

Supporting document 3

Fluoride in packaged water (At Approval) – Application A1043

World Health Organization Limits for Packaged Water

Executive summary

In packaged water, fluoride may be naturally present as a result of the water being extracted from fluoride-bearing water sources or from being added to the packaged water product. Whilst fluoride has demonstrable benefits for human health, especially related to the prevention of dental caries, excessive consumption of fluoride may result in adverse health effects. The WHO Guidelines for Drinking-water Quality (2011)¹ recommend a maximum level of fluoride of 1.5 mg/L. However, FSANZ's own risk assessment from a previous application that sought to add fluoride to packaged water (Application A588), recommended a lower maximum level for total fluoride of 1.0 mg/L based on a regional dietary intake assessment. Currently, Standard 2.6.2 contains a maximum level for naturally occurring fluoride of 2.0 mg/L (table to subclause 2(2)) and a maximum level for naturally occurring and added fluoride of 1 mg/L when fluoride is added to packaged water (clause 2A).

In the current Application, FSANZ has considered the impact of setting a uniform maximum level for fluoride of 1.0 mg/L for packaged water, irrespective of whether the fluoride is present naturally or added during processing. Information provided by the Applicant and from FSANZ's consideration of the earlier Application (A588) indicated that packaged and potable water in Australia and New Zealand typically contained fluoride at levels lower than 1.0 mg/L. Furthermore, most imported 'natural mineral water' contained fluoride at levels less than or equal to 1.0 mg/L.

Consistent with its objectives to protect human health and safety, FSANZ made an exception to adopting the WHO GDWQ as a whole in Standard 2.6.2 with regards fluoride. This exception resulted in setting the maximum level for total fluoride (naturally occurring and added) at 1.0 mg/L.

¹ In this document, Annex 3 Chemical summary tables, Table A3.3 Guideline values for chemicals that are of health significance in drinking-water in the Guidelines for drinking-water quality, 4th edition, World Health Organization, Geneva 2011, will be referred to as 'WHO GDWQ'

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1. Introduction

Any new standard for chemical substances in drinking water should be based on risk analysis using the best available scientific evidence. The WHO GDWQ specify limits for fluoride. However, FSANZ has previously considered the safety of fluoride in drinking water as part of consideration of Application A588 – *Voluntary Addition of Fluoride to Packaged Water*. The recommended safe value based on dietary modelling of Australian and New Zealand consumers differs from the value in the WHO GDWQ. Therefore further consideration was given to the most appropriate value for packaged water.

Fluoride is ubiquitous in the environment and consequently a natural component in food and water. The major dietary source of fluoride is fluoridated water and fluoridated water used in cooking, the preparation of beverages or the manufacture of other foods and beverages. Naturally occurring fluoride levels in 'drinking water' vary, depending on the type of soil and rock through which water drains. Generally, concentrations in surface water are relatively low (0.1 to 0.5 mg/L) while water from deeper wells may have quite high fluoride levels (1-10 mg/L) if the rock formations are fluoride rich. In general, the naturally occurring fluoride levels in 'drinking water' are very low (<0.1 mg/L).

Fluoride is a normal constituent of the human body. It is involved in the mineralisation of both teeth and bones (NRVs, 2006). Due to its role in the prevention of dental caries, fluoride has been classified as essential to human health. Nonetheless, excessive intake of fluoride can result in fluorosis. This term refers to the effects associated with excessive fluoride intake, and can manifest it in two forms, dental and skeletal fluorosis. Dental fluorosis involves the incorporation of fluoride into the enamel of the teeth. The 'very mild' and 'mild' forms of dental fluorosis, although irreversible, are aesthetic in nature (making the teeth stronger and whiter) and are not considered a risk to population health. 'Moderate' and 'severe' forms of dental fluorosis are of greater clinical concern. Skeletal fluorosis is a serious medical condition, which can lead to significant bone degradation and adverse neurological manifestations.

