that they are increasing their risk of dental caries by ingesting too little fluoride. Everyone should be persuaded to practise good personal dental hygiene combined with regular dental checks to maintain control of caries. The only valid reason for compiling likely intake levels is to discover if net fluoride internalisations are being exacerbated for any specific reason before recommending appropriate steps to remove the causes. The most likely source of excessive intakes in a community is a fluoridated water supply, and how the water is used. The remedy is obvious, but dental public health proponents will not willingly stop fluoridating, though they may accept that fluoridation levels should be reduced. If industrial sources are to blame, effective pollution control should be enforced. In 2010, a study by Dr Peter Mansfield revealed that in the UK we are already over-exposed to fluoride, with 25% of us getting more than is safe. This figure rises to 67% in fluoridated areas [Mansfield (2010)].
National Pure Water Association Ltd	3.2.1. Infants	The dangers of using fluoridated water to make up infant formula are being disseminated.
National Pure Water Association Ltd	3.2.2. Children	Dental healthcare programmes should not include methods that augment fluoride ingestion.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
National Pure Water Association Ltd	3.2.3. Adults	Where no fluoridated supply is used, adults generally appear to internalise significantly less F^- daily than the AI would recommend. This is surely a good thing but see Mansfield (2010).
Alliance for Natural Health International	4. Overview of dietary reference values and recommendations	Since the use of fluoride salts to reduce dental caries is a purely medicinal – as opposed to nutritional – exercise, it is entirely inappropriate to set DRVs or an AI for fluoride. The doses of fluoride salts used to reduce the incidence of dental caries are far higher than those at which natural fluoride occurs. In this instance, fluoride operates through a variety of mechanisms, including modulating the mineralisation of the enamel hydroxyapatite crystal and disrupting the metabolism of certain Streptoccus bacteria that cause dental caries. In effect, two separate and distinct pharmacokinetic profiles exist: one, involving very low doses of natural fluoride exclusively during tooth development; and another, involving much higher doses of artificial fluorides. The definition of a medicine in European law (Directive 2001/83/EC, amended by Directive 2004/27/EC) is any substance that is used either to "treat or prevent disease" or one that is used "with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action" (Article 1(2), Directive 2004/27/EC). As such, the use of fluoride to prevent dental caries is obviously a medicinal use of fluoride, and as such, the setting of a DRV in the form of an AI is inappropriate – and outside EFSA's remit. Furthermore, it should be noted that, according to Recital 7 of Directive 2004/27/EC, the only exclusions to EU medicines law are for products that are regarded as "clearly" foods, food supplements, cosmetics or medical devices. Fluoride salts used to prevent dental caries are not covered by the parameters of this exemption. Furthermore, although sodium fluoride and calcium fluoride are permitted in food supplements, courtesy of Regulation (EC) No. 1170/2009, this is a misclassification on the part of EFSA and the Commission. Food supplements are defined in the Directive as having a nutritional or physiological effect, which these fluoride salts do not. In many ways, because of their direct toxicological effect on caries-causing Streptococci, fluoride salts are more suitably regulated by the Biocidal Products Directive (98/8/EC).
National Pure Water Association Ltd	4.1. Adults	The fact that each authority referred to has accepted virtually the same definition of 'adequate intake' merely reflects the fact that fluoridation is currently still presented by dental public health officials as 'a vital strategy for optimal caries control at a population level' and the AI set is still derived from McClure's figure.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
National Pure Water Association Ltd	4.2. Infants and children	UK COMA (1991) advocated a safe fluoride intake of 0.12 mg/kg/day for children up to 6 years. This assumes that they can drink fluoridated water and come to no harm despite their undoubted susceptibility to developmental harms far more serious than dental fluorosis.
National Pure Water Association Ltd	5.1. Biomarkers as endpoints	NDA's reluctance to commit to any practical reference criteria is understandable if the concept of an AI for optimal caries resistance is essentially meaningless.
Fluoride Action Network	5.2. Health consequences	5. The Proposed DRV Cannot Be Considered Safe for the Entire Population Based on recent data, a DRV of 0.05 mg/kg/day cannot be considered safe for the entire population, particularly infants, people with end stage renal disease, people with thyroid disease, and people with iodine and calcium deficiencies. Consider, for example, the following: - In 2006, the National Research Council in the U.S. found that existing research on fluoride and the thyroid gland suggests that fluoride at doses as low as 0.01 mg/kg/day can impair thyroid function among individuals with suboptimal iodine intake. (NRC 2006). This is consistent with clinical research from Europe which found that daily doses of just 2 to 5 mg/day of fluoride ion (= 5 to 10 mg/NaF) was sufficient to reduce thyroid function among individuals with hyperthyroidism. (Galletti 1958). - In the Netherlands, the National Institute for Public Health and Environmental Protection has stated that "about 1.5 mg appears to be the maximum acceptable intake for nephritic patients." For most adults, this translates into a dosage well below 0.05 mg/kg/day. (NIPHEP 1989). - According to the World Health Organization, "Skeletal fluorosis is associated with a systemic uptake exceeding 5 mg/day in a relatively sensitive section of the general population." (WHO 2000). For adults weighing over 100 kg, a dose of 5 mg/day will be less than 0.05 mg/kg/day. - In India, researchers have found that "In calcium-deficient children the toxic effects of fluoride manifest even at marginally high (>2.5 mg/d) exposures to fluoride." (Teotia 1998). REFERENCES:

ORGANISATION	CHAPTER TEXT	COMMENT TEXT

Burt BA. (1999). The case for eliminating the use of dietary fluoride supplements for young children. J Public Health Dent. 59(4):269-74.

