17 December 2012
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Approval Report – Application A1043

World Health Organization Limits for Packaged Water

Food Standards Australia New Zealand (FSANZ) has assessed an application made by the Australasian Bottled Water Institute (ABWI) to adopt limits for certain chemical substances in packaged water to reflect current limits in the World Health Organization Guidelines for Drinking-water Quality, 2011.

On 3 August 2012, FSANZ sought submissions on draft variations and published an associated report. FSANZ received eight submissions.

FSANZ approved the draft variations on 6 December 2012. The COAG Legislative and Governance Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 13 December 2012.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following documents used to prepare this Report are available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1043worl4761.cfm

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 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) and, in particular, the Table to subclause 2(2), to adopt limits for certain chemical substances in packaged water to reflect limits in an international standard established by the World Health Organization (WHO). The particular 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*[2] (WHO GDWQ).

The Table to subclause 2(2) of Standard 2.6.2 has not been comprehensively reviewed 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 was considered questionable. Updating the Table to subclause 2(2) to take into account the current scientific evidence relating to the safety of chemicals found in bottled water was considered justifiable, but required 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 *per se*, 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, was not in keeping with contemporary national and international standards/guidelines for drinking water safety and the respective limits were 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.

As the safety assessment for the WHO guidelines has been undertaken by experts, FSANZ did not conduct its own assessment of each listed chemical substance. 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 WHO GDWQ were established on safety grounds and were an appropriate set of chemical limits with respect to packaged water 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.

[2] 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'.

A single exception was made to adopting the chemical limits of the WHO guidelines as a whole into the Code. A maximum limit for fluoride of 1.0 mg/L was proposed and not 1.5 mg/L as indicated in the WHO guidelines. This value was based on FSANZ's own dietary intake assessment of fluoride in packaged water (Application A588) which recommended a maximum level of 1.0 mg/L. This recommendation reflects the individual, seasonal and geographic variations, including children and higher consumers of water (i.e. those living in hot climates). This maximum level is currently specified in clause 2A of Standard 2.6.2.

The Call for Submissions document also included an additional exception, whereby FSANZ had proposed that the maximum level for styrene in Standard 2.6.2 (based upon the WHO GDWQ) be raised from 0.02 mg/L to 0.03 mg/L. The latter value was equivalent to the current maximum permitted level for styrene as a processing aid in packaged water. However, following consideration of the submissions and FSANZ's reassessment for the basis of the styrene limit in Standard 1.3.3 (Processing Aids), FSANZ withdrew the proposed change to the styrene limit. Instead, the styrene maximum level in Standard 1.3.3 has now been reduced to 0.02 mg/kg, the WHO GDWQ maximum level.

Clarity was also introduced after receipt of the submissions, by introducing some minor changes to Standard 1.4.1 (Contaminants and Natural Toxicants). with respect to 'packaged water', and the transitional requirements for compliance with the existing and new variations to Standard 2.6.2 for the two following gazettal.

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 is 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 approved variations 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 an exception for fluoride. Consequential variations have also been made to Standards 1.3.3 and 1.4.1.

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 formal request for further information from FSANZ, the Applicant indicated that the assessment of A1043 should 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* of *Annex 3 Chemical summary tables* in the *Guidelines for drinking-water quality, 4th edition, 2011, World Health Organization, Geneva.*

http://www.who.int/water_sanitation_health/publications/2011/dwq_guidelines/en/index.html

2.2.1 Previous consideration of the Application

This Application was initially considered under Code Maintenance Proposal IX (P1013) during 2010-2011. However, comments from three jurisdictions (New Zealand Ministry of Agriculture and Forestry (now the Ministry for Primary Industries); 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.

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 in accordance with 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 (Preliminary Provisions – Application, Interpretation and General Prohibitions). For the purpose of this Application, packaged water was 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 for sale (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 was not considered under this Application.

2.4 Reasons for accepting the 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 was 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 was 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.

2.7 Decision

The draft variations as proposed in the Call for Submissions report were approved with amendments.

The draft variations, as varied after submissions were received, are at Attachment A. The draft variations on which submissions were sought are at Attachment C.

3. Risk 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.

3.1.1 Quality versus Safety

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[3]. 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 was satisfied that the chemical limits established by the WHO in the GDWQ were based upon safety parameters and suitable for defining maximum levels (MLs) for drinking water.

3.1.2 Fluoride

FSANZ has previously performed a risk analysis for fluoride in packaged water (*A588 – Voluntary Addition of Fluoride to Packaged Water*) and concluded that 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 GDWQ. This variation from the WHO GDWQ was consistent with the caveat for fluoride in the WHO GDWQ that states that the 'volume of water consumed and intake from other sources should be considered when setting national standards'. FSANZ was not able to identify any packaged water that was locally produced (Australia or New Zealand) or imported into either country, that had fluoride levels greater than 1.0 mg/L. Further information is available in SD3.

[3] BMDL: Benchmark Dose Level; NOAEL: No Observed Adverse Effect Level; LOAEL: Lowest Observed Adverse Effect Level. A threshold is the dose or level of exposure to a chemical above which an adverse health effect can occur. At doses or levels below this threshold, adverse health effects are unlikely to occur. This concept plays an important role in toxicology and has widespread use in chemical regulation around the world.

3.1.3 Other chemicals

FSANZ also considered the consistency between the chemical limits in the WHO GDWQ and the limits for various chemicals permitted in the Code under Standards 1.3.3 – Processing Aids, 1.4.1 – Contaminants and Natural Toxicants and 1.4.2 – Maximum Residue Limits. This consideration included assessing information and comments made in various submissions.

After reconsideration of the scientific basis for the maximum permitted level for styrene in Standard 1.3.3 (Table to clause 11), FSANZ recommended that the current limit in this Standard be reduced from 0.03 mg/kg to 0.02 mg/kg. This value would be equivalent to the styrene limit of 0.02 mg/L in the WHO GDWQ. This was undertaken to ensure that there was no ambiguity with respect to the maximum level for styrene in the Code – without jeopardising human health and safety or technical need. To clarify the interaction between provisions for packaged water resulting from adoption of the chemical limits provided by the WHO GDWQ and limits for specific chemicals in Standard 1.4.1, minor changes were effected to Standard 1.4.1. After consideration of a submission in relation to a proposed exemption for packaged water from Standard 1.4.2, FSANZ proposed that no changes should be made to Standard 1.4.2.

