Healthy Lives, Healthy People: Consultation on the arrangements for consideration of proposals on the fluoridation of drinking water
Department of Health
Gateway Reference 17618
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Response by:

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Introduction

Fluoride is not essential for general or dental health. Its addition to drinking water via the practice of fluoridation has been, since its inception in 1945, a highly controversial issue due to the fundamental ethical objection to water undertakers medicating (Jauncey, 1983) consumers via the public water supply and the total absence of any high-quality evidence to support the claimed efficacy and safety of the practice. This paper sets out our response to the consultation, the supporting documentation and the questions posed. References are available on request.

Despite the questionable ethics (Awofeso, 2012) and absence of high-quality evidence (York, 2000), the Department of Health (the Department) has a policy in favour of fluoridation – it presents water undertakers adding fluoride to drinking water as having the properties to prevent tooth decay. It is not possible for the Department to be objective on this issue and this lack of objectivity is reflected in the documentation supplied. The ethical issue aside, when the Department received the York Review (York, 2000), the only appropriate course of action would have been the immediate cessation of fluoridation and steps by the Government to repeal all fluoridation sections of the *Water Industry Act 1991* (WIA1991). Obviously, this did not happen with subsequent changes to WIA1991 by the *Water Act 2003* and the *Health and Social Care Act 2012*.

If there is a dental health problem in a particular community, Public Health England, an Executive Agency of the Department, cannot be relied upon for an objective view on how such problem can be remedied. An objective view should be sought from the National Institute for Health and Clinical Excellence which has responsibility for Public Health Guidance on all areas of public health including oral health.

Although it will not be absolutely clear to all consultees, the Department is now in the situation where it is consulting on how to arrange the regulation deckchairs (regulations on fluoridation proposals) on a fluoridation ship that is clearly holed beneath the waterline.

The only conceivable situation where a community's water supply might have a substance or combination of substances added is where there is high-quality evidence to support the efficacy and safety of the measure and every person affected gives their individual, informed consent to the intervention. Should only one affected individual object, the intervention should not take place.

Some water undertakers (water companies) in England are in the unenviable position of feeling obliged by current legislation to medicate (Jauncey, 1983) their customers by adding industrial grade fluorosilicic acid to their supplies. NPWA Ltd believes current legislation 'enabling' fluoridation (ref) to be bad law and takes the view that water companies in England should cease fluoridating public water supplies as the intervention constitutes an act of mass battery. By ceasing fluoridation, water companies would, going forward, avoid any liability for committing this act. If the Department wished fluoridation to continue, it would need to be given powers to access water company premises, acquire the fluoridation plant and operate it with its own staff.

For more information on NPWA Ltd's position on water fluoridation we append *NPWA Evidence to UK Health Committee: Public Health, June 2011* as Appendix 1.

Consultation Documents

Impact Assessment

Paragraph 1 No reference to high-quality evidence is given to support the claim that fluoride added to drinking water to 1ppm in drinking water is the "optimum level" for having any effect in reducing tooth decay.

Paragraph 16, 2A There is no reference to the cost of addressing the damage to teeth by dental fluorosis that is likely to increase if fluoridation continues at its present rate or the number of schemes increase.

Equality Analysis

Paragraph 15 This paragraph shows the Department's bias and lack of objectivity on fluoridation. We have permission of the authors of the book *The Case Against Fluoride* (Connett et al, 2010) to reproduce the following section from the book:

> **The Dean Study**
> In describing Dean's early work, the Centers for Disease Control and Prevention (CDC) stated in 1999, "Dean compared the prevalence of fluorosis with data collected by others on dental caries prevalence among children in 26 states (as measured by DMFT) and noted a strong inverse relation. This cross-sectional relation was confirmed in a study of 21 cities in Colorado, Illinois, Indiana, and Ohio."[4] This raises the question, if Dean had access to data from twenty-six

states, why did he use data from only twenty-one cities from four states in this critical two-part report? Did he select the cities that best supported his hypothesis? Dean's twenty-one-city plot is shown in figure 7.1.