2. Nutrient References Values

The National Health and Medical Research Council (NHMRC) and the New Zealand Ministry of Health (NZMOH) (2006)² have established nutrient references values (NRVs) for a wide variety of nutrients for Australian and New Zealand populations. For fluoride, an Adequate Intake (AI)³ and an Upper Level (UL)⁴ have been set for various age groups (Table 1). The fluoride NRVs were adopted by the NHMRC and NZMOH from the US/Canadian Dietary Reference Intakes (DRIs) which were based on the best available data available at the time⁵.

² Nutrient Reference Values for Australia and New Zealand – Including recommended dietary intakes (2006).

³ An Adequate Intake (AI) is defined as the average daily nutrient intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently health people that are assumed to be adequate.

⁴ The Upper Level (UL) is defined as the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.

⁵ Institute of Medicine (IOM). *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride* (1997). Washington DC, USA. Available from: http://books.nap.edu/openbook.php?record_id=5776&page=R1

Table 2: Fluoride NRVs for Australian and New Zealand Populations

Population Subgroup	Adequate Intake (mg/day)		Upper level (mg/day)	
	Males	Females	Males	Females
Infants 0-6 months	0.01		0.7	
Infants 7-12 months	0.5		0.9	
1-3 years	0.7		1.3	
4-8 years	1.0		2.2	
9-13 years	2.0		10.0	
14-18 years	3.0		10.0	
Adults 19+ years (including pregnant/lactating women)	4.0	3.0	10.0	10.0

3. Previous consideration by FSANZ

In an application to FSANZ in 2006 (A588 - *Voluntary Addition of Fluoride to Packaged Water*) from the Australian Beverages Council Limited (ABCL), the Applicant sought an amendment to the Code to voluntarily add fluoride to packaged water. As part of its risk assessment of this Application, FSANZ conducted a dietary intake assessment from the total diet for Australian and New Zealand consumers. FSANZ combined data on food and water consumption patterns, fluoride content of foods and beverages and other relevant information to conduct its dietary intake assessment. FSANZ's dietary intake assessment was based on data that included individual, seasonal and geographic variations, including children and higher consumers of water including those living in hot climates.

Based on FSANZ's dietary intake assessment and utilising the upper levels for fluoride established for Australia and New Zealand (Table 2), FSANZ approved an amendment to Standard 2.6.2 to permit the addition of fluoride to non-carbonated packaged water to between 0.6 and 1.0 mg/L for *the total of naturally occurring and added fluoride*. In addition, the approval also required mandatory labelling for food identification purposes to indicate that fluoride had been added. These outcomes have been captured in Clauses 2A and 2B of Standard 2.6.2.

4. Consideration of fluoride level for packaged water

Currently the fluoride limit for bottled waters other than those to which fluoride has been added is 2.0 mg/L whereas the limit for packaged water to which fluoride has been added is 1.0 mg/L. The limits in the WHO GDWQ, Australian Drinking Water Guidelines and Drinking-water Standards for New Zealand⁶, are 1.5 mg/L. However, it is important to note that the limit in the WHO GDWQ also carries the caveat that for fluoride, 'volume of water consumed and intake from other sources should be considered when setting national standards'. FSANZ's risk assessment, which took account of regionally relevant data, indicated a limit for fluoride of 1.0 mg/L for packaged water, would ensure that consumers are protected from excessive fluoride intake.

FSANZ has therefore considered the impact of adopting a limit which differs from that specified in the WHO GDWQ, as discussed below.

⁶ Drinking-water Standards for New Zealand 2005 (Revised 2008).

