



**Strategy and Policy  
Committee**  
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## **INFANT FORMULA RECONSTITUTED WITH FLUORIDATED TAP WATER**

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### **Purpose of Report**

1. The purpose of this report is to provide the Strategy and Policy Committee with information about the interim guidance issued by the American Dental Association in November 2006 on fluoride intake for infants and young children.
2. This report is in response to a presentation to the Committee at its 7 March meeting by two representatives of the Fluoride Action Network who advised the Committee of the recent “warning” from the American Dental Association (ADA) on the use of fluoridated water to reconstitute infant formula and the risk of an infant later developing dental fluorosis.

### **Recommendation**

That the Committee:

- (i) instructs officers to continue to monitor developments on the issues discussed in this report; and
- (ii) notes that should national policy settings with regard to fluoridation and, in particular, the fluoride intake for infants and young children, be amended following evaluation of further research, the Committee instructs officers to report back and make recommendations on an appropriate response.

### **Executive Summary**

3. Public water supplies are fluoridated for oral health reasons. New Zealand evidence indicates that New Zealand children who live all their lives on optimally fluoridated areas have 30 to 40 percent lower levels of dental decay than those who have lived in low fluoride areas

4. Enamel fluorosis is a change to the colour of the tooth enamel, the severity of which is dependent on the total fluoride intake during the period of tooth development. In New Zealand, evidence published in 2005 found the levels of enamel defects among children who had lived their whole lives in a fluoridated area had not increased since the 1980s and the levels of the most severe enamel defects had declined from 14-15% in the 1980s to about 5%.
5. Fluoridating water within the internationally accepted optimal range of 0.7 mg/l to 1.2 mg/l maximises the oral health benefits while minimising the risk of enamel fluorosis. The Ministry of Health recommends fluoride levels in New Zealand drinking water be adjusted to 0.7-1.0 mg/l. The Wellington Regional Council adds fluoride to achieve an average target of 0.85 mg/l.
6. In November 2006 the American Dental Association (ADA) released "*Interim Guidance on Fluoride Intake for Infants and Young Children*" (Appendix 1). The ADA's interim guidance raised the possibility that infants could potentially receive a greater than optimal amount of fluoride through infant formula that has been mixed with water containing fluoride.
7. On 26 March 2007 the ADA issued a further letter (Appendix 2) regarding its interim guidance stating that it is concerned that some opposed to community water fluoridation may be mischaracterizing its recent interim guidance. The ADA also states that it is important to have fluoridated water and the interim guidance simply indicates that babies less than one year old need less fluoride than everyone else because they are so small.
8. Fluoride is available from a number of sources. The most important sources of fluoride for infants consuming fluoridated water will be the water, diet (including infant formula) and toothpaste. Regular toothpastes contain 1000ppm fluoride; child strength toothpastes contain 400-550ppm for children aged 0-6 years.
9. While theoretical estimates of fluoride consumption by infants fed exclusively on formula made up with fluoridated water consistently indicate that they exceed the accepted threshold, studies measuring actual intake suggest the intake may be much lower. Limited evidence suggests that because absorption of minerals varies according to a range of factors, the amount absorbed may be less than the amount ingested.
10. With regard to reconstituting infant formula using bottled water, it may not be possible for parents to be completely sure that bottled water is fluoride-free. Most bottled water on sale is mineral or spring water and will not have added fluoride but may contain some naturally occurring fluoride at levels similar to un-fluoridated public drinking water. However, unless a bottled water is sold as mineral, spring water or similar, bottled water could be sourced from any potable source, including fluoridated public drinking water. Bottled water is exempt from being labelled with a nutrition information panel (NIP), although many bottled waters are labelled with information about levels of some minerals. In any case, fluoride is not required to be declared.