Centers for Disease Control and Prevention. (2001). Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States. Morbidity and Mortality Weekly Report 50(RR14): 1-42.

Featherstone, JDB. (2000). The Science and Practice of Caries Prevention. Journal of the American Dental Association 131: 887-899.

Fejerskov O. (2004). Changing paradigms in concepts on dental caries: consequences for oral health care. Caries Research 38: 182-91.

Galletti P, Joyet G. (1958). Effect of fluorine on thyroidal iodine metabolism in hyperthyroidism. Journal of Clinical Endocrinology 18(10):1102-1110.

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

National Research Council. (2006). Fluoride in Drinking Water: A Scientific Review of EPA's Standards. National Academies Press, Washington D.C.

National Institute for Public Health and Environmental Protection. (1989). Integrated criteria document fluorides. Report No 758474010. The Netherlands.

Riordan PJ. (1999). Fluoride supplements for young children: an analysis of the literature focusing on benefits and risks. Community Dent Oral Epidemiol. 27(1):72-83.

Rozier RG, et al. (2010). J Am Dent Assoc. 141(12):1480-9.

Teotia M, Teotia SP, Singh KP. (1998). Indian Journal of Pediatrics 65:371-81.

Warren J, et al. (2009). Considerations on optimal fluoride intake using dental fluorosis and dental caries outcomes: A

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		longitudinal study. Journal of Public Health Dentistry 69:111-15. See: http://www.fluoridealert.org/studies/ifs/ World Health Organization Regional Office for Europe. (2000). Air Quality Guidelines for Europe – Second Edition. WHO Regional Publications, European Series, No. 91, p. 158. Zimmer S, et al. (2003). Recommendations for the use of fluoride in caries prevention. Oral Health Prev Dent. 1(1):45-51.
Anonymous	5.2.1. Dental health/caries	Evidence of effectiveness for the prevention of dental caries: The draft report appears to privileged the fact that ingestion of fluoride has a systemic benefit on the prevention of dental caries. The York Review which is still the best assessment of the evidence highlights the poor quality of studies on the effectiveness of water fluoridation (McDonagh et al 2000). Water fluoridation is also a poor delivery mechanism. Only 1-2% of the water is drunk and the rest finds its way into the environment. There is no control over individual dose. Yet the draft scientific opinion refers to 1ppm as an optimal level of fluoride in water. There is no scientific basis for this "optimal level" (essentially the concentration of fluoride added to drinking water). In fact recent moves by governments to reduce levels of fluoride suggests that the concept of an optimal level is completely unsupportable. In their recent review of water fluoridation, the EU (European Union) Scientific Committee on Health and Environmental Risks highlight that young children are likely to exceed the upper tolerable limits for fluoride consumption in areas with water fluoridation greater than 0.8 ppm and using fluoride toothpaste, although the estimates of ingestion are probably underestimated as they are based on ingestion from food and beverages in non-fluoridated areas (SCHER 2011). Warren et al. (2009) have highlighted the complexity of quantifying fluoride intake in areas where there is widespread water fluoridation and increased availability of fluoride-containing products. They argue that ' . . . it is doubtful that parents or clinicians could adequately track children's fluoride intake and compare it with the recommended level, rendering the concept of an 'optimal' or target intake relatively moot' (p. 114). Their conclusion supports Burt and Eklund's (2005) view that the term optimal fluoride intake be dropped from common usage and Ismail and Hasson (2008) also argue that 'We believe that dentists should dismiss the misconception that there is a balance between dental caries and fluorosis, because patients can accrue the benefits of topical fluorides without developing fluorosis and without systemic intake' (p. 1465). The inability to control individual dose renders the notion of an 'optimum concentration' obsolete. Bottenberg P, Declerck D, Ghidey W, Bogaerts K, Vanobbergen J and Martens L (2004) Greater tooth brushing frequency,

ORGANISATION	CHAPTER TEXT	COMMENT TEXT

fluoride supplement use, and tap water fluoride concentrations above 0.7mg/L are risk factors for dental fluorosis Caries Research38(1); 20-28.

Browne D, Whelton H, O'Mullane D, Crowley T, Allen F, and Flannery E (2006) Impact of Fluorosis on Quality of Life of Irish Adolescents Paper presented to the IADR General Session & Exhibition Brisbane June/July 2006.

Commission on Life Sciences (1993) Health effects of ingested fluorides Washington DC: National Academy Press.

Cuhna-Cruz J and Nadanovsky P (2005) Dental fluorosis increases caries risk. Journal of Evidence Based Dental Practice 5: 170-171.