More detailed information is available in Appendix 1.

4 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 GDWQ as the basis for its chemical limits. These limits include those stipulated in the current 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 non-regulatory approach was warranted but considered that reliance on a voluntary approach would not be sufficiently protective of human health and safety, did not promote international trade in packaged water and did not provide a level playing field for domestically produced and imported packaged water products.

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 GDWQ or other drinking water guidelines/standard; and (ii) labelling of specific chemical constituents that pose a health and safety concern, e.g. fluoride. The use of labelling statements is discussed further in SD3. The use of labelling was 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 proposed 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 is consistent with the notes accompanying the limits in the WHO GDWQ, 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) was found to 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 considered compliance with the levels and use indicated in the Table to clause 11 of Standard 1.3.3 for most of these chemicals to be an acceptable risk management measure and not in conflict with the levels in the variation to Standard 2.6.2. However, after reconsideration of the evidence supporting the initial creation of the styrene maximum permitted level of 0.03 mg/kg, FSANZ concluded that this value should be reduced to the same equivalent level in the WHO GDWQ i.e. 0.02 mg/kg. Further discussion of this matter is provided in the SD1 for the assessment summary and Appendix 1. In addition, specific provisions for packaged water were made to Standard 1.4.1. This was undertaken to ensure that there was no ambiguity with respect to chemical limits for packaged water in the Code and to clarify that standard 1.4.1 contains maximum limits for some chemical substance in packaged water, in addition to those contained in Standard 2.6.2.

5 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment. The key issues raised in submission are summarised in Table 1. More detailed discussion has been provided in Appendix 1.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Styrene limit should not be increased above the value in the WHO GDWQ.	Australian Beverages Council Ltd Australian Food and Grocery Council	Reanalysis of the evidence base supporting the higher limit for styrene when used as a processing aid in packaged water revealed levels above 0.02mg/kg were unlikely to occur, particularly from the use of a processing aid. FSANZ has therefore approved a reduction in the permitted level for styrene, from 0.03mg/kg as proposed in the Call for Submission, to the styrene limit in the WHO GDWQ, of 0.02 mg/L. The drafting initially proposed in the Call for Submission document has been removed and a new variation introduced into Standard 1.3.3.
The limit for antimony is too high in the WHO GDWQ.	Dr GL Robertson	The risk assessment by the WHO was reviewed and FSANZ concurs with its conclusions. The antimony levels in potable/packaged water in Australia and New Zealand have not been shown to be above the Human Based Guidance Value (HBGV). No change to the ML for antimony in Standard 2.6.2 was recommended.
Legislative independence	QLD Health	The adoption of the chemical limits from the WHO GDWQ into Standard 2.6.2 would not remove legislative independence. An Application or Proposal would be required before any subsequent changes to the WHO GDWQ were adopted in Standard 2.6.2.
Impacts on existing products with regards to fluoride	New Zealand Ministry for Primary Industries	There was no information or commentary to suggest that the imposition of a fluoride maximum level of 1.0 mg/L in packaged water, would have a negative impact on existing products in the Australian or New Zealand markets. No comments were received during the submission period to suggest that the permissible level of fluoride in packaged water (1.0 mg/L) would have a negative impact on domestically produced or imported packaged water. In its submission, the applicant supported the lower limit for fluoride as proposed by FSANZ.
Transition period for compliance	New Zealand Ministry for Primary Industries	Clarification was sought regarding the transitioning of the new variations in the Standard 2.6.2. FSANZ has changed the commencement date so that industry will be allowed to comply with the new variations of the standard immediately on gazettal. Furthermore modifications have been made to the stock in trade provisions.
No demonstrable regulatory failure	VIC Department of Health	There was difficulty in demonstrating regulatory failure given the current chemical limits in Standard 2.6.2 have been established based on long-term exposure. Importantly, the chemical limits in the WHO GDWQ have been established to reduce the risk of adverse health outcomes in consumers from a lifetime of exposure to a range of chemicals. FSANZ has considered that it would be prudent for the protection of human health and safety, to have these chemical limits reflected in the Code.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Cost burden on small suppliers	VIC Department of Health	The industry has not identified any significant, additional cost burdens associated with a monitoring program for the 90 chemicals listed in the WHO GDWQ, as it is already fulfilling similar or greater requirements as per the current voluntary code of conduct and/or quality assurance programs for regional and international markets. Any monitoring or compliance program should be tailored to the risk of the chemicals present in the particular water source.
Contaminants and natural toxicants	VIC Department of Health	FSANZ has qualified the applicability of Standard 1.4.1 to packaged water.
Zero tolerance and MRLs	VIC Department of Health	In the Call for Submissions document, FSANZ had sought to reduce the possibility of ambiguity in the Code due to different provisions for AgVet chemicals in standards 2.6.2 and 1.4.2, by explicitly excluding packaged water from Standard 1.4.2. FSANZ has now removed the proposed drafting that would have excluded packaged water from Standard 1.4.2. As a consequence, AgVet chemicals which are listed in Standard 2.6.2 are permitted but Standard 1.4.2 continues to prohibit any other AgVet chemicals from being present in packaged water
Vertical versus horizontal standards	VIC Department of Health	The adoption of the chemical limits from the WHO GDWQ into Standard 2.6.2, serves only to update and enhance the current list of chemical limits in that standard. This action was seen as the most appropriate regulatory measure. No other features associated with other packaged water or mineral water standards, e.g. Codex, have been incorporated into Standard 2.6.2.
Guidance on what chemicals have not been permitted in Australia	QLD Health	Guidance on what chemicals have been permitted in Australia was considered outside the scope of this Application. The adoption of the chemical limits from the WHO GDWQ would result in all packaged water produced and imported into Australia and New Zealand requiring compliance with the Standard. A monitoring/compliance plan should be based on a risk analysis of what chemicals were potentially present in a water source. Similar risk management approaches are used in domestic potable water management plans, and these may provide guidance on a suitable testing regimen for packaged water. The Applicant has also provided and suggested testing regime – See SD1.
Contaminants from coal seam and shale gas fracking processes	QLD Health	Outside the scope of the Application.