11. There is some concern that infants fed exclusively on infant formula for prolonged periods could receive a greater than optimal amount of fluoride if the infant formula is mixed with water containing fluoride. The reconstitution of infant formula using fluoridated water may increase the risk of enamel fluorosis.
12. The Ministry of Health considers any increase in risk of enamel fluorosis is likely to be very small, that current New Zealand evidence is that children are not developing inappropriate levels of enamel defects and that New Zealand children receiving optimally fluoridated water, and other fluoride through diet and toothpaste, have 30 to 40 percent lower levels of dental decay.
13. The Ministry of Health and New Zealand Food Safety Authority are aware of the ADA's interim guidance and continue to monitor national and international information. Ministry of Health officials are currently of the view that there is no need to change the advice for New Zealand parents on the water to use in making up infant formula.
14. Council officers consider it appropriate at this stage to continue to monitor developments on the issues discussed in this paper. Should national policy settings with regard to fluoridation and, in particular, the fluoride intake for infants and young children, be amended following evaluation of further research, Council officers will report back and make recommendations on an appropriate response.

## **Background**

### **Fluoridation of public water supplies**

15. Public water supplies are fluoridated for oral health reasons. About 60 countries have water fluoridation covering hundreds of millions of people. Research has shown that fluoride is effective in reducing the prevalence of dental caries in populations. A New Zealand study comparing children in the Canterbury and Wellington regions was published in 2004, confirming that children living in regions with access to fluoridated water show a 30 to 40 percent benefit in lower levels of dental decay compared with those living in non-fluoridated areas. A systematic review of the literature published in the United Kingdom in 2000, known as the York report, estimated that the proportion of children free of any dental caries is 14.8 percent lower in optimally fluoridated areas.
16. Enamel fluorosis, is a change to the colour of tooth enamel that varies from very mild flecks or lines that increase the tooth whiteness to severe changes to the tooth enamel, which can involve discolouration, enamel loss, and pitting. The severity of enamel fluorosis is dependent upon the total fluoride intake during the period of tooth development.
17. Investigation of levels of enamel fluorosis by the UK Medical Research Council, following the York Report, reported that studies of enamel fluorosis in areas where there were naturally occurring optimal fluoride levels in the water showed higher levels of enamel fluorosis than studies from areas where the fluoride level had been artificially increased to the optimal level. Recent UK and Irish studies

of areas with artificially increased levels of water fluoridation indicate that 1-4 percent of the population have aesthetically concerning enamel fluorosis.

18. In New Zealand no areas receive water with optimal naturally occurring levels of fluoride and all areas receiving optimally fluoridated water, receive this through an artificial increase to the naturally occurring fluoride level.
19. The most recent New Zealand information from a Southland study of 9-year-old children published in 2005 found that the levels of enamel defects among children who had lived their whole lives in a fluoridated area had not increased since earlier studies in the 1980s. Further, the levels of the most severe enamel defects have declined from 14-15% in the 1980s to about 5%, and this level did not differ between children who had lived all of their lives in optimally fluoridated areas and children who had lived all of their lives in low fluoride areas.
20. The optimal concentration of fluoride internationally is between 0.7-1.2 mg/l (mg/l is an equivalent measure to parts per million [ppm]). This concentration has been found to provide the maximum oral health benefit while minimising the prevalence of fluorosis.
21. In New Zealand, the Ministry of Health (the Ministry) recommends that the fluoride levels in drinking water supplies be adjusted to 0.7 - 1.0 mg/l of fluoride to maximise the prevention of dental caries and to minimise the risk of enamel fluorosis. The maximum acceptable value (MAV) for fluoride in the 2005 Drinking-Water Standards is 1.5 mg/l.
22. The natural level of fluoride in Wellington's water is around 0.1 mg/l. Greater Wellington Regional Council adds fluoride to achieve an average target of 0.85 mg/l.

## **Discussion**

### **American Dental Association Interim Guidance**

23. In November 2006 the ADA released "*Interim Guidance on Fluoride Intake for Infants and Young Children*". The interim guidance states:

*“The ADA supports community water fluoridation as the single most effective public health measure to prevent tooth decay. It is a powerful strategy to reduce disparities in tooth decay among different populations and is more cost-effective than other forms of fluoride treatments or applications. Fluoridation is endorsed by the Centers for Disease Control and Prevention, which has listed community water fluoridation as one of 10 great public health achievements of the 20th century.”*

24. However, the ADA's interim guidance raised the possibility that infants could potentially receive a greater than optimal amount of fluoride through infant formula that has been mixed with water containing fluoride. This could be during a time when their developing teeth may be susceptible to enamel fluorosis.