Erdal S and Buchanan SN (2005) A Quantitative Look at Fluorosis, Fluoride Exposure, and Intake in Children Using a Health Risk Assessment Approach. Environ. Health Perspect. 113:111–7.

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

Lawson J, Warren JJ, Levy SM, Broffitt B and Bishara SE (2008) Relative esthetic importance of orthodontic and color abnormalities Anglo Orthodontics 78(5): 889-94.

Levy SM, Hong L, Warren JJ and Broffitt B (2006) Use of the fluorosis risk index in a cohort study: the Iowa fluoride study Journal of Public Health Dentistry 66(2); 92-6.

McDonagh M, Whiting P, Bradeley M, Cooper J, Sutton A, Chestnut I, Misso K, Wilson P, Treasure E, Kleijnen J (2000) A systematic report on public water fluoridation. NHS Center for Reviews and Dissemination. York, UK, University of York: 259.

Scientific Committee on Health and Environmental Risk (SCHER), 2011. Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water. SCHER Directorate-General for Health and Consumers, European Commission URL available from: http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_139.pdf

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		Spencer AJ, Slade GD, Davies M. (1996) Water fluoridation in Australia Community Dent Health 13 (Suppl. 2):27–37. Tabari ED, Ellwood R, Rugg-Gunn AJ, Evans DJ and Davies RM (2000) Dental fluorosis in permanent incisor teeth in relation to water fluoridation, social deprivation and toothpaste use in infancy British Dental Journal 189 (4), 216-220. Whelton H, Crowley E, O'Mullane D, Donaldson M, Kelleher V and Cronin M (2004) Dental caries and enamel fluorosis among the fluoridated and non-fluoridated populations in the Republic of Ireland in 2002. Whelton H, Ketley CE, McSweeney F and O'Mullane DM (A review of fluorosis in the European Union: prevalence, risk factors and aesthetic issues Community Dentistry and Oral Epidemiology, Volume 32, pages 9–18, April 2004 WHO (2001) Water Related Diseases. Fluorosis: The Disease and How it Affects People Geneva: WHO. WHO (2002) World Water Day 2001:Oral Health Geneva: WHO. Williams DM, Cheshunt IG, Bennett PD, Hood K, Lowe R and Heard P (2006) Attitudes to fluorosis and dental caries by a response latency method Community Dentistry and Oral Epidemiology 34:153-159. Yeung, C. A., Hitchings, J. L., Macfarlane, T. V., Threlfall, A. G., Tickle, M., & Glenny, A. M. (2005). Fluoridated milk for preventing dental caries. Cochrane Database of Systematic Reviews, 20. http://summaries.cochrane.org/CD003876/fluoridated-milk-for-preventing-dental-caries#sthash.z3hw4fs2.dpuf
National Pure Water Association Ltd	5.2.1. Dental health/caries	Optimal caries control has been pioneered in Sweden [Axelsson (1993)] and adopted by other Scandinavian countries. It involves the inculcation of personal responsibility for oral health, combined with very effective professional observation and interventions starting from before birth, when mothers-to-be are screened for Strep mutans counts and dental/oral treatments prescribed to delay for as long as possible the infective transmission of S mutans from mother to infant. The other key procedures are assessment of likely carious sites in an individual's mouth, plus appropriate preventive measures e.g. fissure sealants and oral fluoride use, and thorough plaque removal sessions at regular intervals. Fluoridation is not practised in any Scandinavian country.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Anonymous	5.2.1. Dental health/caries	The NDA panel correctly states that caries is not a fluoride deficiency desease in line 904 (5.2.1) However, I miss a statement that a) ingested fluoride can only possibly and in certain cases lower caries: b) that other influences such as vitamin D may reduce caries more than fluoride, c) that at least part of the effects attributed to fluoride are or may be due to fluoride-induced later tooth eruption (few months up to 1 or 2 years) and may produce pretended caries reductions of up to 50% or more without any tooth being less prone to caries. This possibly major influence is NOT AT ALL ACCOUNTED FOR in MOST (OR ALL) CITED STUDIES, THUS THE WHOLE CHAPTER 5.2.1.1 rests on much too weak foots for being a reason for a reference value for ingestion of fluoride. d) that NOT ANY BENEFIT CAN BE SEEN in countries where the vitamin D supply seems to be sufficient: No caries in Nigeria, possibly only increasing caries with increasing fluoride in water in countries like Spain, Greece, Malta, Sri Lanka http://www.fluorideresearch.org/264/files/FJ1993_v26_n4_p237-298.pdf, p.263-266 e) considering all influences except fluoride to be random, worldwide, a possible benefit of fluoride in water seems to be limited to about 0.3 ppm – not more: http://www.fluorideresearch.org/143/files/FJ1981_v14_n3_p098-146.pdf (see PDF p. 30!) This fact alone REQUIRES A MUCH LOWER DAILY REFERENCE VALUE THAN 0.05 mg/kg body weight, in my opinion. For the above reasons it's ONLY A BELIEF that ALL OF THE WORLDWIDE OBSERVED 10 to 20% CARIES REDUCTION by F IS A TRUE ONE (NOT ONLY PRETENDED IN YOUNG YEARS) AND ALL DUE TO FLUORIDE. Details: The EU SCHER committee's ONLY (SINGLE) seemingly impressive proof for a protective effect of fluoride in water is HEAVILY CONFOUNDED by the KNOWN CARIESTATICUM VITAMIN D from the SUN's UVB radiation. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3219170/,