6 Risk communication

6.1 Consultation

The Call for Submissions and related summary of assessment was notified to the community through the FSANZ Notification Circular and related media alert, 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 were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Individuals and organisations that made submissions on this Application have been notified of FSANZ's approval.

The decision of the FSANZ Board has been 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.

6.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated 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.

Although the proposed variations were consistent with international guidelines, FSANZ made a notification to the WTO for this Application in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures to determine if there was any potential impact on internationally traded packaged water. No WTO member nation provided comment on the draft variation.

7. Reasons for decision

FSANZ had regard to the following matters under 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
- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application
- any relevant New Zealand standards
- any other relevant matters.

At the conclusion of Call for Submission, the FSANZ Act required FSANZ to do one of the following:

1. Approve the draft variation circulated in the Call for Submissions;
2. Approve that draft variation subject to such amendments as considered necessary;
3. Reject the draft variation.

For the reasons outlined in this Approval Report, the first option above was not considered appropriate.

For approval, FSANZ therefore considered the following options:

1. Approve the draft variation subject to amendments (Option1)
2. Reject the draft variation (Option 2)

The draft variation to Standard 2.6.2 adopts 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, limits the use of fluoride to 1.0 mg/L and lowers the permitted level of the use of styrene in a processing aid to a maximum level of 0.02 mg/L.

These options are considered in detail in SD1 and in response to comments received in submissions (Appendix 1). Overall, FSANZ concluded that the adoption of Option 1 would enhance the protection of the health and safety of consumers, and be advantageous to industry in terms of international and domestic trade. Apart from some minor costs associated with increased testing of packaged water, no other disadvantages were identified relative to the status quo (Option 2).

7.1 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).

7.2 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.

7.3 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, 2008) were considered under Option 3 in the Call for Submissions document. See SD1 for further detail regarding the consideration of adopting the Drinking Water Standards New Zealand into Standard 2.6.2 of the Code.

7.4 Other relevant matters

There were no other relevant matters that could be identified.

7.5 Addressing FSANZ's objectives for standards-setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

7.5.1 Protection of public health and safety

FSANZ has concluded that the adoption of Option 1 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.

7.5.2 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.

7.5.3 The prevention of misleading or deceptive conduct

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

7.5.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters set out 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[4].

These subsection 18(2) considerations have been noted as part of the analysis of the various regulatory options in SD1.

8 Transitional arrangements

FSANZ supports industry members complying with the new variations in Standard 2.6.2 immediately so has brought forward the commencement date to start on gazettal of the standard.

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. FSANZ has recommended that this 36 month transition period should take into consideration the 12 month stock in trade provision given in Standard 1.1.1. Thus a transitional period for two years after gazettal has been approved.

9 Implementation

The variations will come into effect on gazettal with the exception of the variation made by item [3.2] of the Schedule which will commence 2 years after gazettal.

10 References

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

Tukur A, Sharp L, Stern B, Tizaouic C, Benkreira H (2012) PET bottle use patterns and antimony migration into bottled water and soft drinks: the case of British and Nigerian bottles. *Journal of Environmental Monitoring* **14**:1237-1247.

Westerhoff P, Prapaipong P, Shock E, Hillaireau A (2008) Antimony leaching from polyethylene terephthalate (PET) plastic used for bottled drinking water. *Water Research* **42**:551-556.

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WHO (2008) Guidelines for Drinking-water Quality, Third Edition, Volume 1: Recommendations. Geneva, World Health Organization. http://www.who.int/water_sanitation_health/dwq/fulltext.pdf

Attachments

A. Approved variations to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft variations on which submissions were called

Attachment A – Approved 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 variation commences on the date specified in clause 3.

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 **on gazettal**, other than variation [3.2] which commences **2 years after the date of gazettal**.

SCHEDULE

[1] **Standard 1.3.3** is varied by omitting from the Table to clause 11 "0.03 (as styrene)" and substituting "0.02 (as styrene)"

[2] **Standard 1.4.1** is varied by omitting from the Table to clause 3

"

Vinyl chloride	All food	0.01

"

and substituting

"

Vinyl chloride	All food except packaged water	0.01

"

[3] **Standard 2.6.2** is varied by

[3.1] inserting after clause 2 the following –

"

2AA Limits for chemicals in packaged water

(1) Water presented in packaged form may or may not contain added carbon dioxide.

(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,* at a level greater than the guideline value for the chemical specified in that Table.

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

(4) Water presented in packaged form must not contain fluoride that is naturally-occurring in the water at a level greater than 1.0 mg/L.

Editorial note:

Clause 3 of Standard 1.4.1 sets a maximum level for Acrylonitrile of 0.02 mg/kg in all food. Clause 4 of Standard 1.4.1 sets a maximum level for Pulegone of 250 mg/kg in beverages.

2AB Compliance with clause 2 or 2AA

Water presented in packaged form must comply with clause 2 or 2AA, but not a combination of both.

"

[3.2] repealing clauses 2 and 2AB

[3.3] updating the Table of Provisions to reflect these variations.

Attachment B – 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 adopt limits for certain chemical substances in packaged water that 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

Standard 2.6.2 of the Code currently specifies chemical limits for packaged water (Table to subclause 2(2) 2). The purpose of this variation to the Standard is to provide producers, bottlers, importers and marketers of packaged water with a more contemporary and comprehensive list of chemicals and their respective limits. 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* of *Annex 3 Chemical summary tables* in the *Guidelines for drinking-water quality, 4th edition, 2011, World Health Organization, Geneva.* (WHO GDWQ).

This variation will come into force at gazettal but with a two year transitional period (plus the subsequent one year exemption provided by clause 2 of Standard 1.1.1 for stock in trade) to permit industry to clear current stock and to implement a testing regimen for the chemicals so listed in the WHO GDWQ. The variation therefore permits compliance with either the existing chemical limits in the Table to subclause 2(2) or the chemical limits adopted by reference to the WHO GDWQ. The latter will permit industry to comply with chemical limits of the WHO GDWQ during the above-mentioned 36 month period.