25. On 26 March 2007 the ADA issued a further letter regarding its interim guidance and stated that it was concerned that some opposed to community water fluoridation may be mischaracterizing its recent interim guidance. The ADA also states that the bottom line is that it is important to have fluoridated water and the interim guidance simply indicates that babies less than one year old need less fluoride than everyone else because they are so small.

### **Background to ADA's advice**

26. The ADA's advice is based on a 2006 United States National Research Council (NRC) report and a 2005 report from the United States Centres for Disease Control and Prevention (CDC).
27. The 2006 NRC report was a 10 yearly review of the United States' Environmental Protection Agency's (EPA) maximum allowed concentration of 4.0 mg/l of fluoride in drinking water. The United States has wide ranging levels of naturally occurring fluoride in drinking water supplies. In some areas the naturally occurring fluoride level must be reduced to the optimal level and in other areas water is artificially fluoridated to the optimal level.
28. The NRC reviewed evidence from the last decade and recommended that the maximum allowable concentration be reduced to 2.0 mg/l. Studies cited in the report raised the possibility that infants could receive a greater than optimal amount of fluoride through infant formula being mixed with water containing fluoride. The review found that severe enamel fluorosis does occur in the United States, but the prevalence is very low in areas served by drinking-water where the fluoride concentration is below 2 mg/l.
29. The review did not look at the potential health risks of optimally fluoridated water where the concentration of fluoride is 0.7 - 1.2 mg/l in the United States. As a result, the "conclusions regarding the potential for adverse effects from fluoride at 2 to 4 mg/l in drinking water do not apply at the lower water fluoride levels commonly experienced by most U.S. citizens."
30. The 2005 CDC report compared the findings of the two national surveys: the first undertaken in 1988-1994 of school children and the second in 1999-2002 of households. A 9% increase in the prevalence of very mild or greater fluorosis was observed in children and adolescents aged 16-19 years.
31. Based on this information, the ADA included in the interim guidance some simple precautionary advice for those parents, caregivers and health care professionals who may be concerned:

*"If liquid concentrate or powdered infant formula is the primary source of nutrition, it can be mixed with water that is fluoride free or contains low levels of fluoride to reduce the risk of fluorosis..."*

32. The interim guidance also advises:

*“Enamel fluorosis is not a disease but rather affects the way that teeth look. Most cases of fluorosis result in faint white lines or streaks on tooth enamel that are not readily apparent to the affected individual or the casual observer”.*

33. Enamel fluorosis can occur as a result of high fluoride intake during tooth development and in considering the potential for this to occur it is important to consider the range of fluoride sources. For infants and children consuming fluoridated water the most important sources will be the water, diet (including infant formula for infants) and toothpaste. It is important to appreciate that in the United States all toothpaste contains a minimum 1000mg/l fluoride and to consider that some areas of the United States receive naturally occurring levels of fluoride in water that are above the optimal level of water fluoridation recommended for New Zealand.

### **International response to ADA’s interim guidelines**

#### *Government-level responses*

34. The CDC, which is part of the United States Department of Health and Human Services, recognises that there may be an increased risk of very mild fluorosis if infant formula reconstituted with fluoridated water is the sole source of nutrition for a child. The CDC advises that parents may consider using a low fluoride alternative water source if tap water has a fluoride concentrate of 0.7 mg/l or higher.

35. In Australia the federal and state governments have yet to formulate a response to the ADA's interim guidance. However, in October 2005 a workshop on the use of fluorides in Australia was held that included representatives from all states and territories of Australia, as well as the Australian Dental Association.

36. The workshop noted that, historically, infant formula was manufactured with varying, but relatively high, fluoride content, but now has very low amounts of fluoride. Australian population-based studies reveal no association between consumption of infant formula and levels of enamel fluorosis. The workshop concluded that infant formula nowadays is safe for consumption by infants when reconstituted with fluoridated water.