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		http://www.landesbioscience.com/journals/29/article/15841/, a paper which proves that in the U.S. vitamin D acts at least by far more caries protecting than water fluoridation).The UVB map and the fluoride-in-water-map of Denmark, where SCHER's example comes from, are evidently "linearly dependent" (="overlapping"; they seem almost identical for a non-scientific eye). Therefore SCHER's only impressive example for a caries-protective effect might be largely due to solar UVB, not to fluoride. Almost no fluoridation study accounts for sunshine and vitamin D as a confounder. There's even a second hint in favour of this hypothesis: Dean's famous 21 cities study of 1941/42 is an extreme "flash photograph" since, as my father demonstrated from data gathered for the whole USA, partly by the same team, only 8 years earlier (1933/34) and which included the same cities: Caries findings in the same cities were – in average – about 2 times lower(!) only 8 years earlier – a clear proof that low fluoride in water CANNOT be the CAUSE for the high caries findings at low fluoride concentrations, see e.g. Fig. 18 in http://www.laleva.cc/food/fluoride_commentsFAO_WHO.doc Figs. 12-20 Many more proofs available by email, See also my full comments. on sect. 2.2
National Pure Water Association Ltd	5.2.1.1. Fluoride in drinking water and dental health/caries	Since the 1970's when topical/oral fluoride treatments were widely introduced caries has been declining in child populations towards a common low value irrespective of fluoridation status. NHS/CRD caries data was pooled between the 1960s and 2000, and the time trend towards lowest caries experience was not sufficiently brought out. The residual contributions of fluoridation to childhood caries reductions are no longer cost effective [Hampshire County Council Report (2008)].
Alliance for Natural Health International	5.2.1.1. Fluoride in drinking water and dental health/caries	The doses of fluoride salts used to reduce the incidence of dental caries far exceed those of naturally occurring fluoride. In this instance, fluoride operates through a variety of mechanisms, e.g. modulating mineralisation of the enamel hydroxyapatite crystal and disrupting the metabolism of certain caries-causing Streptocci. In effect, two separate and distinct pharmacokinetic profiles exist: one, involving very low doses of natural fluoride exclusively during tooth development; and another, involving much higher doses of artificial fluorides. The definition of a medicine in European law (Directive 2001/83/EC, amended by Directive 2004/27/EC) is any substance that is used either to "treat or prevent disease" or one that is used "with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action" (Article 1(2), Directive 2004/27/EC). As such, the use of fluoride to prevent dental caries is obviously a medicinal use of fluoride, and the setting of a DRV in the form of an AI is inappropriate – and outside EFSA's remit. Furthermore, it should be noted that, according to Recital 7 of Directive 2004/27/EC, the only exclusions to EU medicines law are for products that are regarded as "clearly"

