FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

3 August 2012
[18-12]

Call for submissions – Application A1043

World Health Organization Limits for Packaged Water

FSANZ has assessed an Application made by the Australasian Bottled Water Institute to adopt limits for certain chemical substances in packaged water to reflect current limits in international standards established by the World Health Organization and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist its consideration of the draft food regulatory measure. A consolidated list of questions has been provided to assist submitters (Attachment C).

For information about making a submission, visit the FSANZ website at information for submitters.

Under the Information Publication Scheme all submissions on applications and proposals, will be published on our website. We will not publish any material provided in-confidence. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 13 September 2012

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au. Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

SD1 Consideration of various regulatory and non-regulatory measures for the control of chemicals in packaged water.
SD2 Comparative table of chemical guidelines/standards for drinking water.
SD3 Fluoride in packaged water.

Material relating to Application A588 – *Voluntary Addition of Fluoride to Packaged Water*, has also been used in the preparation of the current report with respects to the limit for fluoride in packaged water. This material is available from the FSANZ website at:

http://www.foodstandards.gov.au/foodstandards/applications/applicationa588volun3872.cfm

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from the Australasian Bottled Water Institute (ABWI), a Division of the Australian Beverages Council (ABC) on 25 January 2010. The Applicant has requested a variation to Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks, in the *Australia New Zealand Food Standards Code* (the Code), to adopt limits for certain chemical substances in packaged water to reflect limits in the international standard established by the World Health Organization (WHO). The limits are set out in WHO Guidelines for Drinking-water Quality, Fourth Edition (2011), Table A3.3, *Guideline values for chemicals that are of health significance in drinking-water*.[1] The Table to subclause 2(2) of Standard 2.6.2 has not been comprehensively amended since the Code was published on 20 December 2000. Thus, the currency of the Table to subclause 2(2) in terms of safety for water for human consumption is questionable and updating it to take account of current scientific evidence relating to the safety of chemicals found in bottled water requires an application to amend the Code.

The primary objectives of FSANZ in developing or varying a food regulatory measure, as stated in section 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), are the protection of public health and safety; the provision of adequate information relating to food to enable consumers to make informed choices; and the prevention of misleading or deceptive conduct . While there was no information to demonstrate regulatory failure for packaged water in terms of these primary objectives, regulatory intervention was supported on the grounds that: (1) The current selection of chemicals and their respective limits listed in the Table to subclause 2(2) of Standard 2.6.2, are not in keeping with contemporary national and international standards/guidelines for drinking water safety and are not based on the best currently available evidence; (2) The need to ensure a level playing field for locally produced (Australia and New Zealand) and imported packaged water. The latter would also purportedly assist industry to access export markets.

As the safety assessment for the WHO guidelines has been undertaken by experts, FSANZ has not conducted its own assessment of each listed chemical substance. In this assessment, FSANZ has considered the merits of adopting the WHO guidelines or, alternatively, another set of relevant drinking water guidelines or standards, to replace the current Table to subclause 2(2) of Standard 2.6.2 in the Code. A key consideration from a risk assessment perspective was whether the WHO guidelines represented maximum limits from a safety rather than a quality perspective. FSANZ was satisfied that the guidelines were established on safety grounds and are an appropriate set of chemical limits for adoption into the Code.

FSANZ also took into account the relevance of other guidelines or standards associated with water for human consumption and concluded that the WHO guidelines represented the most contemporary international set of limits that could be used for such purposes.

[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 20*11, will be referred to as 'WHO GDWQ'.

Two exceptions to adopting the chemical limits of the WHO guidelines as a whole into the Code have been recommended. Firstly, a maximum limit for fluoride of 1.0 mg/L is proposed not 1.5 mg/L as indicated in the WHO guidelines. This value is based on FSANZ's dietary intake assessment of fluoride in packaged water (Application A588), which recommended a maximum level of 1.0 mg/L, and is specified in Clause 2A of Standard 2.6.2 of the Code. Secondly, a maximum limit for styrene of 0.03 mg/L is proposed and not 0.02 mg/L as indicated in the WHO guidelines. This value would be consistent with its maximum permitted level when used as a processing aid in packaged water (Table to clause 11, Standard 1.3.3).