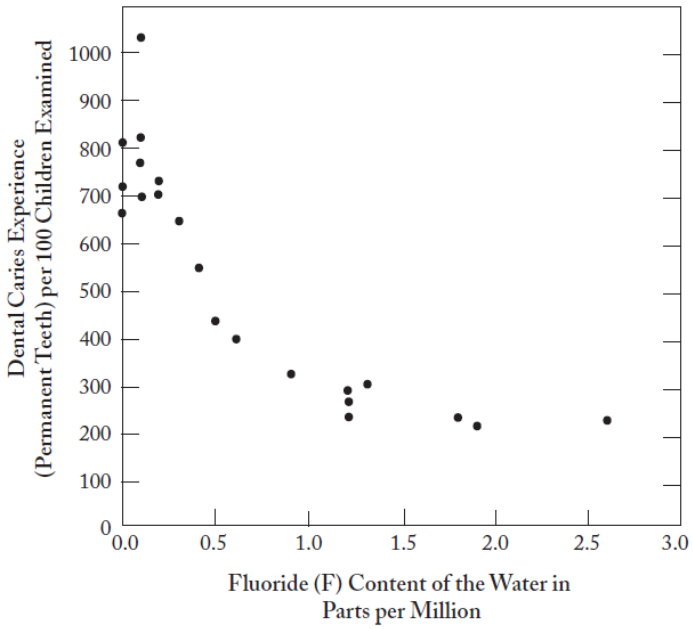

Figure 7.1. Dean's twenty-one-city graph. The original caption read, "Relation between the amount of dental caries (permanent teeth) observed in 7257 selected 12–14 year old white school children of 21 cities of 4 states and the fluoride (F) content of the public water supply." Source: Adapted from Dean, Arnold, and Elvove, 1942.[5]

Dean claimed that he limited the cities to those for which he had evidence that the water supply had been a constant source of natural fluoride for twenty years or more. However, according to Dr. Fred Exner, a well-known radiologist and prominent critic of fluoridation, during cross-examination in court (Schuringa v. Chicago, 1960), Dean admitted that some of the cities did not meet that criterion. The late Rudolf Ziegelbecker, an Austrian statistician, pursued this issue. When he added in all the data he could find from the United States and Europe that compared prevalence of tooth decay with natural fluoride levels in the water, the inverse relationship reported by Dean was absent (see figure 7.2).

However, when he examined the same data for dental fluorosis, he found a robust direct relationship—that is, as the level of fluoride in the water increased, so did the prevalence of dental fluorosis (see figure 7.3). One relationship (between fluoride levels and dental fluorosis) holds up over the "background noise"; the other (between fluoride levels and dental decay) does not.[7]

In a subsequent study Ziegelbecker and his son examined tooth decay data collected by the World Health Organization (WHO) in several individual countries, and again they found no relationship between tooth decay and levels of natural fluoride in drinking water.[9] Ziegelbecker Senior further elaborated on his critique of Dean's twenty-one-city study and the practice of fluoridation in general in a submission he made to Codex Alimentarius in 2003."[10]

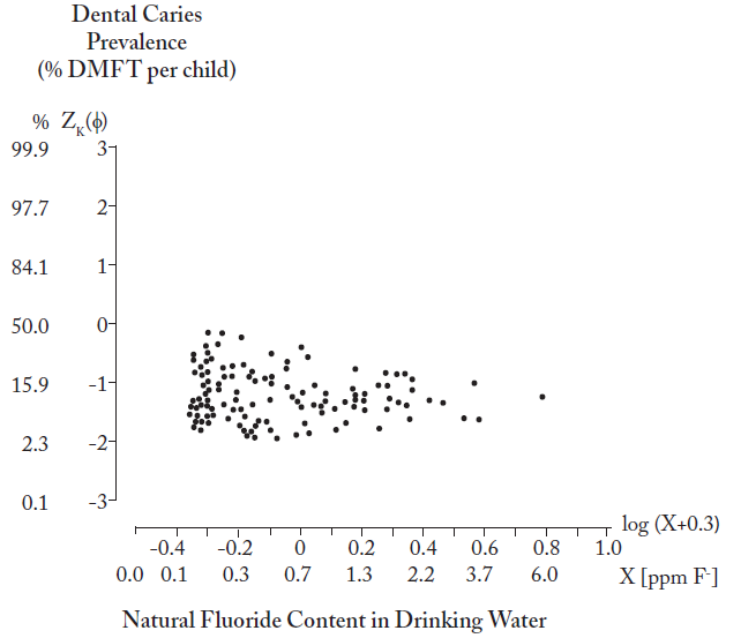

Figure 7.2. Ziegelbecker's plot of prevalence of tooth decay versus water fluoride levels. Tooth decay is plotted as the probit values of the percentages of the average DMFT in each community (the Z scale). The probit transformation is a standard procedure for making percentage data linear and more amenable to statistical analysis. The fluoride water levels (X ppm) in each community are plotted on a logarithmic scale as log (X + 0.3). The addition of 0.3 is Ziegelbecker's adjustment for other sources of fluoride in addition to water. Source: Reproduced from Ziegelbecker, 1981.[8]