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		foods, food supplements, cosmetics or medical devices. Fluoride salts used to prevent dental caries are not covered by the parameters of this exemption. Further, although sodium fluoride and calcium fluoride are permitted in food supplements (Regulation (EC) No. 1170/2009), this is a misclassification on the part of the European Commission. The Directive defines Food supplements as having a nutritional or physiological effect. These fluoride salts do not. In many ways, because of their direct toxicological effect on caries-causing Streptococci, fluoride salts are more suitably regulated by the Biocidal Products Directive (98/8/EC). The European Commission's Scientific Committee on Health and Environmental Risks (SCHER) report, entitled 'Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water', has the following to say about the relative benefits of topical and dietary fluoride: "Scientific evidence for the protective effect of topical fluoride application is strong, while the respective data for systemic application via drinking water are less convincing. No obvious advantage appears in favour of water fluoridation as compared with topical application of fluoride...A vast number of clinical studies have confirmed that topical fluoride treatment in the form of fluoridated toothpaste has a significant cariostatic effect...[whereas] the caries preventive effect of systemic fluoride treatment is rather poor...The effect of continued systemic exposure of fluoride from whatever source is questionable once the permanent teeth have erupted." Thus, the Commission's own experts have clearly stated that there are no dental health benefits of fluoridated water over topical fluoride application. Water fluoridation is unnecessary in order for EU citizens to achieve the AI. The status of this science has likely been the main reason why the vast majority of EU Member States have rejected water fluoridation schemes.
Anonymous	5.2.1.1. Fluoride in drinking water and dental health/caries	I'm sorry I can't repeat all the information on the flaws seeming effects of drinking water fluoirdation. The following document contains most of the necessary information about the inefficacy of fluoridation in any form of ingested fluoride: http://www.laleva.cc/food/fluoride_commentsFAO_WHO.doc There's no effect at least above 0.3 ppm in drinking water. Studies on more fluoride in drinking water or an equivalent intake are already possibly confounded (and in almost no cases corrected - in which case any benefit uses to vanish) by tooth eruption delay. "Impressive" caries reductions as observed in Denmark (Kirkeskov 2010,....) are severely confounded by vitamin D from sunshine or other influences.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		As a result it isn't at all clear how large fluoride's effect really is, if any in average. It would be, however, necessary to be able to predict a benefit - which is not the case at the stage of actual knowledge. See also my comments on other sections!
National Pure Water Association Ltd	5.2.1.2. Total fluoride intake and dental health/caries	The Iowa study provides little or no evidence that ingested fluoride has any relationship with caries experience, but only with dental fluorosis, as Warren et al confirmed.
Alliance for Natural Health International	5.2.1.2. Total fluoride intake and dental health/caries	The doses of fluoride salts used to reduce the incidence of dental caries far exceed those of naturally occurring fluoride. In this instance, fluoride operates through a variety of mechanisms, e.g. modulating mineralisation of the enamel hydroxyapatite crystal and disrupting the metabolism of certain caries-causing Streptocci. In effect, two separate and distinct pharmacokinetic profiles exist: one, involving very low doses of natural fluoride exclusively during tooth development; and another, involving much higher doses of artificial fluorides. The definition of a medicine in European law (Directive 2001/83/EC, amended by Directive 2004/27/EC) is any substance that is used either to "treat or prevent disease" or one that is used "with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action" (Article 1(2), Directive 2004/27/EC). As such, the use of fluoride to prevent dental caries is obviously a medicinal use of fluoride, and the setting of a DRV in the form of an AI is inappropriate – and outside EFSA's remit. It should also be noted that, according to Recital 7 of Directive 2004/27/EC, the only exclusions to EU medicines law are for products that are regarded as "clearly" foods, food supplements, cosmetics or medical devices. Fluoride salts used to prevent dental caries are not covered by this exemption. Further, although sodium fluoride and calcium fluoride are permitted in food supplements (Regulation (EC) No. 1170/2009), this is a misclassification on the part of the European Commission. The Directive defines Food supplements as having a nutritional or physiological effect. These fluoride salts do not. In many ways, because of their direct toxicological effect on caries-causing Streptococci, fluoride salts are more suitably regulated by the Biocidal Products Directive (98/8/EC). The European Commission's Scientific Committee on Health and Environmental Risks (SCHER) report, entitled 'Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		agents of drinking water', has the following to say about the relative benefits of topical and dietary fluoride: "Scientific evidence for the protective effect of topical fluoride application is strong, while the respective data for systemic application via drinking water are less convincing. No obvious advantage appears in favour of water fluoridation as compared with topical application of fluoride...A vast number of clinical studies have confirmed that topical fluoride treatment in the form of fluoridated toothpaste has a significant cariostatic effect...[whereas] the caries preventive effect of systemic fluoride treatment is rather poor...The effect of continued systemic exposure of fluoride from whatever source is questionable once the permanent teeth have erupted." Thus, the Commission's own experts have clearly stated that there are no dental health benefits of fluoridated water over topical fluoride application. Water fluoridation is unnecessary in order for EU citizens to achieve the AI. The status of this science has likely been the main reason why the vast majority of EU Member States have rejected water fluoridation schemes. Most health authorities that have evaluated the risks of fluoridation have not distinguished between different forms of fluoride. For example, calcium fluoride, the principal form of naturally occurring fluoride in mineral waters, is poorly absorbed by the body, and most of what is ingested is excreted. However, synthetic fluorides, e.g. hexafluorosilicic acid, are almost completely absorbed. Many of the older studies were undertaken using less bioavailable forms of fluoride, such as sodium fluoride.
National Pure Water Association Ltd	5.2.1.3. Prenatal fluoride supplements and dental health/caries	The Panel appears to be well aware that there is little or no justification for prenatal interventions, that caries control is multifactorial, and the fact that effective oral fluoride use does not support any relationship between fluoride intakes and caries experience. Yet the Panel refrains from declaring the relationship entirely baseless.
National Pure Water Association Ltd	5.2.2. Bone health	The Panel agrees that the data available to it does not support any association between improved bone health and fluoride internalisation.
National Pure Water Association Ltd	6. Data on which to base dietary reference values	There is no alternative but to reiterate that caries experience was claimed (Dean 1942) to have an inverse relationship with drinking water fluoride content up to 1-2 ppm - but both this and the much later study of total fluoride intakes in relation to caries (Warren 2009) are not able to confirm the validity of this relationship. It is clear that the setting of an AI of 0.05mg/kg/day is no more than a formalisation that is intended to maintain a rationale