37. There has been no official position taken to date in England by the Department of Health, but the Department is commissioning further research on levels of fluorosis in England. It should be noted, however, that England only has 10% water fluoridation coverage.

#### *Responses from professional groups and groups supporting fluoridation*

38. The Canadian Dental Association (CDA) has reviewed the ADA guidance and decided that currently no changes to the CDA position are required, since fluoride levels in Canadian drinking water tend to be lower (0.8 - 1.0 mg/l compared to 0.7

- 1.2 mg/l) than in the United States, and the maximum allowable concentration in Canada is 1.5 mg/l.

39. In February 2007 the British Fluoridation Society (BFS) released a briefing outlining the lack of clarity in scientific knowledge about this issue. The briefing makes suggestions on what dentists might say to parents expressing concern and seeking advice about reducing their infants' risk of dental fluorosis including: "*powdered formulae could be made up with suitable bottled water*".

The BFS intends to review and update this briefing in August 2007.

*Responses from groups opposed to fluoridation of water supplies*

40. Groups opposed to the fluoridation of drinking water such as the Fluoride Action Network (FAN) and the Environmental Working Group (EWG) have quickly picked up on some parts of the ADA interim guidelines and some of the issues covered by the NRC report.
41. Groups opposed to the fluoridation of drinking water are already targeting drinking-water supply authorities in the United States, presenting the ADA's interim guidance as a health warning.

**National Fluoride Information Centre review**

42. In March 2007 the National Fluoride Information Centre at Manchester University (UK) reviewed the international literature on estimates and measurement of fluoride intake in infants and epidemiological studies relating to the consumption of infant formula to the appearance of enamel fluorosis.
43. Over the last 30 years, theoretical estimates of fluoride consumption by infants fed exclusively on formula made up with fluoridated water consistently indicate that they exceed the accepted threshold of international expert advisory groups. However, studies that have measured actual intake suggest that the intake be much lower than these theoretical estimates. Limited evidence indicates that fluoride from water combines with calcium and other complexes in infant formula, which means that the amount of fluoride absorbed may be less than the amount ingested. This is because absorption of most minerals varies considerably according to factors such as the bioavailability of the form of the mineral in the food, the amount available in the diet, and the other substances present which may facilitate or block absorption.
44. Epidemiological studies show that enamel fluorosis is more common in children fed infant formula than in breast-fed children. The severity of enamel fluorosis was very mild or mild and unlikely to be of aesthetic concern. However, the strength of the evidence is important and epidemiological evidence identifies associations, but not a cause and effect relationship. Further research is required.

### **The New Zealand context**

45. The Ministry and the New Zealand Food Safety Authority (NZFSA) have joint responsibility over this issue. The Ministry has responsibility for setting standards and monitoring drinking-water in New Zealand; the NZFSA has responsibility for monitoring the safety of food supply, including the administration of the Australia New Zealand Food Standards Code (FSC). Food Standards Australia New Zealand (FSANZ) is responsible for setting the food standards in the FSC, which covers labelling and composition of foods for sale, including infant formula products.
46. Infant formula in New Zealand is regulated under Standard 2.9.1 of the FSC. Under clause 19 of this standard, labels on packages of powdered or concentrated infant formula products, or ready-to-drink formula, containing more than specified amount of fluoride must indicate that consumption of the formula has the potential to cause dental fluorosis. The labels must also recommend that the risk of dental fluorosis should be discussed with a medical practitioner or other health professionals. Fluoride is not permitted to be added to infant formula.

#### *Bottled water*

47. With regard to reconstituting infant formula using bottled water, it may not be possible for parents to be completely sure that bottled water is fluoride-free. Water, including bottled water, usually contains some fluoride that is naturally present. Most bottled water on sale is mineral or spring water and will not have added fluoride but may contain some naturally occurring fluoride at levels similar to un-fluoridated public drinking water. However, unless a bottled water is sold as mineral, spring water or similar, bottled water could be sourced from any potable source, including fluoridated public drinking water.
48. Bottled water in New Zealand is treated as a food. Standard 2.6.2 of the FSC allows packaged water to contain up to 2.0 mg/l of fluoride. However, there is no permission to add fluoride to bottled water. Fluoride may only be present naturally or as a result of water treatment by municipal authorities. Bottled water is exempt from being labelled with a nutrition information panel (NIP), although many bottled waters are labelled with information about levels of some minerals. In any case, fluoride is not required to be declared.