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 has included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 3 August 2012 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 Standard 1.3.3

Item [1] amends Standard 1.3.3 to reduce the maximum permitted level for styrene listed in the Table to clause 11 from 0.03 mg/kg to 0.02 mg/kg.

6.2 Standard 1.4.1

Item [2] amends the Table to clause 3 in Standard 1.4.1 to provide that the maximum level for vinyl chloride imposed by that clause does not apply to packaged water.

6.3 Standard 2.6.2

Item [3.1] inserts two new clauses after clause 2 of Standard 2.6.2.

Clause 2AA introduces four subclauses.

Subclause 2AA(1) notes that packaged water may or may not contain added carbon dioxide.

Subclause 2AA(2) provides the prescribed 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 *Guidelines for drinking-water quality, 4th edition, 2011, World Health Organization, Geneva,* (WHO GDWG).

Subclauses 2AA(3) and 2AA(4) provide that the maximum permitted level for naturally occurring fluoride in packaged water is 1.0 mg/L. That is, the fluoride maximum level listed in the WHO GDWQ does not apply to packaged water.

An editorial note is also inserted into this clause to highlight specific chemical limits in Standard 1.4.1.

Clause 2AB provides that packaged water must comply with either the current clause 2 or the new clause 2AA, but not a combination of both. This permits industry to comply with either the WHO GDWQ and the maximum level of 1.0 mg/L for fluoride or the current provisions in Standard 2.6.2 during the two year transition period.

Item [3.2] removes clause 2 and 2AB of Standard 2.6.2, two years after the gazettal of these variations. This effectively removes the current clause 2 (including the chemical limits in Table to clause 2(2)) two years after gazettal and leaving clause 2AA in its place (including the clauses related carbon dioxide and fluoride). The stock in trade exemption provided by clause 2 of Standard 1.1.1 will apply when Item [3.2] commences.

Item [3.3] updates the Standard's Table of Provisions to reflect the above changes.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* as consulted on in the Call for Submissions report

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."

Appendix 1 – Consideration of issues raised in submissions

Executive summary

FSANZ has considered the written submissions prepared in response to the Call for Submissions for Application A1043. FSANZ thanks those submitters for their input. The key issues related to the submissions were identified and addressed in this document and are summarized in the Approval Report.

The key changes in the FSANZ recommendations include:

Not making an exception to the styrene limit as proposed for Standard 2.6.2, but instead reducing the maximum permitted level for the use of styrene as a processing aid in Standard 1.3.3 (Table to clause 11), to be consistent with the maximum level for styrene in the World Health Organization, Guidelines for Drinking-water Quality, 2011 (WHO GDWQ)[5].

Altering the commencement date so as to allow industry to comply with the new chemical limits of Standard 2.6.2 immediately on gazettal if they so desire, but still permitting up to three years after gazettal to become compliant (taking into consideration the 12 month stock-in-trade provisions (Standard 1.1.1) that apply to all new standards and variations to the Code).

[5] 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'.

1. Styrene

During the consideration of the various chemical limits proposed for Standard 2.6.2 by the adoption of the chemical limits from the WHO GDWQ (see Call for Submissions documents), FSANZ identified that an existing limit for styrene was present in Standard 1.3.3 (Table to clause 11). The limit for styrene in this standard was 0.03 mg/kg. This level was slightly higher than the proposed maximum level in Standard 2.6.2 at 0.02 mg/L. FSANZ considered that the higher level should also be adopted in Standard 2.6.2 based on its previous assessment and the need to ensure consistency for limits throughout the Code. Two submissions requested a reconsideration of this issue. FSANZ clarified the basis for the styrene limit in Standard 1.3.3 and the likelihood of styrene contamination of drinking water.

1.1 Background to existing limit in Standard 1.3.3

The Table to clause 11 (Permitted processing aids used in packaged water and in water used as an ingredient in other foods) of Standard 1.3.3 (Processing Aids) of the Code, currently contains an entry for 'styrene-divinylbenzene cross-linked copolymer'. The maximum permitted level for this substance is given as 0.03 mg/kg (as styrene).

At the time of the formation of the Australia New Zealand Standards Code in 2000, the value of the maximum permitted level for this styrene equivalent was listed as GMP (Good Manufacturing Practice). As a result of a review of the Standard for processing aids in 2006 (P277 Review of Processing Aids – (http://www.foodstandards.gov.au/foodstandards/proposals/proposalp277reviewof2369.cfm), a number of substances were assigned values based on the Australian Drinking Water Guidelines (ADWG) and the Drinking Water Standards for New Zealand (DWSNZ). The maximum permitted limit for 'styrene-divinyl benzene cross-linked copolymer' was changed from 'GMP' to '0.03 mg/kg'.

FSANZ did not conduct its own risk assessment for styrene in packaged water in P277, but relied on the risk assessment at the time for the ADWG and the DWSNZ.

For the purposes of converting mg/kg to mg/L, water is considered to have a density of 1 kg/L. Thus a limit of 0.03 mg/kg (as per the Table to clause 11, Standard 1.3.3) would be equivalent to 0.03 mg/L for water. This was the proposed limit for styrene as outlined in the Call for Submissions document for A1043.

1.2 Calculation of the Styrene limit

The calculation of the health-based guidance value (HBGV) for styrene in drinking water has been based on the no observed adverse effect level (NOAEL) from a 2-year drinking water study in rats (Beliles *et al*, 1985).

The value of this NOAEL has been used by the WHO, NHMRC and the NZMOH in the derivation of their HBGV or Tolerable Daily Intake (TDI) for styrene in drinking water.

It is important to note that the WHO has used an adult body weight of 60 kg for the derivation of its value, whereas the NHMRC and the NZMOH have used an adult body weight of 70 kg.

The effect of this can be demonstrated by the following two calculations using the same animal NOAEL.