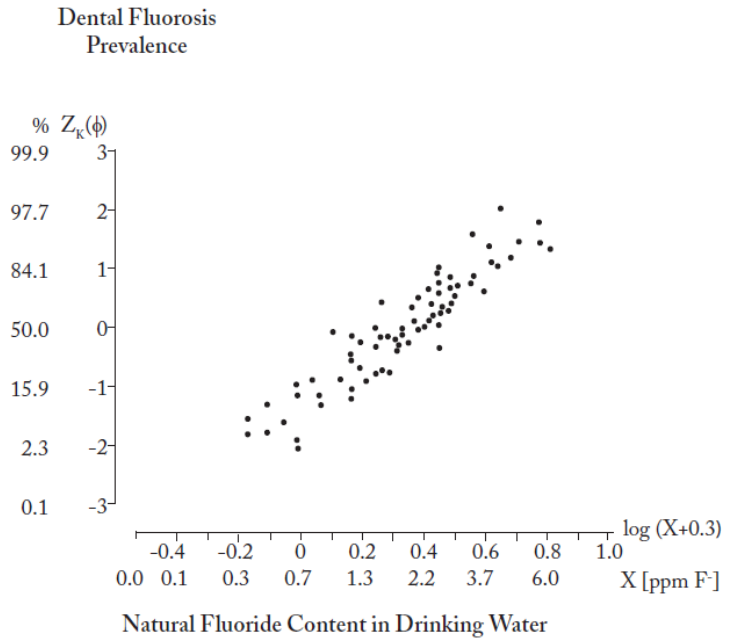

Figure 7.3. Ziegelbecker's plot of the prevalence of dental fluorosis versus water fluoride levels. Dental fluorosis is plotted as the probit values of the percentages of the children in each community with this condition (the Z scale). The scale used in the horizontal axis is explained in the legend to Figure 7.2. Source: Reproduced from Ziegelbecker, 1981.11

References

2. H. T. Dean, F. A. Arnold Jr., and E. Elvove, "Domestic Water and Dental Caries. V. Additional Studies of the Relation of Fluoride Domestic Waters to Dental Caries Experience in 4425 White Children, Age 12-14 Years, of 13 Cities in 4 States," Public Health Reports 57, no.

32 (1942): 1155–79, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1968063/pdf/pubhealthreporig01481-0001.pdf

4. Centers for Disease Control and Prevention, "Achievements in Public Health, 1900–1999: Fluoridation of Drinking Water to Prevent Dental Caries," Mortality and Morbidity Weekly Review 48, no. 41 (October 22, 1999): 933–40, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm. Note: The authors of this report were Scott Tomar and Susan Griffin, as cited in Tomar's curriculum vitae, paper number 27 on page 27, http://fluoridealert.org/re/tomar.scott.cv.ref.27.pdf
5. H. T. Dean et al., "Domestic Water and Dental Caries. V" (n. 2 above).
6. F. B. Exner, "Analytical Commentary on the 1960 Testimony of Dr. H. Trendley Dean in the Suit to Enjoin Fluoridation of Chicago's Water, Part II," in Fluoridation: Its Moral and Political Aspect; A New and Comprehensive Study (New York), The Greater New York Committee Opposed to Fluoridation (undated).
7. R. Ziegelbecker, "Fluoridated Water and Teeth," Fluoride 14, no. 3 (1981): 123–28, http://fluoridealert.org/re/ziegelbecker-1981.pdf
8. Ibid.
9. R. Ziegelbecker and R. C. Ziegelbecker, "WHO Data on Dental Caries and Natural Fluoride Levels," Fluoride 26, no. 4 (1993): 263–66, http://fluoridealert.org/re/ziegelbecker-1993.pdf
10. R. Ziegelbecker, "Comments and Scientific Critique on the Report of the Working Group to Consider Section 3.1 Essential Composition in the Proposed Draft Revised Standard for Infant Formula at (Step 3)," submitted to Codex Alimentarius Commission FAO/WHO, Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), March 30, 2003, http://fluoridealert.org/re/ziegelbecker.2003.codex.pdf
11. R. Ziegelbecker, "Fluoridated Water and Teeth" (n. 7 above).