### **Current New Zealand research**

49. A report for the Ministry of Health on the Estimated Dietary Fluoride Intake for New Zealanders is being prepared by ESR. The aim of the study is to identify for further investigation any groups at risk of high exposure to fluoride. The Ministry is also aware that a further New Zealand study of tooth enamel defects is being conducted that will add further information.
50. ESR is also undertaking a study for the Ministry of Health to ascertain the fluoride levels in infant formula, and to estimate the fluoride levels in infant formula reconstituted with water containing fluoride at levels of 0.7-1.0 mg/l.

## **Conclusion**

51. When considering an appropriate response, it is important to take into consideration the very large benefit to the people of Hutt City from fluoridation of the water supply with regard to reduced levels and severity of dental decay.
52. Fluoridating water within the internationally accepted optimal range of 0.7 mg/l to 1.0 mg/l. maximises the oral health benefits while minimising the risk of enamel fluorosis. The local concentration of fluoride in drinking water is 0.85 mg/l.
53. There is some concern that infants fed exclusively on infant formula for prolonged periods could receive a greater than optimal amount of fluoride if the infant formula is mixed with water containing fluoride. The reconstitution of infant formula using fluoridated water may increase the risk of enamel fluorosis. The Ministry of Health considers any increase in risk of enamel fluorosis is likely to be very small, that current New Zealand evidence is that children are not developing inappropriate levels of enamel defects and that New Zealand children receiving optimally fluoridated water, and other fluoride through diet and toothpaste, have 30 to 40 percent lower levels of dental decay.
54. The interim guidance from the ADA is not a health warning, as the interim guidance states that enamel fluorosis is not a disease. The ADA's advice is for those parents and caregivers who are concerned about the possibility of children developing enamel fluorosis.
55. The Ministry of Health and NZFSA are aware of the ADA's interim guidance and continue to monitor national and international information. Ministry of Health officials are currently of the view that there is no need to change the advice for New Zealand parents on the water to use in making up infant formula.
56. Council officers consider it appropriate at this stage to continue to monitor developments on the issues discussed in this paper. Should national policy settings with regard to fluoridation and, in particular, the fluoride intake for infants and young children, be amended following evaluation of further research, Council officers will report back and make recommendations on an appropriate response.

## **Legal Considerations**

57. There are no legal considerations associated with this paper.

## **Financial Considerations**

58. There are no financial considerations associated with this paper.

## **Consultation**

59. The Ministry of Health, Regional Public Health and New Zealand Food Safety Authority were consulted in the preparation of this paper.

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## Appendix 1

### Interim Guidance on Fluoride Intake for Infants and Young Children

Recent studies cited in the report of the National Research Council (NRC), "Fluoride in Drinking Water: A Scientific Review of EPA's Standards," have raised the possibility that infants could receive a greater than optimal amount of fluoride through liquid concentrate or powdered baby formula that has been mixed with water containing fluoride during a time that their developing teeth may be susceptible to enamel fluorosis.

The appropriate amount of fluoride is essential to prevent tooth decay. But fluoride intake above optimal amounts can create a risk for enamel fluorosis in teeth during their development before eruption through the gums.

Enamel fluorosis is not a disease but rather affects the way that teeth look. Most cases of fluorosis result in faint white lines or streaks on tooth enamel that are not readily apparent to the affected individual or the casual observer.

While more research is needed before definitive recommendations can be made on fluoride intake by bottle-fed infants, the American Dental Association (ADA) issues this interim guidance because we know that parents and other caregivers are understandably cautious about what is best for their children.

#### ADA Interim Guidance: Infant Formula

The ADA offers these recommendations so parents, caregivers and health care professionals who are concerned have some simple and effective ways to reduce fluoride intake from reconstituted infant formula.