Overall, a comprehensive impact analysis was undertaken of this Application, including a cost estimate of the associated testing regimen under the WHO guidelines. The impact analysis included consideration of consumer, industry and government perspectives. While recognising the attributes of the current, voluntary industry Code of Practice with regards to chemical limits and safety, which are being followed by up to 80% of Australian producers, FSANZ has considered a regulatory approach to be the most appropriate means to ensure the continued protection of all consumers in Australia and New Zealand of domestically produced and imported bottled waters.

Therefore, FSANZ has prepared a draft variation to the Code to remove the existing Table to subclause 2(2) in Standard 2.6.2 and to include a reference to the WHO guidelines, with exceptions for fluoride and styrene.

2. Introduction

2.1 The Applicant

The Applicant is the Australasian Bottled Water Institute (ABWI), a Division of the Australian Beverages Council. The ABWI is an industry organisation with membership in Australia, New Zealand and Fiji.

2.2 The Application

Application A1043 – World Health Organization limits for packaged water, has sought approval for a variation to Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drink.

The specific request for variation included the removal of:

(1) subclause 2(2) in Standard 2.6.2, and
(2) Table to subclause 2(2) in Standard 2.6.2.

and for it to be replaced with the following sentence:

> Water presented in packaged form must not contain substances in greater corresponding proportion than those limits specified in Annex 4 of Chemical Summary Tables of WHO Guidelines for Drinking Water Quality (2nd Addendum to 3rd Edition, Volume 1) 2008. Table A4.3 Guideline values for chemicals that are of health significance in drinking water.

In response to a request for further information from FSANZ under Section 108(1) of the FSANZ Act, dated 9 October 2011, the Applicant indicated that it wished the assessment of A1043 to proceed on the basis of the 4th edition of the WHO Guidelines Drinking-water Guidelines (2011). In the 2011 edition of the WHO guidelines, the relevant chemical summary table is *Table A3.3 Guideline values for chemicals that are of health significance in drinking-water* (Annex 3 (Chemical Summary Tables)).

Under section 108(1) of the FSANZ Act, FSANZ requested further information from the Applicant on two occasions. Responses from the Applicant were received on 19 October 2011 and 6 February 2012. The information provided in these responses has been incorporated into the assessment where appropriate.

2.2.1 Previous consideration of the Application

This Application was considered under Code Maintenance Proposal IX (P1013) during 2010-2011. However, comments from three jurisdictions (New Zealand Ministry of Agriculture and Forestry; South Australia Health; and the Victorian Department of Health) indicated that this Application should not proceed under that Proposal. As a result, FSANZ withdrew consideration of this Application under the Code Maintenance Proposal, and re-initiated its consideration (27 June 2011) to allow for further analysis and consultation.

2.3 The current Standard

The current Clause 2 to Standard 2.6.2 stipulates the composition of packaged water. Subclause 2(1) notes that water presented in packaged form may or may not contain added carbon dioxide. Subclause 2(2) and the Table to subclause 2(2) lists 17 chemical substances (including ‘organic matter’) and their respective limits that are permitted in

packaged water.

Clauses 2A and 2B of Standard 2.6.2, stipulate chemical limits and labelling requirements for the addition of fluoride to packaged water.

The Table to clause 11, Standard 1.3.3, stipulates chemical limits for various processing aids used in packaged water and in water used as an ingredient in other foods.

An application to FSANZ was required because any change to the list of chemicals and their respective limits needs to be assessed on its merits for the protection of public health and safety, and other matters relevant to s 18 of the FSANZ Act.