Paragraph 41 The reference Griffin et al (Griffin, 2007) is used by the Department to support the claim that fluoridation benefits adults. Following a complaint to the Advertising Standards Authority, the paper was independently reviewed by the University of York and deemed to be of a quality too poor to support the view that fluoride benefits adults. The claim that fluoride benefits adult teeth was withdrawn. The Department should be aware of this and should not have used the same statement with reference to Griffin et al in its Equality Analysis.

Paragraph 48 Research in the USA by Beltran and Barker (Beltran and Barker, 2007) has clearly demonstrated that certain ethnic groups are at higher risk of dental fluorosis including moderate to severe fluorosis.

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Paragraph 5 No reference to high-quality evidence is given to support the claim that fluoride added to drinking water to 1ppm, or a lower practicable level, has any effect in reducing tooth decay. The British Fluoridation Society is an organisation established under the auspices of the British Dental Association to promote fluoridation despite the ethical concerns and absence of high-quality evidence. The Department, which cannot be objective on the fluoridation issue for reasons given above, cites a publication published by another organisation that cannot be objective on the practice.

Paragraph 6 In 2000, 55 years after fluoridation began in the USA, the York Review (York,

2000) team was unable to identify one high-quality study to show that the practice is effective or safe. On 28 October 2003, because of misrepresentation of its findings by fluoridation proponents, the York team issued a statement - *What the York Review on the fluoridation of drinking water really found* (NHSCRD, 2003), which includes:

> "We were unable to discover any reliable good-quality evidence in the fluoridation literature world-wide. What evidence we found suggested that water fluoridation was likely to have a beneficial effect, but that the range could be anywhere from a substantial benefit to a slight disbenefit to children's teeth.
>
> This beneficial effect comes at the expense of an increase in the prevalence of [dental] fluorosis."

Paragraph 7 This paragraph refers to surveys of childhood dental health by the British Association for the Study of Community Dentistry. These surveys were rejected by the York Review team as they did not meet the team's minimum criteria for evidence, which was Grade C – Low quality, High Risk of Bias. It is our concern that unscientific and selective geographical comparisons of dental health and fluoride levels in drinking water may be used by Directors of Public Health (joint appointees by Public Health England and upper-tier authorities) to initiate consultations on fluoridation proposals.

If there is a dental health problem in a particular community, Public Health England, an Executive Agency of the Department, cannot be relied upon for an objective view on how such problem can be remedied. An objective view should be sought from the National Institute for Health and Clinical Excellence which has responsibility for Public Health Guidance on all areas of public health including oral health.

Paragraph 8
Professor Trevor Sheldon, Chairman of the York Review's Advisory Group said in an open letter dated 3 January 2001:

> " The review found water fluoridation to be significantly associated with high levels of dental fluorosis which was not characterised as "just a cosmetic issue"."

and

> " The review did not show water fluoridation to be safe. The quality of the research was too poor to establish with confidence whether or not there are potentially important adverse effects in addition to the high levels of fluorosis. The report recommended that more research was needed."

To date there has been no research into the possible harmful effects of fluoridation. If the Department does not look (or get someone to look), it will not find.

Paragraph 9 It is wrong of the Department to conflate fluoridated water with 1 ppm fluoride with topical fluorides (e.g. fluoride toothpastes with typically 1,450 ppm fluoride and varnishes with even higher levels). There is good quality evidence to support the efficacy of topical fluorides but there is no high-quality evidence to support the claimed

efficacy of fluoridated water with 1 ppm fluoride. The summary of the report by the SCHER Committee (SCHER, 2011) includes the following:

> ”Fluoride is not an essential element for human growth and development...', '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.', '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.' and 'For younger children (1-6 years of age) the UL (The upper tolerable intake level) was exceeded when consuming more than 1 litre of water at 0.8 mg fluoride/L (mandatory fluoridation level in Ireland) and assuming the worst case scenario for other sources. For infants up to 6 months old receiving infant formula, if the water fluoride level is higher than 0.8 mg/L, the intake of fluoride exceeds 0.1 mg/kg/day, and this level is 100 times higher than the level found in breast milk (less than 0.001 mg/kg/day).”