(i) WHO calculation

HBGV = 7.7 mg/kg body weight per day x 60 kg x 0.1 divided by (2 L/day x 1000)
= 0.0231 mg/L
= 0.02 mg/L (rounding down to two decimal points)

(ii) ADWG and DWS NZ calculation

HBGV = 7.7 mg/kg body weight per day x 70 kg x 0.1 divided by (2 L/day x 1000)
= 0.02695 mg/L
= 0.03 mg/L (rounding up to two decimal points)

where:

- 7.7 mg/kg body weight per day is the no observed adverse effect level based on reduced body weight in a 2-year drinking water study using rats (Beliles *et al* 1985).
- average weight of an adult for the WHO (70 kg) and ADWG/DWSNZ (60 kg).
- 0.1 is the proportion of total daily intake attributable to the consumption of water.
- 2 L/day is the average amount of water consumed by an adult.
- 1000 is the safety factor in using the results of an animal study as a basis for human exposure (10 for interspecies variations, 10 for intraspecies variations and 10 for carcinogenic and genotoxic effects).

1.3 Levels of styrene in drinking water

Styrene is used primarily for the production of plastics and resins and is found in trace amounts in surface water, drinking-water and food (WHO, 2011).

The ADWG (2011) noted that styrene has not been found in Australian drinking waters, but the maximum level provided in the ADWG was included to provide guidance in the unlikely event of contamination and because it has been detected occasionally in drinking water supplies overseas. The NZMOH (2005) reported that under its Priority 2 (P2) Chemical Determinand Identification Programme[6], styrene was not detected from 301 water supply zones with a limit of detection of 0.0005 mg/L.

In the 'WHO Styrene in drinking water' (2003) report, styrene was detected in the Rhine (1985) at a maximum concentration of 0.0001 mg/L. Furthermore, styrene was detected at 0.0001 – 0.0005 mg/L in the Great Lakes, USA. The WHO report further notes that styrene "… was not detected in the raw water of groundwater pumping stations in Germany (*6*)[7], but has been found in finished drinking-water in the USA at concentrations of less than 1 µg/litre and in commercial, charcoal-filtered drinking-water in New Orleans, USA (*1*)[8]."

[6] The DWSNZ requires Priority 2 determinands to be monitored, as set out in section 8 of the DWSNZ, so that their health significance can be evaluated. The Priority 2 Chemical Determinands Identification Programme (P2) identifies for water suppliers determinands in their supply that need to be monitored. The presence of a determinand at a concentration more than 50 percent of its Maximum Accepted Value (MAV), in any sample obtained during the Programme, is sufficient for the determinand to be recommended for assignation as a P2 determinand.

[7] GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance. *Styrene*. Weinheim, VCH, 1990 (BUA report 48).

[8] International Agency for Research on Cancer. *Some monomers, plastics and synthetic elastomers, and acrolein.* Lyon, 1979:231-274 (IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Volume 19).

Two submitters requested the WHO styrene limits were adopted. The Applicant noted in its submission, (13 September 2012):

> *We have recently confirmed with ion exchange resin suppliers (Pheta Industries, pers comm) and filtration suppliers (Pall Australia, pers comm) that increases in styrene levels are not associated with the processing aids they supply. We have also discussed with packaging consultant, Edward Kosior of Nextek (Nextek, pers comm) who confirmed that polycarbonate, polyethylene terephthalate (PET), polycarbonate and glass are commonly used bottled water packaging. These do no contribute any significant amount of styrene into bottled water.*
>
> *Styrene is used in some food packaging although there is no history of use in manufacture of beverages in Australia*

The Australian Food and Grocery Council (AFGC) in its submission (September 2012) noted:

> *…there are significant taint and odour problems which diminish the acceptability and use of foods and beverages. Thresholds for styrene monomer detection in water is report[ed] as very low (taste threshold: 0.022 – 0.37 mg/kg)[9]. This makes the proposed level of 0.03 mg/L unacceptably high and likely to result in consumer complaints and product recalls.*

1.4 Discussion

It would appear that the maximum permitted level for styrene in Standard 1.3.3 of the Code was based on the same level in the ADWG and DWSNZ, when the standard was reviewed in 2006. Moreover, the risk assessment for styrene in both of these documents was based on the WHO GDWQ. Importantly, the HBGV in all three cases was based on the same toxicological endpoint, but the use of different adult body weights and the effect of rounding to the nearest decimal point have led to slightly different values. The lower limit of 0.02 mg/L is more protective of the health and safety of consumers.

Information has been gathered that indicates that the presence of styrene in food/beverages at levels commensurate with the maximum permitted level of styrene as a processing aid, i.e. 0.03 mg/kg, would more than likely arise as a result of contamination rather than as a residue from processing. There was evidence to indicate that drinking water in Australia and New Zealand has no or undetectable levels of styrene, and that the use of styrene as a processing aid did not result in increased styrene levels.

Thus, there would appear to be no technological need for the higher styrene maximum level of 0.03 mg/kg (0.03 mg/L) in Standard 1.3.3 compared to the maximum level of 0.02 mg/L adopted in the WHO GDWQ, and proposed for adoption in Standard 2.6.2. Therefore, FSANZ concluded that it would be more prudent to have a single maximum level of styrene in packaged water in the Code, i.e. 0.02 mg/L. Adopting the styrene maximum level of 0.02 mg/L from the WHO GDWQ in both Standards would provide regulatory certainty for industry and regulatory agencies, in that the new chemical limits in Standard 2.6.2 are wholly consistent with the WHO GDWQ. The sole exception of the fluoride maximum level would remain.

[9] Duncan SE, Webster JB (2009). Sensory impact of food-packaging interactions. *Adv Food Nutrit Res* 56:17-64.

2. Antimony

As noted in the Call for Submissions document, FSANZ did not undertake a risk assessment of each chemical and their respective maximum levels contained in the WHO GDWQ. Instead, it recognised that the WHO GDWQ was established by experts and that the HBGVs for the 90 chemicals were based on safety grounds and derived using established methods of analysis. Two exceptions were made in the Call for Submissions document with respects to the maximum levels for styrene and fluoride. A single submission requested FSANZ's reconsideration of the antimony levels in packaged water. The submitter wanted a lower level of antimony in packaged water (value not specified) compared to the maximum level given in the WHO GDWQ (0.02 mg/L) due to concerns related to the potential for antimony to leach from plastic bottles into the packaged water. FSANZ reconsidered the risk assessment for antimony in drinking water and the likelihood of antimony contamination in packaged and drinking water.