2.3.1 The relationship between packaged water and other forms of water for human consumption

The term 'packaged water' is not explicitly defined in the Code. Standard 2.6.2 does define 'mineral water or spring water' to mean ground water obtained from subterranean water-bearing strata that, in its natural state, contains soluble matter. A definition for 'package' is provided in Standard 1.1.1 of the Code. For the purpose of this Application, packaged water is considered to include various sources of water that are suitable for human consumption, including but not limited to: spring water, mineral water, artesian water, demineralised water, sterile water, purified water, distilled water, deionized water and glacial water. Water prepared for human consumption and generally supplied via a reticulated plumbing system such as potable or municipal tap water is not subjected to controls under the Code. However, if potable water is packaged (e.g. in bottles or plastic containers), then it is subject to the requirements of the Code. Water used as an ingredient in food or beverages or in the processing of food is not captured under Standard 2.6.2 and will not be considered under this Application.

2.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

2.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2.6 Approach to the assessment

FSANZ considered a number of factors during assessment including whether the chemical limits in the WHO guidelines were about quality or safety. FSANZ also considered whether:

- the pesticides, industrial chemicals and disinfection products/by-products which are listed in the WHO guidelines were relevant to the production of packaged water produced in Australia and New Zealand

- other drinking water guidelines or standards, such as from Codex Alimentarius, the National Health and Medical Research Council or the New Zealand Ministry of Health were more applicable to packaged water or production in Australia and New Zealand

- there is a justifiable reason to make an exception to the WHO guidelines or other guideline/standard.

These considerations are discussed in more detail in SD1 and SD3.

3. Summary of the assessment

3.1 Evidence base

A comprehensive safety assessment of the chemicals and their respective limits/guideline values, as listed in Table A3.3 of the WHO guidelines was not undertaken by FSANZ. FSANZ considers the WHO guidelines have been established by experts using contemporary data and methods of analysis.

The approach taken by the WHO experts was verified by FSANZ. Briefly, a tolerable daily intake (TDI) was calculated for chemicals which may have an adverse effect via a threshold mechanism, based on an appropriate BMDL, NOAEL or LOAEL[2]. Standard uncertainty factors were used to control for interspecies and intraspecies effects; the adequacy of the database and the nature and severity of the toxicological effect. Subsequently, the guideline value was determined by considering the total intake of the chemical in question from all sources, and allocating a proportion of the TDI or Acceptable Daily Intake (ADI) to drinking water. For chemicals where exposure from food was very low, such as some of the water disinfection by-products, the allocation to drinking water may be as high as 80%. In the case of some pesticides, for which exposure from food was considered high, the allocation to drinking water may be as low as 1%. For carcinogens for which there was no threshold, the guideline value was calculated based on a reference risk set to a lifetime excess cancer risk of 10^{-5}.

FSANZ has previously performed a risk analysis for fluoride in packaged water and concluded the maximum level for Australian and New Zealand consumers should be set at 1.0 mg/L and not 1.5 mg/L as indicated in the WHO guidelines.

FSANZ also considered the consistency between the limits permitted for certain chemicals as processing aids in Standard 1.3.3 and noted a higher level was permitted for styrene as a processing aid than that in the WHO guidelines. Current values in the Code are considered to be protective of human health and safety and commensurate with technical need. The impacts of lowering the values to ensure consistency with the WHO guidelines were not available to FSANZ.

3.2 Risk management

Various regulatory and non-regulatory options were considered during assessment of this Application. The benefits and costs of these measures have been considered in more detail in SD1.

The key non-regulatory option available for the control of chemical contaminants in packaged water is the current industry Code of Practice. The ABWI currently maintains a voluntary Code of Practice (Model Code) for the maximum limits of 49 chemical substances in packaged water. This 'Model Code' currently utilises the 3rd edition (2008) of the WHO guidelines as the basis for its chemical limits. These limits include those stipulated in the

[2] BMDL: Benchmark Dose Level; NOAEL: No Observed Adverse Effect Level; LOAEL: Lowest Observed Adverse Effect Level.

Table to subclause 2(2) of Standard 2.6.2, but with lower maximum limits for cadmium, fluoride, lead, manganese and nitrate. FSANZ considered whether a regulatory approach was warranted but considered that reliance on a voluntary approach would not be sufficiently protective of human health and safety and did not promote fair trading in packaged water.