5. Fluoride levels in drinking water

During the assessment of A588, FSANZ collected information on actual water fluoride levels of reticulated (potable) water in Australia and New Zealand. In Australia, mean fluoride concentrations in non-fluoridated areas were around 0.1-0.2 mg/L and between 0.7-1 mg/L in fluoridated areas, with lower levels in some places in the Northern Territory at around 0.5 mg/L. In New Zealand, the Drinking-water Standards for New Zealand (2008) included a maximum acceptable value (MAV) for fluoride of 1.5 mg/L and recommended a target fluoride range of 0.7-1.0mg/L for oral health reasons⁷. Actual fluoride concentrations in reticulated water in New Zealand were found to average about 0.8-0.9 mg/L in fluoridated areas and around 0.15 mg/L in non-fluoridated areas⁸.

The current Applicant for A1043 was asked to provide information on the fluoride levels in packaged water that have been bottled in Australia and New Zealand. Information was provided of 45 test results from Australia (19 NSW, 11 Qld, 8 SA and 8 WA). Fluoride levels were found to range from < 0.08 to 0.28 mg/L with an average less than 0.1 mg/L. The highest value (0.28 mg/L) was recorded in SA. Information was also provided of 40 test results from New Zealand. Fluoride levels were found to range from 'not detected' to 0.47 mg/L. The latter result was found in Auckland.

Thus it would appear from the data available, that water supplied/packaged in Australia and New Zealand could comply with a total fluoride limit (naturally occurring and added) of 1.0 mg/L.

6. Fluoride levels in imported packaged water

International packaged water, and in particular packaged/bottled water derived from spring water or other water bearing strata, may have fluoride levels in excess of 1.0 mg/L. The introduction of a fluoride limit of 1.0 mg/L for all packaged waters in Australia and New Zealand may have the effect of restricting the import of certain 'mineral waters'. The Applicant provided information on the levels of fluoride in some imported packaged water, e.g. San Pellegrino (0.14 mg/L (ppm) on label and 0.64 mg/L in the laboratory), Calabria (0.1 mg/kg), San Benedetto (<0.15 mg/L), Santa Vittoria (<0.1 mg/L) and Fonteviva (0.04 mg/L). In addition, reference was made to a review of declared fluoride levels in 1205 mineral waters prepared by 'mineralwaters.org'. (<http://www.mineralwaters.org/>). Of the 1205 mineral water products analysed at the time, 191 (15.8%) of the products indicated levels of fluoride equal to or greater than 1.0 mg/L from sources around the world. Eighty one of these 1205 mineral water products had fluoride levels in excess of 2.0 mg/L. Thus, a number of international packaged mineral waters could potentially fail to meet a limit of 1.0 mg/L fluoride.

⁷ New Zealand Ministry of Health. Drinking-water Standards for New Zealand 2005 (Revised 2008). Wellington: Ministry of Health. Available from: <http://www.health.govt.nz/publication/drinking-water-standards-new-zealand-2005-revised-2008-0>

⁸ Watercare Services Limited (2007). Annual Water Quality Report 2007. Auckland, New Zealand.

However, it is important to put this potential imposition on trade into context. In the USA, the Food and Drug Administration (FDA) regulates bottled (packaged) water in accordance with the Code of Federal Regulations⁹. The Environmental Protection Agency (EPA) regulates the quality of tap (potable) water. The 'Code of Federal Regulations' defines different types of packaged water such as 'spring water' and 'mineral water'. No minerals, including fluoride, may be added to packaged water defined as 'mineral water'. Fluoride concentrations ranging from 1.4 to 2.4 mg/L (temperature dependent) are permitted for naturally occurring fluoride and the fluoride content need not be indicated on the label. A maximum concentration of 1.4 mg/L of naturally occurring fluoride is permitted in imported packaged water with no added fluoride. The fluoride concentration in imported bottled water with added fluoride must be less than 0.8 mg/L.

Canada's Food and Drugs legislation¹⁰ permits the addition of fluoride to mineral water, spring and packaged water provided that the total fluoride concentration does not exceed 1 part per million (1 mg/L). The principal display panel of the label for mineral and spring water must state that fluoride has been added and the total fluoride content. For other bottled water containing fluoride (either naturally occurring or added), bottlers must state the total fluoride content and list any added fluoride as an ingredient on the principal display panel of the panel.