2.1 Maximum levels for antimony in drinking water guidelines

There is some variation in the maximum levels for antimony in different drinking water standards/guidelines, as there is for a number of chemicals. FSANZ identified a number of these maximum levels in its SD2. There is currently no limit for antimony in packaged water in the Code. The WHO GDWQ and the DWSNZ provide a limit of 0.02 mg/L, whereas the ADWG has a lower limit of 0.003 mg/L. Lower limits for antimony may be found in the Codex Standard for Natural Mineral Waters (CODEX STAN 108-1981) (0.005 mg/L) and the ABWI Model Code (0.006 mg/L). The Codex Standard for Bottled/Packaged Waters (CODEX STAN 227-2001) utilises the chemical limits in the WHO GDWQ.

2.2 WHO guideline value

The WHO GDWG specify a guideline value for antimony of 0.02 mg/L (WHO 2008). A guideline value represents the "concentration of a constituent that does not exceed tolerable risk to the health of the consumer over a lifetime of consumption". WHO indicated that antimony levels in drinking water are typically less than 0.005mg/L which is well below the safe level of 0.02 mg/L. The derivation of the WHO guideline value for antimony is presented below.

An acceptable database of toxicological information on antimony enabled the WHO to establish a tolerable daily intake (TDI) of 0.006 mg/kg bodyweight (WHO 2003). The TDI was derived from a 90-day study in which groups of rats were administered a highly water soluble antimony compound (potassium antimony tartrate) in drinking-water (Poon *et al*, 1998; Lynch *et al*, 1999). Decreased body weight gain and reduced food and water intake were observed in rats receiving an antimony dose of 60 mg/kg bw/day, while no treatment related adverse effects were observed at the next lowest dose of 6 mg/kg bw/day. The No Observed Adverse Effect Level (NOAEL) was therefore 6 mg/kg bw/day. The TDI of 0.006 mg/kg bw was derived from this NOAEL by applying an uncertainty factor of 1000 (100 for inter- and intraspecies variation, and an additional 10-fold factor for the short duration of the study).

The guideline value of 0.02 mg/L (rounded figure) was derived from this TDI by assuming a 60-kg adult drinking 2 litres of water per day and allocating 10% of the TDI to drinking water. It was noted that this value could be highly conservative because of the nature of the end-points and the large uncertainty factor; further data could result in a lower uncertainty factor (WHO 2003).

2.3 Antimony levels in packaged water

Most published studies on antimony levels in packaged water (both glass and plastic packaging), investigated over a wide range of storage times and temperatures, indicate no samples above the guideline value of 0.02 mg/L (Andra *et al*, 2012, Shotyk *et al*, 2006; Shotyk & Krachler, 2007; Westerhoff *et al*, 2008). Slight exceedances above 0.02 mg/L were only observed when packaged water items were heated to unreasonably high temperatures for extended periods (e.g. heating to 80°C for 48 hours: antimony level ~0.022 mg/L); however, heating to 60°C for 48 hours resulted in a level of only ~0.003 mg/L (Tukur *et al*, 2012).

2.4 Antimony levels in drinking water

The NZMOH (2005) noted the following sources of antimony in drinking water with respect to New Zealand.

> ***Source waters***
>
> *Antimony can reach the aquatic environment from the weathering of minerals and rocks, run-off from soils and atmospheric deposition. Over 100 antimony containing minerals occur in nature. In New Zealand stibnite (Sb_2S_3), antimony sulphide, is the chief ore of antimony and is found in many quartz lodes, especially in the Reefton Goldfield and in Otago. Other examples of known major occurrence in New Zealand include near Russell, Reefton, Westland, Great Barrier Island and on the Coromandel Peninsula.*
>
> *Antimony can also get into water via the discharge of wastes from industries in which it is used. These include the production of semi-conductors, batteries, safety matches, electronic equipment, paint pigments, ceramic enamels, glass and pottery, plastics, ammunition primers, antifriction materials, cable sheathing, flame-proofing compounds and fireworks. Antimony is released into the atmosphere from coal-fired power plants and inorganic chemical plants. It is also found in gasolines.*

The NZMOH could not identify treatment sources which would result in the presence of antimony in drinking water but noted that in distribution systems, antimony might be present as a result of the dissolution of antimony-tin solder used in household plumbing. Nonetheless, the NZMOH determined for drinking water

> *The P2 Chemical Determinand Identification Programme, sampled from 897 zones, found antimony concentrations to range from 'not detectable' (nd) to 0.012 mg/L, with the median concentration being 'nd' (limit of detection = 0.0005 mg/L).*

The WHO (2003) also reported concentrations in surface water and groundwater normally in the range of 0.0001- 0.0002 mg/L, and less than 0.005 mg/L in drinking-water.

2.5 Discussion

FSANZ considered the concerns regarding the presence of antimony in potable and packaged water, and the differences in the maximum level for antimony in different drinking water guidelines/standards. It was concluded that the maximum level for antimony that was established by the WHO was protective of human health and safety. Furthermore, antimony levels in packaged water would only exceed the WHO HBGV in exceptional conditions. Levels typically found in potable water were below the maximum level established by the WHO in the GDWQ. FSANZ recommended that no change would be made to the maximum level for antimony in packaged water, as set out in the variations to Standard 2.6.2.

3. Legislative independence

Concern was raised that the adoption of the chemical limits in the WHO GDWQ could potentially bypass the scrutiny of the legislative system in Australia by allowing any changes made by the WHO to be automatically to become legal requirements in Australia. Moreover, concern was also raised of the potential this would have on excluding Australian stakeholders from consultation on future changes to the WHO GDWQ.

FSANZ noted that the adoption of the WHO GDWQ into the Code does not bypass the scrutiny of the Australian or New Zealand legislative systems. The adoption of the WHO GDWQ into Standard 2.6.2 is specific to the fourth edition (2011) version of the chemical limits in the WHO GDWQ. Any updates to the WHO GDWQ are not automatically reflected in the Code by virtue of the wording in the Code. Either an Application or a Proposal would be required to effect a change to this. This would enable any stakeholder to comment on any future changes to the chemical limits for packaged water in the Code.

The recommendation that it would be important for Australia to either actively engage in the WHO development process or to actively monitor proposed changes to the WHO GDWQ so as to advocate or provide comment on behalf of Australia is considered out of scope for this this Application.