Paragraph 10 The Department’s use of the case of *Jehl Doberer against Switzerland*, 1991, does not accurately reflect the ethical and legal aspects around the issue of fluoridation. Article 8 of the Council of Europe’s Convention on Human Rights is not an absolute right. The European Commission of Human Rights accepted that fluoridation amounted to an interference with personal liberty but set against this the perception at that time that fluoridation provided some benefit to “popular health”.

In 2003, Basel’s Health & Social Commission [GSK] voted 11-2 to recommend stopping fluoridation of the city’s water supply for the following two reasons:

1. Lack of evidence that water fluoridation is more effective than salt fluoridation in reducing tooth decay.
2. The inefficiency/wastefulness of water fluoridation.

On 9 April 2003, Basel's City Parliament, after receiving GSK's recommendation, voted 73-23 to stop fluoridating the city’s water supply.

It is now over 20 years since the Jehl-Doberer decision was made. There is still no high quality evidence to show that fluoridation is either effective or safe. Meanwhile, toxicological evidence has accumulated, which shows that fluoridation gives no adequate margin of safety to protect those subsets of the population who are more susceptible to fluoride’s toxic effects. If Article 8 of the Convention was tested today, the outcome could well be different from the decision made in 1991.

Although the Council of Europe’s Convention on Human Rights and Biomedicine and the European Union’s Charter of Fundamental Rights do not have legal effect in the UK, their

articles enshrining the individual right to withhold consent to a medical intervention should be viewed by the Department as ethical 'writing on the wall'.

The European Commission of Human Rights' view on medication in their decision on Jehl Doberer against Switzerland is seriously flawed. The Commission acknowledged that fluorosilicic acid was added to drinking water to prevent dental caries but failed to consider the definition of a medicinal product in *Directive 65/65/EEC*:

a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.'

Responses to consultation questions

1. Do you agree with our proposals for the arrangements to enable a joint decision to proceed with a proposal?

No, we disagree with fluoridation entirely and believe that all fluoridation legislation should be repealed with immediate effect.

2. Do you agree that a decision to proceed with fluoridation should be made on a super-majority basis?

No, The only conceivable situation where a community's water supply might have a substance or combination of substances added is where there is high-quality evidence to support the efficacy and safety of the measure and every person affected gives their individual, informed consent to the intervention. Should only one affected individual object, the intervention should not take place.

3. Are there any other approaches that you believe could work better?

See our introduction and answers to 1 and 2 above.

4. Do you agree that: the membership of the committee established to progress a proposal on fluoridation should be prescribed in regulations[?]

See our introduction and answers to 1 and 2 above.

5. Do you agree that we do not need to make regulations in relation to holding and vacating office?

See our introduction and answers to 1 and 2 above.

6. Do you agree that regulation in relation to minimum and maximum membership would be too prescriptive?

See our introduction and answers to 1 and 2 above.

7. Do you agree that there should be an alternative approach in the regulations when there are a large number of affected local authorities?

See our introduction and answers to 1 and 2 above.

8. If so, would this be adopted when there are four or more local authorities?

See our introduction and answers to 1 and 2 above.

9. Do you agree a joint committee of Health and Wellbeing Boards might be an efficient approach?

See our introduction and answers to 1 and 2 above.

10. Do you agree that the existing requirements for conducting consultations at option 2 remain appropriate; or are there any further steps in relation to consultations that you feel a local authority or the joint committee should take?

See our answers to 1 and 2 above.

11. Should there be any other further changes to the proposed consultation requirements?

See our introduction and answers to 1 and 2 above.

12. Are there any requirements that you would like to suggest that we include in regulations to minimise or remove any potential adverse impacts or disadvantages for groups with a "protected characteristic" as set out under the Equality Act?

See our introduction and answers to 1 and 2 above.

13. Do you agree that children and young families in deprived areas be encouraged to participate in consultations on proposals for new fluoridation schemes?

See our introduction and answers to 1 and 2 above.

14. Will this contribute to implementation of the duty on the Secretary of State to have regard to the need to reduce health inequalities between people with respect to the benefits they can obtain from the health service?