Regulatory options relevant to this application included: (i) varying the chemicals and limits to those chemicals in the Table to subclause 2(2), based on an appropriate set of limits established through a rigorous risk assessment e.g. WHO guidelines and (ii) labelling of specific chemical constituents that pose a health and safety concern, e.g. fluoride. The use of labelling statements is considered further in SD3. They were not considered appropriate given that the risk assessment and risk management associated with the previous consideration of fluoride in packaged water (Application A588) supported the setting of a maximum limit for fluoride. FSANZ therefore proposes to set a maximum limit for fluoride of 1.0 mg/L on the basis of protection of health and safety. This exception to the WHO guidelines would be consistent with the notes accompanying the limits in the WHO guidelines whereby local water consumption information should be considered when setting national standards.

A number of chemical substances listed in the WHO guidelines are currently listed in Standard 1.3.3 (Table to clause 11) for the purposes of permitting processing aids to be used in packaged water and water used as an ingredient in other foods. Of these chemical substances, the maximum permitted level in the Table to clause 11 for styrene (0.03 mg/kg) will be marginally greater than the maximum level for styrene in the WHO guidelines, i.e. 0.02 mg/L (assuming 1 kg of water is equivalent to 1 L of water). Furthermore, some of the chemical substances when used as processing aids do not have a numerical limit and can be used at a level commensurate with good manufacturing practice. FSANZ considers compliance with the levels and use indicated in the Table to clause 11 of Standard 1.3.3 to be an acceptable risk management measure and not in conflict with the levels in the proposed changes to Standard 2.6.2. Therefore it is proposed that the maximum level for styrene would be raised from the WHO guidelines value of 0.02 mg/L to 0.03 mg/L, to be consistent with the maximum permitted level of styrene as a processing aid in packaged water that has already been stipulated in the Table to clause 11, Standard 1.3.3 of the Code.

Further discussion of this matter is provided in SD1.

3.3 Regulatory options and impacts

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- there are no other measures that would be more cost-effective than a variation to Standard that could achieve the same end
- any relevant New Zealand standards
- any other relevant matters.

3.3.1 Impact analysis

The Office of Best Practice Regulation (OBPR) was consulted to determine if a Regulation Impact Statement (RIS) was required for this Application. Based on the information provided, the OBPR considered the proposal was likely to have a minor regulatory impact. Therefore a RIS was not required (OBPR Reference: 12956).

Three regulatory options have been considered in detail as part of the assessment of this Application:

1. Reject the Application and maintain the *status quo.*

2. Prepare a draft variation to Standard 2.6.2 to adopt limits for specific chemical substances in packaged water to reflect the current limits in place established by the World Health Organization (WHO) for drinking water, to limit the use of fluoride to 1.0 mg/L and to permit the use of styrene at a higher maximum level of 0.03 mg/L.

3. Prepare a draft variation to Standard 2.6.2 to adopt limits for specific chemical substances in packaged water to reflect the current limits in place established by another authority, to limit the use of fluoride to 1.0 mg/L and to permit the use of styrene at a higher maximum level of 0.03 mg/L.

3.3.1.1 Option 1

There was no information to demonstrate regulatory failure for the current control of chemical limits in packaged water in terms of the three primary objectives of the FSANZ Act (see section 2 of SD1). However, the selection of chemicals and their respective limits currently listed in the Table to subclause 2(2) is not in keeping with current national and international standards/guidelines for drinking water safety. If this option was adopted, no amendment to the Code would be required. The benefits and costs of option 1 have been summarised below.

Affected party	**Benefits**
Consumers	No new benefits were identified.
Industry	No new benefits were identified.
Government	No new benefits were identified.