- Breast milk is widely acknowledged as the most complete form of nutrition for infants. The American Academy of Pediatrics recommends human milk for all infants (except for the few for whom breastfeeding is determined to be harmful).
- For infants who get most of their nutrition from formula during the first 12 months, ready-to-feed formula is preferred to help ensure that infants do not exceed the optimal amount of fluoride intake.
- If liquid concentrate or powdered infant formula is the primary source of nutrition, it can be mixed with water that is fluoride free or contains low levels of fluoride to reduce the risk of fluorosis. Examples are water that is labeled purified, demineralized, deionized, distilled or reverse osmosis filtered water. Many grocery stores sell these types of drinking water for less than \$1 per gallon.
- The occasional use of water containing optimal levels of fluoride should not appreciably increase a child's risk for fluorosis.

Parents and caregivers should consult with their pediatrician, family physician or dentist on the most appropriate water to use in their area to reconstitute infant formula. Ask your pediatrician or family physician whether water used in infant formula should be sterilized first (sterilization, however, will not remove fluoride).

#### ADA Guidance: Other Sources of Fluoride for Young Children

The ADA offers this additional guidance on other sources of fluoride for young children, each of which is beneficial under the circumstances described below:

- **Fluoride Toothpaste**  
Parents and caregivers should ensure that young children use an appropriate size

toothbrush with a small brushing surface and only a pea-sized amount of fluoride toothpaste at each brushing. Young children should always be supervised while brushing and taught to spit out rather than swallow toothpaste. Many children under age six have not fully developed their swallowing reflex and may be more likely to inadvertently swallow fluoride toothpaste. Unless advised to do so by a dentist or other health professional, parents should not use fluoride toothpaste for children less than two years of age.

- **Fluoride Mouthrinse**  
Fluoride mouthrinses have been shown to help prevent tooth decay for both children and adults. However, the ADA does not recommend use of fluoride mouthrinses for children under six years of age, unless recommended by a dentist or other health professional. Children under age six may be more likely to inadvertently swallow fluoride mouthrinse.
- **Dietary Fluoride Supplements**  
Children should only receive dietary supplemental fluoride tablets or drops as prescribed by their physician or dentist based on the dietary fluoride supplement schedule approved by the ADA, the American Academy of Pediatrics and the American Academy of Pediatric Dentistry. Supplements are not recommended for children under six months of age.
- **Naturally Occurring Fluoride in Water**  
The optimal fluoride level in drinking water is 0.7 – 1.2 parts per million, an amount which has been proven beneficial in reducing tooth decay. Naturally occurring fluoride may be below or above these levels in some areas. Under the Safe Drinking Water Act, the U.S. Environmental Protection Agency requires notification by the water supplier if the fluoride level exceeds 2 parts per million. People living in areas where naturally occurring fluoride levels in drinking water exceed 2 parts per million should consider an alternative water source or home water treatments to reduce the risk of fluorosis for young children.

### **ADA Supports Community Water Fluoridation**

The ADA supports community water fluoridation as the single most effective public health measure to prevent tooth decay. It is a powerful strategy to reduce disparities in tooth decay among different populations and is more cost-effective than other forms of fluoride treatments or applications. Fluoridation is endorsed by the Centers for Disease Control and Prevention, which has listed community water fluoridation as one of 10 great public health achievements of the 20th century.

As the leader of a science-based profession, the ADA continually reviews new information about fluoride's impact on health. As part of its ongoing assessment, the ADA will convene workshops with government and other professional organizations involved in this issue to determine the best way to evaluate the scientific literature on this topic and formulate more definitive recommendations on fluoride intake, including intake by infants and young children. The ADA also is pursuing other ways to address appropriate fluoride intake with medical, public health and other dental organizations.

November 8, 2006

Source: [http://www.ada.org/prof/resources/positions/statements/fluoride\\_infants.asp](http://www.ada.org/prof/resources/positions/statements/fluoride_infants.asp)

## APPENDIX 2



Source: [http://www.ada.org/prof/resources/topics/fluoride\\_letter\\_interim.pdf](http://www.ada.org/prof/resources/topics/fluoride_letter_interim.pdf)