7. Labelling considerations for fluoride

The risk assessment for Application A588 supported the establishment of a maximum level (ML) for total fluoride as the most appropriate regulatory measure for permission to add fluoride to packaged water. Additionally labelling to indicate that the packaged water contained added fluoride was required.

As part of the current application, FSANZ considered requiring labelling for high fluoride levels due to natural presence in packaged waters as an alternative to setting a maximum level. This would permit the sale of waters with higher fluoride levels and would be of particular benefit to some imported packaged waters where fluoride levels may exceed 1.0 mg/L.

Currently both the Codex Standard and EU Directive require labelling for high fluoride levels in packaged waters. The *Codex Standard for Natural Mineral Waters* (CODEX STAN 108-1981) includes the following labelling recommendations:

If the product contains more than 1 mg/L of fluoride, the following term shall appear on the label as part of, or in close proximity to, the name of the product or in an otherwise prominent position: "*contains fluoride*".

In addition, the following sentence should be included on the label: "*The product is not suitable for infants and children under the age of seven years*" where the product contains more than 1.5 mg/L fluorides.

⁹ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=165> (accessed 4 Apr 2012)

¹⁰ http://laws.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/page-134.html#docCont (accessed 4 Apr 2012)

In the European Union, the EU Commission Directive 98/83/EC of 3 November 1998¹¹ regulates the quality of water intended for human consumption (other than natural mineral waters), including water for sale in bottles or containers. The permitted level of fluoride specified in Annexe 1 of the Directive is 1.5 mg/L, which is based on the *WHO Guidelines for Drinking-water Quality*. The EU Commission Directive 2003/40/EC of 16 May 2003¹² regulates the quality of 'natural mineral waters'. The Directive states that the constituents must be naturally occurring and may not result from contamination at the source. Moreover, if the fluoride level is above 1.5 mg/L, the label must state:

“contains more than 1.5 mg/L of fluoride: not suitable for regular consumption by infants and children under 7 years of age.”

Furthermore, the actual fluoride content must also be included on the label. The maximum permissible level of naturally occurring fluoride in 'natural mineral water' is 5 mg/L.

A requirement for labelling would promote consistency between domestic and some international food standards and provide information which may assist consumers to make informed choices. However on the assumption that many consumers would not know what a safe level of fluoride is, particularly for vulnerable population groups such as infants and children, FSANZ considered that, consistent with the earlier A588 risk assessment, labelling by itself may not be adequately protective of human safety.

8. Summary

Based on the best available scientific information, FSANZ is of the opinion that a limit for fluoride in packaged water should be set at 1.0 mg/L irrespective of the source of that fluoride (naturally occurring or added). This limit for fluoride would be lower than that noted in the WHO GDWQ, the Australian Drinking Water Guidelines and the Drinking-water Standards for New Zealand which have a limit of 1.5 mg/L. Given the levels of fluoride in packaged waters currently produced in Australia and New Zealand, this new, lower limit of 1.0 mg/L for total fluoride is considered to have a minor impact on industry although some imported products may be affected. Labelling for high fluoride levels, consistent with the *Codex Standard for Natural Drinking Waters*, was considered as an alternative risk management measure but was rejected on the basis that the most appropriate regulatory measure to protect human health and safety was the establishment of a ML for total fluoride in packaged water.

Furthermore, the adoption of a limit of 1.0 mg/L ensures consistency for fluoride levels for all packaged water, whether containing added fluoride or not (Clauses 2 and 2A of Standard 2.6.2), and reduces the inconsistency of having two different values for fluoride for waters with and without added fluoride.

¹¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0083:EN:NOT> (accessed 3 April 2012)

¹² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003L0040:EN:NOT> (accessed 3 April 2012)