Affected party	**Costs**
Consumers	No costs were identified.
Industry	No financial costs were identified. Industry, however, fails to gain a more comprehensive and internationally recognised set of safety standards for chemical limits in packaged water, and the ability to use claims relating to adherence to international standards for access to international markets.
Government	There would be no new financial costs associated with the assessment of compliance against the Code. From a public health perspective, chemical limits for packaged water would remain less conservative than for potable water

3.3.1.2 Option 2

The adoption of this option would fulfil the primary objective of protecting public health and safety along with a number of secondary objectives of the FSANZ Act. The WHO guidelines reflect a credible risk analysis by experts that has been based on contemporary scientific data to ensure the safety of drinking water. The WHO guidelines are the basis for chemical limits in the *Codex Standard for Bottled/Packaged Water*, the Australian Drinking Water Guidelines and the Drinking Water Standards for New Zealand. It is also the basis for the current ABWI Model Code.

This option also includes two exceptions to the WHO guidelines. Firstly, the total fluoride content of packaged water would be limited to 1.0 mg/L, based on FSANZ's risk assessment. FSANZ has previously considered limits for fluoride in packaged water when it assessed Application A588 (Voluntary Addition of Fluoride to Packaged Water) in 2009 – see SD3 and link to additional supporting material for further information. Modelling of water consumption in both Australia and New Zealand indicated that fluoride may be added to packaged water, provided that the total amount of the naturally occurring and any added fluoride be no less than 0.6 mg/L (0.6 ppm) and no more than 1 mg/L (1 ppm). Secondly, the maximum level for styrene in packaged water would be raised from the value given by the WHO guidelines of 0.02 mg/L to 0.03 mg/L. This would ensure a consistent maximum level for styrene in packaged water under Standard 2.6.2 and that already in place for its use as a processing aid in packaged water under Standard 1.3.3.

The adoption of the WHO guidelines has industry support, with claims that it would also support access to export markets. Cost estimates have been provided against a proposed testing regimen. The adoption of this option would provide regulatory certainty and consistency for Australian and New Zealand producers/bottlers and importers of packaged water. The benefits and costs of option 2 have been identified as follows.

Affected party	**Benefits**
Consumers	Consumers would benefit from a standard that would now capture a range of organic contaminants. Packaged water would meet an international recognised set of guideline values; and would meet similar standards as potable water. All packaged water would also have the same maximum permissible level for total fluoride, irrespective of whether it was naturally occurring or added to the water. Overall, this option offers an enhanced level of protection for consumers.
Industry	The current, voluntary compliance to the ABWI Model Code would be replaced by a regulatory standard which sets the same limits. The majority of packaged water suppliers/bottlers in Australia and New Zealand are already using the proposed chemical limits and they would no longer need to comply with two separate sets of chemical limits, the Code and the voluntary Model Code. The Applicant claims this option would assist with international market access. There would also be no inconsistency in the different fluoride levels currently in Standard 2.6.2. This option would ensure a consistent approach to domestic and imported packaged water with respects to fluoride.
Government	Packaged water would be subjected to the same level of chemical scrutiny as potable water.

Affected party	Costs
Consumers	Possible small cost from testing would be passed on to consumers. Possible loss from the market of some imported waters with fluoride levels in excess of 1.0 mg/L; and other inorganic constituents found naturally in some imported spring/mineral waters.
Industry	Increase in testing costs – small for those already testing, but considerably more for those that are not testing as per the ABWI Model Code or per comprehensive product specifications for domestic or export markets e.g. local supermarkets. See Table 1 in SD1 for sampling plan and cost estimates. There is the potential for negative effects if domestic or imported water contained fluoride levels in excess of 1.0 mg/L. This is considered negligible for domestically produced packaged water and a small proportion of mineral waters available in the world.
Government	There may be additional costs associated with testing compliance against the new Standard. Regulatory agencies may need to establish a compliance testing plan for packaged waters, if warranted on the basis of risk, similar to current potable water guidelines/standards.