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		for supporting ongoing drinking water fluoridation together with other forms of fluoride intake that can be significant in contemporary populations. In reality there is no proper justification for any AI setting for children, nor for adults.
Anonymous	6. Data on which to base dietary reference values	line 1046: The Panel states that fluoride is not an essential nutrient and that no AR can be defined. However, questionable or relatively small caries differences between fluoridated and unfluoridated populations are used to be found. The author of these lines wants to emphasize that publications on benefits of fluoride suffered and probably still suffer from a) a strongly selective "publication bias" (far more "positive" findings = in favour of fluoride have been published than "negative" findings like many observations of NO increase in caries after discontinuing water fluoridation, b) IMPORTANT COFOUNDERS which have NOT BEEN TAKEN INTO ACCOUNT, such as c) pretended caries "reductions" of up to 50% (depending on age) caused by the enzyme-inhibiting effect of fluoride which may lead to later tooth eruption, causing less teeth to be exposed for a shorter time until the child's same chronological age without any tooth being less susceptible to caries (see my handout to SCHER – available by email). In the historic fluoridation trials.relative caries increase rates in the fluoridated children used to be higher among the fluoridated children. No significant significant differences are likely to occur when caries is referred to the same age of the compared teeth: http://biostatistics.oxfordjournals.org/content/6/1/145.full.pdf+html d) vitamin D as a stronger means against caries than fluoride might possibly be, affecting probably all "impressive" studies using Danish data (Kirkeskov, Ekstrand, …) because the regions low in natural fluoride in the water mainly correspond to the regions with little UVB from vitamin D-forming sunshine in spring and autumn (see again my handout to the SCHER committee ob Sept. 2010 – available by email). Furthermore the author and his father found NO minimum of caries at 1.0 ppm natural fluoride in water, but a possible minimum at about 0.3 ppm from all available data worldwide between about 1941 to 1981, a lack of ANY minimum in more southern countries (no deficiency in vitamin D) and virtually undetectable dental fluorosis at until about 0.3 ppm, see e.g. PDF-page 38, 39 of http://www.oehha.org/prop65/public_meetings/052909coms/fluoride/RZiegelbecker.pdf, http://www.fluorideresearch.org/143/files/FJ1981_v14_n3_p098-146.pdf (see PDF p. 30!) No Dean(1942)-like study, even if confounded, finds an essential further decrease of caries above 0.3 ppm in water. Any other effort (vitamin D supplementation, adequate nutrition) easily produces a benefit which is larger "by a factor" than any

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		increase of the fluoride concentration. At the contrary, caries decreased almost everywhere after the stop of a water fluoridation (http://www.fluorideresearch.org/313/files/FJ1998_v31_n3_p171-174.pdf, p.172, PDF-page 2) On the other hand, since already massive side-effects of incorporated fluoride, up to a reduction of IQ and Alzheimers by the transfer of aluminium to the brain (Doug Cross 2013), are observed at or below 1 ppm or must occur due to the variability of parameters within the population. Therefore, all recommendations for fluoride CAN, SHOULD or better MUST BE REDUCED by a FACTOR OF 3 (to 1/3) at once in order to avoid harm, while not altering a possible influence on caries in some regions. In my opinion it would be IRRESPONSIBLE to recommend an AI above 0.02 mg/kg bw. because of the clear lack of an essential caries reduction by a further increase while "exponentially" entering the region of detectable harm. http://www.fluoridealert.org/studies/brain01/, LETTER TO the NDA PANEL by the fluoride expert Rudolf Ziegelbecker Sen (of Feb 12, 2006 – again sent by email today). On the other hand, ANY intentional addition of fluoride to food or water is a medication.
National Pure Water Association Ltd	Conclusions	The Panel appears to be obliged to set an AI, and so they take the logical step of agreeing to maintain a recommendation in line with the level of dietary supplementation that other bodies have agreed is warranted if fluoridation is to be maintained on dental grounds. NPWA does not accept this formalisation of a strictly unsupported requirement to internalise fluoride in regular daily amounts in order to combat dental caries: 1. It is incorrect to present fluoride as a part of normal human nutrition that needs to be supplemented. EFSA's NDA Panel only did so because they were obliged to do so under the terms of reference given to them to make provision for fluoride supplementation from drinking water and from other sources in the context of dental caries control. 2. Dental public health and industrial vested interests have insisted, ever since artificial fluoridation was proposed, that internalisation of substantial amounts of daily fluoride was both quite safe and effective in combating dental caries. The evidence on which these assertions were based is once again used by the Panel to define an 'acceptable daily intake' despite the fact that the original supportive evidence has in the meantime been thoroughly discredited. 3. Fluoridation is not a sufficiently dentally effective treatment to justify its continuation in the light of present knowledge and acquired expertise in controlling dental caries; also it has become - and is still becoming - increasingly clear just how harmful a practice it is. NPWA's Recommendation to NDA Panel All of the NDA Panel's recommendations for dietary fluoride supplementation and the setting of an 'AI' of 0.05 mg/kg/day