See our introduction and answers to 1 and 2 above.

15. Do you agree that the new duty which is due to be imposed on the Secretary of State to have regard to the need to reduce inequality- whatever its cause - is relevant to proposals to introduce fluoridation schemes?

See our introduction and answers to 1 and 2 above.

16. Do you have any information
    - on the cost benefits of fluoridation schemes and/or
    - the costs a local authority would incur in conducting a consultation?

See our introduction and answers to 1 and 2 above.

17. Do you agree that: no specific requirements are needed on consultation material or other information provided to the public (other than those specified in public law and in paragraphs 74 – 76)?

See our introduction and answers to 1 and 2 above.

18. Do you agree that the proposing local authority or joint committee should nevertheless be required to obtain advice from the director(s) of public health?

See our introduction and answers to 1 and 2 above.

19. If no, what requirements do you think should be imposed?

See our introduction and answers to 1 and 2 above.

20. What role should Public Health England play in supporting local authorities with their fluoridation functions?

See our introduction and answers to 1 and 2 above.

21. What role (if any) should Public Health England play in supporting local authorities to gather equality data?

See our introduction and answers to 1 and 2 above.

22. Do you agree that the method by which local authorities ascertain public opinion on fluoridation proposals be left to their discretion?

See our introduction and answers to 1 and 2 above.

23. If not, what methods of ascertainment would you wish to see imposed in regulations?

See our introduction and answers to 1 and 2 above.

24. Do you agree that option 3 is the most appropriate option and that existing provision should be revised so that, in particular, an authority or committee is specifically required to have regard to the views of the local population and to the financial implications of the proposal?

See our introduction and answers to 1 and 2 above.

25. Do you agree that a decision for two or three local authorities should be made by a super-majority?

See our introduction and answers to 1 and 2 above.

26. What alternative mechanisms might work better?

See our introduction and answers to 1 and 2 above.

27. Do you agree that there should be a different voting mechanism for a joint committee of four or more affected local authorities?

See our introduction and answers to 1 and 2 above.

28. Should population-weighted voting be prescribed?

See our introduction and answers to 1 and 2 above.

29. What other factors should be considered?

See our introduction and answers to 1 and 2 above.

30. Do you agree with the proposed model of population weighting and the approach to calculating the affected population?

See our introduction and answers to 1 and 2 above.

31. How easy will it be to determine an accurate population number?

See our introduction and answers to 1 and 2 above.

32. Should population-weighted voting also apply to proposals where there are only two or three affected local authorities?

See our introduction and answers to 1 and 2 above.

33. Do you agree that the Secretary of State should have regulatory powers to vary or terminate a fluoridation scheme without a local authority proposal where a general risk to health is identified from fluoridation or a specific local risk emerges?

See our introduction and answers to 1 and 2 above.

34. Do you agree that, as with the current provisions, consultation should not be required for minor variation of schemes?

See our introduction and answers to 1 and 2 above.

35. If not, in what cases should consultation be required?

See our introduction and answers to 1 and 2 above.

36. Does the power in section 88K(5) whereby the Secretary of State can disapply the duty of a proposer local authority to enable the authorities affected by a proposal to terminate a fluoridation scheme to decide whether further steps should be taken on the proposal need to be exercised?

See our introduction and answers to 1 and 2 above.

37. What are your views on the benefits of consultation in relation to the maintenance of existing arrangements?

See our introduction and answers to 1 and 2 above.

38. Should the regulations prescribe a process for requiring local authorities to consult and decide on whether to maintain or request a termination of a fluoridation scheme?

See our introduction and answers to 1 and 2 above.

39. If so, what should the procedural requirements be in such cases eg should time intervals be set at which the continuation of the scheme should be reviewed as suggested at paragraph 157?

See our introduction and answers to 1 and 2 above.

40. Do you agree that the procedural approach for a consultation proposal on terminating a contract for a fluoridation scheme should mirror the approach for a new proposal?

See our introduction and answers to 1 and 2 above.

41. Are there any additional requirements that local authorities should be required to consider?

See our introduction and answers to 1 and 2 above.

42. What are your views on the benefits of imposing minimum interval between consultations on the termination of existing fluoridation schemes?

See our introduction and answers to 1 and 2 above.

43. If so, what interval do you suggest would be appropriate?

See our introduction and answers to 1 and 2 above.