3.3.1.3 Option 3

Alternative sets of chemical limits have been developed for drinking water e.g. the Codex *Standard for Natural Mineral Waters*, the Codex *Standard for Bottled/Packaged Water*, the Australian Drinking Water Guidelines and the Drinking Water Standards New Zealand. The WHO guidelines have been used in the development of the Australian (Australian Drinking Water Guidelines) and New Zealand (Drinking Water Standards New Zealand) guideline/standard for potable drinking water but there are some differences in the chemicals specified and the limits in the two countries. The adoption of regionally specific guidelines/standards for packaged water that parallel those used for potable water such as the Australian Drinking Water Guidelines and the Drinking Water Standards New Zealand would appear to have merit from the perspective of reducing the current discordance for chemical limits in packaged and potable water. If this option was adopted, FSANZ would also recommend adopting a limit of 1.0 mg/L for fluoride and raising the limit for styrene to 0.03 mg/L in packaged water.

Notwithstanding the merits of adopting one of the abovementioned sets of regional guidelines/standards, the adoption of the Australian Drinking Water Guidelines and the Drinking Water Standards New Zealand into Standard 2.6.2 would be problematic from a regulatory perspective and would be inconsistent with the intent of the FSANZ Act and the Trans-Tasman treaty. See SD1 for further discussion.

Similar costs and benefits associated with limiting the total level of fluoride in packaged water to 1.0 mg/L that have been outlined in Option 2, would also apply under Option 3. The benefits and costs of option 3 have been identified as follows:

Affected party	Benefits
Consumers	Consistent safety standards for drinking water irrespective of source.
Industry	Use of locally relevant safety standards for water. This option provides for a level playing field as all water suppliers (potable and packaged) would be subjected to the same testing regimen.
Government	Testing facilities and test methods have already been established for the potable water industry.

Affected party	Costs
Consumers	Consistent with the costs associated with Option 2. There could be a loss of imported bottled waters from domestic markets due to failure to comply with Australian & New Zealand guidelines/standards or compliance costs exceeding economic viability in the Australian/New Zealand domestic market.
Industry	Increased financial costs associated with compliance testing, due to the number of new chemical analytes. Questionable improved domestic and international market access. Could make some businesses economically unviable. Potential for loss of imported packaged waters.
Government	Inconsistency with the Trans-Tasman treaty. Regulatory difficulty with ensuring compliance against two guidelines/standards.

3.3.2 Other measures

There were no other regulatory measures relevant to the consideration of this Application. FSANZ considered and rejected the use of labelling as an alternative to setting a maximum limit for fluoride (see SD3). The continued use of the industry Code of Practice (Model Code) as a non-regulatory measure was not supported by FSANZ. For further information, see the discussion under Option 1 of the SD1.

3.3.3 New Zealand standards

There were no relevant New Zealand only standards related to packaged water. The potable Drinking Water Standards for New Zealand (Drinking Water Standards New Zealand) were considered under Option 3. See SD1 for the consideration of adopting the Drinking Water Standards New Zealand into Standard 2.6.2 of the Code.

3.3.4 Other relevant matters

There were no other relevant matters that could be identified.

3.3.5 Proposed approach

FSANZ has considered the merits of a number of options in light of subsections 18(1) and 18(2) of the FSANZ Act, during the assessment of this Application.

FSANZ recommends adoption of Option 2, i.e.

1. Replacing subclause 2(2) and the table to subclause (2) with a reference to the 'guideline values for chemicals that are of health significance in drinking-water' as listed in the Chemical Summary Tables, from the WHO guidelines.
2. That an exception is made for fluoride, to specify a maximum limit of 1.0 mg/L for total fluoride, irrespective of whether it is added or naturally occurring fluoride.
3. That an exception is made for styrene, to specify a maximum limit of 0.03 mg/L for styrene, consistent with its maximum permitted use as a processing aid in packaged water (Table to clause 11, Standard 2.6.2).