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		should be reconsidered and, after open and frank discussion, they should be found to be strictly untenable and abandoned. The only sound advice to offer would be to the effect that all fluoride intakes, and whatever their sources - all being proportionately biotoxic - should be minimised as effectively as possible. Particularly this is the case when considering the integrity of human gamete cells, the entire process of gestation, neonatal and post-neonatal health and optimal childhood development. As tissues are artificially aged via cumulative fluoride exposures, there is also an accelerated decline into increasing old age with all its associated health deficits. Above all else, it should by now be clear that optimal human health, including dental health, cannot be preserved by augmenting fluoride internalisations of all kinds. Only net health decrements are obtained, and their severity reflects the sizes of the toxic doses to which individuals are exposed and the developmental stages that they have reached. Genetic susceptibility is also involved.
Anonymous	Conclusions	Line 1064: According to my and my father's findings from independent analyses and independently gathered data and to the documents referenced, as previously presented in the sections of Introduction, fluoride in water and caries, excess fluoride etc. etc., the "Conclusions" should read: "The Panel concludes that, in the case an AI of fluoride …. is set, it should be set to 0.02 mg/kg body weight per day. The reasons are that ingested fluoride produces side effects (dental fluorosis, effects caused by endocrine disruption, lowering of the IQ in a dose-reponse manner already at the formerly recommended intake at least in part of the population, i.e. in more sensible individues or individues who consume more). Since harm has to be avoided, since a caries reducing effect is not any more essentially increased above a water fluoride level of about 0.3 ppm which is 1/3 of the formerly recommended concentration, in the case such an effect exists in the target population and in the case it is not manly due to artefacts (tooth eruption delay, due to sufficient supply with vitamin D, etc.) an relevant increase of the beneficial effect by an equivalent intake via nutrition can also not be expected. Such recommended levels are normally reached without any supplements. Therefore, if it turns out that supplements containing fluoride are a medication since their only intention is to reduce dental caries, the setting of any AI for fluoride can and should be completely avoided."
Fluoride Action Network	Conclusions	Reasons # 3 and 4 why the proposed DRV should be rejected: 3) EFSA's Basis for for Relying on 1930s/1940s Data Is Flawed: The EFSA Panel derived the proposed DRV by relying solely on data published in the 1930s and 1940s. The EFSA Panel

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		justified its reliance on this 70-year-old data by noting that, unlike modern studies, these earlier studies were able to determine the anti-caries effect of total daily intake (because water was the only known source of fluoride in those studies). This rationale is flawed, however, because a recent, carefully conducted study by Warren, et al. (2009) assessed the anti-caries effect of total fluoride intake from all sources in a modern child's diet (e.g., water, toothpaste, processed food/beverages, etc). It makes little sense, therefore, for the EFSA Panel to rely on very old studies with crude methods when new data, from much more sophisticated studies, are now available. 4) The Proposed DRV Runs Contrary to Recent Data & Recommendations: The EFSA Panel's proposal to create a DRV of 0.05 mg/kg/day runs contrary to recent data and recommendations. In the Warren (2009), the authors monitored the total fluoride intake of over 600 children for the first nine years of their life. When the authors conducted dental exams of these children, they found that the caries status of the children bore no statistically significant relationship to the amount of fluoride the children's consumed. Based on these finding, the authors concluded that "achieving a caries-free status may have relatively little to do with fluoride intake." By contrast, the authors found that fluoride intake had an obvious and statistically significant effect on fluorosis rates. Accordingly, the authors suggested that the concept of an "optimal fluoride intake" is "problematic" and that "perhaps it is time that the term optimal fluoride intake be dropped from common usage." Other dental researchers have issued similar recommendations in recent years. According to Burt: "There was a time when the ingestion of fluoride in the range of 0.05 to 0.07 mg F/kg body weight/day was considered 'optimal' for preeruptive caries prevention. In light of present knowledge that preeruptive fluoride has little preventive effect, this range has better application has better application as an estimate of the maximum amount to be ingested by young children if fluorosis is to be kept at its lowest level." Consistent with these recommendations, fluoride supplements (which are designed to ensure a fluoride intake of 0.05 mg/kg/day) are no longer recommended for the general population, as they are a major risk factor for dental fluorosis and have only "weak" evidence of benefit. (Zimmer 2010; Ismail 2008; Rozier 2003; Riordan 1999). In light of these recommendations, it makes little sense to adopt a DRV of 0.05 mg/kg/day, as doing so would run directly counter to recent data and recommendations. [To be continued...]

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Anonymous	Recommendations for research/need for data	Need for further research: Further research on the systemic effects of fluoridation have been consistently called for in all reviews of water fluoridation (McDonagh et al 2000, MRC 2003, NHMRC 2007, NRC 2006, SCHER 2011). The Iowa cohort study with circa 1000 children has been useful but is not of sufficient size to detect al problems. A more detailed analysis of thyroid effects is also needed as a priority (NRC 2006). Fluoride, whether topically applied or ingested is not a necessary human supplement or nutrient and is necessary for caries prevention. However, the preventive effect of topical fluoride application is supported by good evidence in systematic reviews (eg Cochrane review). The efficacy of water fluoridation as a preventive measure is not supported by the same high standard of evidence and there is no evidence to support dietary supplement as having a preventive effect on dental caries. For example, a Cochrane review of fluoride added to milk consumed at school found that there is insufficient evidence to show the effectiveness of fluoridated milk in preventing tooth decay. Topical application is both the most effective and most efficient delivery method for fluoride for prevention of dental caries and has fewer risks related to ingestion subject to clear messages about use of fluoride toothpastes being given to parents to avoid excess ingestion in young children and infants.
National Pure Water Association Ltd	Recommendations for research/need for data	NPWA's Recommendations for research/need for data NPWA believes that there is already sufficient evidence deriving from excessive human gestational damage in areas under fluoridation to refute any attempt to claim otherwise. The evidence would be even clearer if professional obstetricians and those concerned with human postnatal development now took it upon themselves to examine in detail all the additional unpublished data available to them that can confirm just how harmful a practice is.
Anonymous	Recommendations for research/need for data	line 1085 Research priorities should be: IQ lowering, other side effects at low fluoride intake, "sine ira et studio" research which should clarify the role of vitamin D from sunshine and its confounding of studies from countries where sunshine and fluoride in water are known to be related, the part tooth eruption delay has in the caries reduction i.e. how much of them is pretended, if and how the results of older studies can be only partly or fully explained by the 2 mentioned effects plus by possible errors and scientific misconduct. The parallel priority should be to develop alternative, toxin-(fluoride-)free methods of maintaining teeth (there are already