4. Impacts on existing products with regards to fluoride levels

A request had been made to provide additional information and comment on the impacts of the new MLs on existing products on the market, particularly relating to fluoride levels.

In response, FSANZ noted that no additional information was forthcoming from the submissions or from the WTO notifications to suggest that the new ML for fluoride in packaged water from naturally occurring sources would have a negative impact on existing products. Information was provided in the CFS documents and in particular Supporting Document 3, that highlighted the past and current reported levels of fluoride in potable and packaged water. Australian and New Zealand drinking water that has not had fluoride added to it has been shown to have less than the proposed fluoride limit of 1.0 mg/L. Whilst the CFS Supporting Document 3 identified that a number of natural mineral waters from around the world could exceed the proposed ML for naturally occurring fluoride in packaged water, not all natural mineral waters or spring waters are necessarily available in Australia or New Zealand. The vast majority of bottled/packaged water imported into Australia comes from Italy and France. An ad hoc survey of imported bottled/packaged water in supermarkets in Australia and New Zealand revealed that the eight different brands from Italy and France had fluoride levels below the maximum level of 1.0 mg/L.

Given that a sizeable proportion of the packaged/bottled water industry were already testing their water to the ABWI Model Code requirements and/or meeting stringent specifications set by domestic retailers or export markets, FSANZ considered the impact to be minimal on existing products in the market.

5. Transition period for compliance

The New Zealand Ministry for Primary Industries sought clarification regarding the intent of the commencement date for the new variations to Standard 2.6.2 and noted that industry should be allowed to comply with the new provisions or the current Standard during the transition period.

Clarification has been provided in the revised drafting for the Approval report for this Application. The revised drafting will allow packaged water producers, bottlers and importers to comply with the new chemical limits for Standard 2.6.2 immediately and not have to wait for the variations to the Standard to come into force. That is it no longer has a commencement date of 36 months as originally given in the Call for Submissions document. The latter change will still allow up 36 months for the industry to become compliant with the standard, given the 12 month stock-in-trade provisions noted in Standard 1.1.1.

6. No demonstrable regulatory failure

Concern was raised by one of the submitters that there was no evidence of regulatory failure with respects to Standard 2.6.2 and that the potential burden that would be imposed on parts of the bottled water industry was not justified.

FSANZ had previous noted in the Call for Submission's document, that there was no direct evidence to indicate a demonstrable regulatory failure for packaged water in terms of the three primary objectives of the FSANZ Act. However, FSANZ did note that the current set of chemicals and their respective limits listed in the Table to subclause 2(2) of Standard 2.6.2 were not in keeping with national and international standards/guidelines for drinking water safety and were no longer based on the best currently available scientific evidence.

It should be noted that the premise for establishing an ADI or TDI for a chemical substance is based upon the reduction in the risk of an adverse health outcome in consumers from a *lifetime of exposure* to that chemical. Thus it would be difficult to demonstrate a regulatory failure for the chemical limits currently listed in Standard 2.6.2 because of difficulties in attributing adverse effects to a single food/beverage or chemical. That is, apart from a clinically obvious reaction to a contaminant e.g. acute toxicity, identifying an adverse health outcome that was related to the long term intake of a particular chemical is difficult. The WHO through the development of the GDWQ has established a set of HBGV for a number of chemicals in drinking water that are considered to pose a risk to human consumers from long-term exposure. It would be prudent for these chemical limits for drinking water to be reflected in the Code.

7. Cost burden on small suppliers

Concern was raised that the adoption of a broader range of chemicals in Standard 2.6.2, which have to be compulsorily tested for or complied with, would likely result in the imposition of an unnecessary cost burden on small suppliers.

FSANZ considered the imposition upon industry in Supporting Document 1. FSANZ noted that the bottled/packaged water industry association, the Applicant, supported the adoption of the chemical limits from the WHO GDWQ into Standard 2.6.2. Members of the ABWI already test their product for a range of chemicals outlined in the ABWI Model Code. The Model Code was based upon the WHO GDWQ, 2008. The ABWI recognised that the adoption of the WHO GDWQ (2011) into Standard 2.6.2 would result in an increased number of chemicals that would require compliance testing compared with the number of chemicals listed in its Model Code. Nonetheless, the ABWI indicated that it had widespread industry support in both Australia and New Zealand for this course of action. The ABWI represents a considerable cross-section of the packaged water industry including small, medium and large scale businesses. FSANZ did not receive any submissions from the industry that was contrary to this position. On the other hand, support was noted in the submissions from the AFGC and NZFGC.

In its submission (13 September) the NZFGC noted:

> *The larger manufacturers in New Zealand have confirmed to NZFGC that they already manufacture to standards that exceed the WHO Guidelines for bottled water …*
>
> *The NZFGC notes that the proposed amendment to Standard 2.6.2 will involve a compliance cost for industry. Many in the packaged water industry are already paying for the range of tests proposed and while there may be a slight increase to these, the benefits of increased consumer confidence and improved market access for exports outweighs this cost.*

Further concern was raised about the inability to tailor the testing program according to an appropriate risk assessment. FSANZ noted that there is no specification within the Code for the adoption of the WHO GDWQ in Standard 2.6.2 that indicated the minimum testing program for this commodity. The onus would be upon the industry and compliance agencies to determine the most appropriate testing regimen, ensuring that the frequency of testing was commensurate with the risk assessment of each chemical in that particular water source used in the packaged water product. Guidance on this compliance issue could be sought from the various regional potable water management plans currently in use in Australia and New Zealand. This matter is also discussed further in the matters listed below.

8. Contaminants and natural toxicants (Standard 1.4.1)

One submission noted that Standard 1.4.1 included three listings of 'All Foods' against acrylonitrile, pulegone and vinyl chloride. Vinyl chloride was noted as having a maximum level of 0.01 mg/kg in this standard, compared with 0.0003 mg/L in the WHO GDWQ. The submitter thought this was significant because the WHO guidelines have been prepared for drinking water and not specifically bottled water. Given the potential for vinyl chloride, for instance, to leach from plastic bottles, it was further suggested that FSANZ investigate this issue further both in terms of Standard 1.4.1 and Standard 2.6.2.