3.3.6 Addressing FSANZ's objectives for standards setting

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

3.3.6.1 Protection of public health and safety

FSANZ has concluded that the adoption of Option 2 supports the primary objective of protecting public health and safety. The key attributes of this option that support this objective include:

- The WHO guidelines have been developed by experts to produce a contemporary and extensive list of chemical substances and their respective limits for use with drinking water.
- The guidelines are based on a scientifically justifiable risk assessment.
- The guidelines provide the basis for the Australian Drinking Water Guidelines, Drinking Water Standards New Zealand and the CODEX *Standard for Bottled/Packaged Drinking Waters (other than natural mineral waters*) (CODEX STAN 227-2001).
- The limit for fluoride as an exception to the WHO guidelines is justified from a regional (Australian and New Zealand) perspective.
- Adopting this option would enhance the safety of packaged water compared to the current chemical specifications in Standard 2.6.2 of the Code.

Further detail of the consideration of the preferred option from the perspective of this objective has been discussed in detail in SD1 and SD3.

FSANZ considered introducing new labelling requirements for packaged water containing levels of fluoride greater than 1.0 mg/L, as an alternative regulatory measure for fluoride. However, this measure was rejected because previous consideration by FSANZ under Application A588 (*Voluntary Addition of Fluoride to Packaged Water*) supported establishing a maximum limit (ML) for fluoride as the most appropriate regulatory measure. A single ML for all packaged water ensures that all consumers are protected against excessive fluoride intake. The labelling aspects for high fluoride content in packaged water are discussed in more detail in SD3.

3.3.6.2 The provision of adequate information relating to food to enable consumers to make informed choices

The current requirements for provision of certain information to enable consumers to make informed choices in regard to packaged water are unchanged by this Application. There were no other relevant issues identified under this objective with respect to the preferred option.

3.3.6.3 The prevention of misleading or deceptive conduct

There were no relevant issues identified under this objective with respect to the preferred option.

3.3.6.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2):

- the need for standards to be based on risk analysis using the best available scientific evidence
- the promotion of consistency between domestic and international food standards
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food
- any written policy guidelines formulated by the Ministerial Council[3].

These subsection 18(2) considerations have been noted as part of the impact analysis (SD1).

3.4 Risk communication

3.4.1 Consultation

All calls for submissions are notified to the community through the FSANZ Notification Circular, a media release and through FSANZ's social media tools and the *Food Standards News*.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Individuals and organisations that make submissions on this Proposal will be notified at each stage of the assessment.

If a draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the COAG Legislative and Governance Forum on Food Regulation. If the decision is not subject to a request from the Forum for a review, stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

3.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Amending the Code to adopt the chemical limits in Table A3.3 of the WHO guidelines and setting a total maximum level of fluoride (added and naturally occurring) at 1.0 mg/L and styrene at 0.03 mg/L, may have a significant effect on international trade as some mineral/spring waters may contain various naturally occurring chemicals at levels greater than that stipulated in the guidelines. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Sanitary and Phytosanitary Measures Agreement has been made to enable other WTO member countries to comment on the

[3] Now known as the COAG Legislative and Governance Forum on Food Regulation

proposed amendments.

4. Draft variation

The draft Standard to Standard 2.6.2 is given at Attachment A.

The draft Explanatory Statement is given at Attachment B.

4.1 Transitional arrangements

The Applicant has indicated that a 36 month transition period from gazettal would be preferred. FSANZ supports this transition period so as to allow sufficient time for the industry to clear their existing stock and to establish their testing regimen.

5. Attachments

A. Draft variation/s to the *Australia New Zealand Food Standards Code*
B. Draft Explanatory Statement
C Consolidated list of questions for submitters

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1043 – World Health Organization Limits for Packaged Water) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated XXXX

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1043 – World Health Organization Limits for Packaged Water) Variation.*

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

These variations commence **3 years after the date of gazettal**.

SCHEDULE

[1] Standard 2.6.2 is varied by omitting subclause 2(2) including the Table to the subclause, and substituting –

"(2) Water presented in packaged form must not contain a chemical listed in *Table A3.3 Guideline values for chemicals that are of health significance in drinking-water* of *Annex 3 Chemical summary tables* in the *Guidelines for drinking-water quality, 4th edition, 2011, World Health Organization, Geneva 2008,* unless the level of the chemical is equal to or less than the guideline value for the chemical specified in that Table.

(3) Subclause (2) does not apply to fluoride and styrene.