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		several ways of letting teeth repair themselves naturally or get optimal teeth by proper nutrition).
Fluoride Action Network	Recommendations for research/need for data	Reason #5: 5. The Proposed DRV Cannot Be Considered Safe for the Entire Population Based on recent data, a DRV of 0.05 mg/kg/day cannot be considered safe for the entire population, particularly infants, people with end stage renal disease, people with thyroid disease, and people with iodine and calcium deficiencies. Consider, for example, the following: - In 2006, the National Research Council in the U.S. found that existing research on fluoride and the thyroid gland suggests that fluoride at doses as low as 0.01 mg/kg/day can impair thyroid function among individuals with suboptimal iodine intake. (NRC 2006). This is consistent with clinical research from Europe which found that daily doses of just 2 to 5 mg/day of fluoride ion (= 5 to 10 mg/NaF) was sufficient to reduce thyroid function among individuals with hyperthyroidism. (Galletti 1958). - In the Netherlands, the National Institute for Public Health and Environmental Protection has stated that "about 1.5 mg appears to be the maximum acceptable intake for nephritic patients." For most adults, this translates into a dosage well below 0.05 mg/kg/day. (NIPHEP 1989). - According to the World Health Organization, "Skeletal fluorosis is associated with a systemic uptake exceeding 5 mg/day in a relatively sensitive section of the general population." (WHO 2000). For adults weighing over 100 kg, a dose of 5 mg/day will be less than 0.05 mg/kg/day. - In India, researchers have found that "In calcium-deficient children the toxic effects of fluoride manifest even at marginally high (>2.5 mg/d) exposures to fluoride." (Teotia 1998). REFERENCES: Burt BA. (1999). The case for eliminating the use of dietary fluoride supplements for young children. J Public Health Dent.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT

59(4):269-74.

Centers for Disease Control and Prevention. (2001) Morbidity and Mortality Weekly Report 50(RR14): 1-42.

Featherstone, JDB. (2000). The Science and Practice of Caries Prevention. Journal of the American Dental Association 131: 887-899.

Fejerskov O. (2004). Changing paradigms in concepts on dental caries: consequences for oral health care. Caries Research 38: 182-91.

Galletti P, Joyet G. (1958). Effect of fluorine on thyroidal iodine metabolism in hyperthyroidism. Journal of Clinical Endocrinology 18(10):1102-1110.

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

National Research Council. (2006). Fluoride in Drinking Water: A Scientific Review of EPA's Standards. National Academies Press, Washington D.C.

National Institute for Public Health and Environmental Protection. (1989). Integrated criteria document fluorides. Report No 758474010. The Netherlands.

Riordan PJ. (1999). Fluoride supplements for young children: an analysis of the literature focusing on benefits and risks. Community Dent Oral Epidemiol. 27(1):72-83.

Rozier RG, et al. (2010). J Am Dent Assoc. 141(12):1480-9.

Teotia M, Teotia SP, Singh KP. (1998). Endemic chronic fluoride toxicity and dietary calcium deficiency interaction syndromes of metabolic bone disease and deformities in India: year 2000. Indian Journal of Pediatrics 65:371-81.

Warren J, et al. (2009). Considerations on optimal fluoride intake using dental fluorosis and dental caries outcomes: A longitudinal study. Journal of Public Health Dentistry 69:111-15. See: http://www.fluoridealert.org/studies/ifs/

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		World Health Organization Regional Office for Europe. (2000). Air Quality Guidelines for Europe – Second Edition. WHO Regional Publications, European Series, No. 91, p. 158. Zimmer S, et al. (2003). Recommendations for the use of fluoride in caries prevention. Oral Health Prev Dent. 1(1):45-51.

ABBREVIATIONS

AI	Adequate Intake
AR	Average Requirement
CI	Confidence interval
DMFT	Decayed, missing or filled teeth in the permanent dentition
DRV	Dietary Reference Value
EFSA	European Food Safety Authority
EU	European Union
IQ	Intelligence quotient
NRC	National Research Council
PRI	Population Reference Intake
SCF	Scientific Committee on Food
RI	Reference Intake range for macronutrients
UL	Tolerable Upper Intake Level
UV	Ultra-violet