The maximum level for pulegone (250 mg/kg in 'Beverages' and 350 mg/kg in 'Confectionery') was limited to its presence as a natural toxicant from the addition of flavouring substances to food (Table to clause 4). The maximum level for pulegone was not related to 'All foods' and was not listed in the WHO GDWQ, the ADWG or the DWSNZ. Therefore, the presence or the maximum level of pulegone to packaged water was not considered relevant to current Application by FSANZ.

A check of Standard 1.4.1, confirmed that the maximum level for acrylonitrile and vinyl chloride in 'All food' was 0.02 and 0.01 mg/kg, respectively. There are currently no maximum levels for acrylonitrile (CAS No. 107-13-1) in the chemical limits for the WHO GDWQ, the ADWG or the DWSNZ for drinking water. The maximum level for vinyl chloride (CAS No. 75-01-4) in the WHO GDWQ, the ADWG and the DWSNZ is currently 0.0003 mg/L.

With respects to the current Application and the three highlighted chemicals in particular, FSANZ has amended the drafting to clarify any exceptions to 'All foods' in Standard 1.4.1 where there are specific chemical limits with the adoption of the WHO GDWQ in Standard 2.6.2.

9. Zero tolerance and MRLs (Standard 1.4.2)

As part of its submission, the Victorian Department of Health noted that that FSANZ had proposed to exclude 'packaged water' from the application of Standard 1.4.2. This Australia-only Standard sets out the Maximum Residue Levels (MRL) for various agricultural and veterinary chemicals in various food commodities. The submission noted that Standard 1.4.2 currently creates a zero tolerance (none detectable) of any agricultural or veterinary chemical (agvet chemical) in packaged water, whether or not that chemical is listed in the standard.

The submission noted that zero tolerance is a significant policy issue currently under consideration by FSANZ and the jurisdictions. The Victorian Department of Health has noted the proposed approach by FSANZ to adopt a process whereby detections of low levels of chemicals without MRLs are dealt with on a case-by-case basis, under the general requirements of the Food Act to sell safe and suitable food. FSANZ noted that this process is still consistent with a zero tolerance perspective.

The Victorian Department of Health in its submission noted its preference for an approach where this process applies to residues of chemicals that are listed in Standard 1.4.2, but which are detected in foods that do not have an MRL 'permission'. Chemicals not listed (and which do not have Codex/other international recognised MRLs) should continue to have no detectable residues (zero tolerance). The proposal to exclude packaged water from the current requirements of Standard 1.4.2 appeared to be pre-empting the broader consideration of the zero tolerance issue.

In proposing the variation to Standard 1.4.2 for packaged water FSANZ did not consider this to be pre-empting the broader consideration of the zero tolerance issue but was inserted to remove ambiguity which might arise from an ML in Standard 2.6.2 for certain agvet chemicals whilst they did not have an MRL in Standard 1.4.2 for packaged water. FSANZ highlighted the fact that agvet chemicals are not used in the production of the commodity, known as packaged water, and thus it was not appropriate to classify the chemical limits from the WHO GDWQ as residues.

However, to ensure that agvet chemicals other than those with MLs in the WHO GDWQ should not be present in packaged water, FSANZ has amended its drafting and removed the explicit exclusion applied to packaged water in Standard 1.4.2.

10. Vertical versus horizontal standards

FSANZ acknowledged that the inclusion of compositional parameters for packaged water in Standard 2.6.2, may have the appearance of providing a commodity only or 'vertical' standard for packaged water. However, the current Application only sought to make a variation to the chemical limits in Standard 2.6.2, and did not attempt to introduce a commodity-only standard for packaged water such as the *Codex Standard for Natural Mineral Waters* (CODEX STAN 108-1981) or the *Codex Standard for Bottled/Packaged Waters (other than natural mineral waters)* (CODEX STAN 227-2001). Moreover, the adoption of the chemical limits from the WHO GDWQ into Standard 2.6.2 was limited to the chemicals of health significance (i.e. Table A3.3, WHO GDWQ) and not to any other part of the WHO GDWQ e.g. microbiological limits. In addition, provisions relating to other aspects of packaged water are also contained in other standards, e.g. Standards 1.3.3 and 1.4.1. Given that there was an existing list of chemical limits (n = 17) in Standard 2.6.2, FSANZ considered the expansion of the list to be the most appropriate regulatory measure.

It was noted that Standard 1.4.2 that lists various agricultural and veterinary chemical limits in food, is only applicable to Australia. Thus, this standard is not appropriate for defining contaminants in a product covered by a joint Australian and New Zealand standard. Furthermore, this standard is also not applicable to packaged water, as these agricultural & veterinary chemicals are not used in the production of packaged water and as such, are not 'residues' from production.

11. Guidance on what chemicals have not been permitted in Australia

Guidance had been sought in one submission on what chemicals would not be expected to be found in Australian sources of bottled water and so could be excluded from routine tests.

The adoption of the chemical limits from the WHO GDWQ provides an internationally recognised standard for drinking water for packaged water in both Australia and New Zealand. The use of another drinking water standard or set of guidelines was considered as part of the assessment of this Application, but was not supported (See SD2). Importantly, packaged water imported into Australia and New Zealand would also require compliance with the new chemical limits under Standard 2.6.2. Thus, guidance on what chemicals have not been permitted in Australia would not be useful in this situation.

In developing a monitoring plan for the systematic sampling and testing of packaged water, the Applicant provided a testing regimen that may assist in the risk management of chemicals in packaged water. Industry members and government agencies would be free to develop their own monitoring plans consistent with the risk of chemicals present in the source water for the packaged water product. This risk stratification will influence the number and frequency of sampling and testing, and subsequent reporting and management of exceedances. Similar risk management approaches are already evident in domestic potable water management plans in Australia and New Zealand, e.g. *Draft Guidelines for Drinking-water Quality Management for New Zealand* (2005). These plans may provide guidance on a suitable testing regimen for domestically produced packaged water.

12. Contaminants from coal seam and shale gas fracking processes

The recommendation to include chemical contaminants that may be present in contaminated ground water as a result of coal seam and shale gas fracking processes, was considered outside the scope of this Application.