(4) Water presented in packaged form must not contain fluoride that is naturally occurring in that water unless the level of that chemical is equal to or less than 1.0 mg/L.

(5) Water presented in packaged form must not contain styrene unless the level of that chemical is equal to or less than 0.03 mg/L.

Editorial note:

Clause 11 of Standard 1.3.3 sets a similar maximum permitted limit for styrene when it is present in packaged water as a result of use of a polymer containing styrene as a processing aid.

"

[2] Standard 1.4.2 is varied by inserting after clause 1

"1A Application

This Standard does not apply to water presented in packaged form."

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1043 which seeks to institute to adopt limits for certain chemical substances in packaged water to reflect the current limits in place in international Standards established by the World Health Organization. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

2. Purpose and operation

Currently, the Code specifies chemical limits for packaged water (Table to subclause 2(2) of Standard 2.6.2). The purpose of this variation to the Standard is to provide a more contemporary and comprehensive list of chemicals and their respective limits, for producers, bottlers, importers and marketers of packaged water. This variation will enhance the safety of packaged water for consumers. The variation will result in the adoption by reference to the chemical limits listed in *Table A3.3 Guideline values for chemicals that are of health significance in drinking-water* (Annex 3 (Chemical Summary Tables)) of the WHO guidelines.

This variation will come into force 36 months after gazettal to permit industry to clear current stock and to implement a testing regimen for the chemicals so listed in the WHO guidelines.

3. Documents incorporated by reference

The variations to the current food regulatory measure will be undertaken by reference to the appropriate section of the WHO guidelines.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1043 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A Call for Submissions (which includes the draft variation) will be released for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variations to Standard 2.6.2 are likely to have a minor impact on business and individuals (OBPR Reference 12956).

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human

rights as it is a non-disallowable instrument under section 97 of the FSANZ Act.

6. Variations

6.1 Item [1]

Item 1 of the variation amends Standard 2.6.2 by amending subclause 2(2) and inserting new subclauses 2(3) to 2(5).

Subclause 2(2) of that Standard is amended to prescribe maximum limits for certain chemical substances in packaged water by reference to the relevant chemical limits listed in *Table A3.3 - Guideline values for chemicals that are of health significance in drinking-water* of *Annex 3 Chemical summary tables* in the 4th edition of the World Health Organization's *Guidelines for drinking-water quality,* published in 2011.

New subclause 2(3) provides that subclause 2(2) does not prescribe maximum limits for fluoride and styrene in packaged water. As such, the limits listed in the World Health Organization's Guidelines for those two chemicals are not applied to packaged water by subclause 2(2).

New subclause 2(4) prescribes a maximum limit for packaged water of 1.0 mg/L for fluoride that naturally occurs in water.

New subclause 2(5) prescribes a maximum limit of 0.03 mg/L for styrene in water presented in a packaged form. (Clause 11 of Standard 1.3.3 sets a similar limit for styrene present in packaged water as a result of the use of a polymer containing styrene as a processing aid.)

6.2 Item [2]

Item 2 of the variation amends Standard 1.4.2 to make it clear that that Standard does not apply to packaged water.

Attachment C – Consolidated list of questions for submitters

Submitters may wish to consider some or all of the following questions in response to this call for submissions document.

1. Is access to international markets important to your business' success or survival? If so, what are the compositional requirements or chemical specifications for entering and maintaining access to those markets?

2. For consumers of packaged water, what are the expectations or perceptions of packaged water safety or quality?

3. How will packaged water businesses benefit domestically and/or internationally from the adoption of the WHO guidelines?

4. How will bottled/packaged water imported into either Australia or New Zealand be affected by the adoption of the WHO guidelines?

5. What is your current testing regimen for packaged water?

6. The Australian Drinking Water Guidelines and the Drinking Water Standards for New Zealand incorporate a comprehensive risk management strategy to ensure water safety. Would industry and government utilise a similar strategy for packaged water?

7. Will imported packaged/bottled water be adversely affected by a limit of 1.0 mg/L for fluoride?