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

Supporting document 1

Consideration of various regulatory and non-regulatory measures for the control of chemicals in packaged water (at Approval) – Application A1043

World Health Organization Limits for Packaged Water

Executive summary

There were two regulatory options available to FSANZ with respect to this Application.

Option 1 considered the merits of replacing the current chemical specifications in Standard 2.6.2 with the chemical limits stipulated in the World Health Organization Guidelines for Drinking-water Quality (2011).

Option 2 considered the merits of rejecting the Application and maintaining the status quo. The latter is a combination of a regulatory chemical specification for 17 chemical substances in Standard 2.6.2 of the Code, together with a non-regulatory, industry Code of Practice.

FSANZ's analysis concluded that the preferred approach was to adopt Option 1, i.e. to replace the current Table to clause 2 of Standard 2.6.2 with a reference to the WHO GDWQ. A single exception would be made to adopting the WHO GDWQ as a whole. This would entail limiting total fluoride (naturally occurring and added) to 1.0 mg/L. This exception would be consistent with FSANZ's previous consideration under Application A588.

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1. Options considered

The following two regulatory options were considered as part of this Application during the approval stage of the assessment process.

Option 1: To 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 and to limit the use of fluoride to 1.0 mg/L.

Option 2: Reject the Application and maintain the *status quo.*

The costs and benefits of these options were considered from various perspectives, such as the protection of the health and safety of consumers, monetary and regulatory impacts, reputational outcomes and market access. Details regarding these two options are given in this document.

The preferred option was Option 1.

A third option was considered as part the assessment process at the Call for Submissions stage. The three options were addressed in detail in the Call for Submissions Supporting Document 1. The Call for Submissions related documents, also included consideration of an additional exception to accepting the WHO GDWQ[1] or other drinking water standard/guidelines. This additional exception sought to raise the styrene maximum level from 0.02 mg/L as per the WHO GDWQ to 0.03 mg/L as per Standard 1.3.3 (Table to clause 11). Following the Call for Submissions, the initial recommended changes to the styrene maximum level were subsequently withdrawn. Details regarding the evidence base for this decision are given in Appendix 1 of the Approval Report.

2. Option 1

To 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 and to limit the use of fluoride to 1.0 mg/L.

2.1 The WHO Guidelines for Drinking Water Quality

The Applicant has sought the adoption of the WHO GDWQ as the basis for regulatory control in the Code for chemical limits for packaged water.

The WHO GDWQ note that:

> "The primary purpose of the Guidelines for drinking water quality is the protection of public health. The Guidelines provide the recommendations of the World Health Organization (WHO) for managing the risk from hazards that may compromise the safety

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

of drinking water."

The WHO GDWQ provide an extensive risk analysis of various microbiological, physical and chemical contaminants for drinking water. The WHO GDWQ have recently been updated (2011) and provide the most up to date scientific basis for maximum levels of substances in drinking water. The guideline values represent an extensive risk assessment, negating the need for FSANZ to undertake its own analysis of each of the chemical substances listed in Table A3.3 of the WHO GDWQ.

2.2 The use of the WHO GDWQ

The WHO GDWQ values in Table A3.3 for chemical substances also provide the basis for the Codex *Standard for Bottled/Packaged Waters (other than natural mineral waters)* (CODEX STAN 227-2001). Furthermore, the Australian Drinking Water Guidelines (2011) published by the NHMRC and the Drinking-water Standards for New Zealand (2005, revised 2008) published by the New Zealand Ministry of Health, use the WHO GDWQ as the basis of their potable water specifications as described below.

"The Australian Drinking Water Guidelines were last released in in October 2011 by the National Health and Medical Research Council based on information from the WHO standards for use by the Australian community and all agencies with responsibilities associated with the supply of drinking water, including catchment and water resource managers, drinking water suppliers, water regulators and health authorities in Australia."

"The *Drinking-water Standards for New Zealand 2005* were the result of a consensus among members of the Expert Committee on Drinking-water Quality set up to advise the Ministry of Health (Ministry of Health 2005a). Following submissions from water suppliers, section 10 (small supplies) was significantly rewritten for this edition and other sections were clarified as required. The opportunity was also taken to update the maximum acceptable value (MAV) tables based on the latest World Health Organization (WHO) information.

In the preparation of the Drinking-water Standards for New Zealand, extensive use was made of:

- *Guidelines for Drinking-water Quality 2004* (WHO guidelines) (WHO 2004)
- *Drinking-water Standards for New Zealand* 1984, 1995, 2000 and 2005 (Ministry of Health 1984, 1995, 2000, 2005a respectively)
- *National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule: Final Rule* (USEPA 2006a). "

2.3 Comparison to the Code

The WHO GDWQ contain a list of 90 chemicals of concern to the safety of drinking water for human consumption. In comparison, the Table to subclause 2(2) of Standard 2.6.2 contains 17 analytes (including 'organic matter'). For a comparison of all the chemicals and the respective limits, see SD2. Of the chemicals listed in the Table to subclause 2(2), adoption of the WHO GDWQ would result in lower limits for arsenic, barium, boron, cadmium, fluoride and lead; and an increase in limits for chromium, copper, mercury, nitrate, nitrite and selenium. Since these higher values are based on the expert review by WHO they are considered to be protective of human health. The WHO GDWQ do not provide a limit for 'organic matter' or sulphide, and has removed limits for cyanide, manganese and zinc. The latter are not considered to be a health concern by the WHO at levels typically found in drinking water.

The Table to clause 11 of Standard 1.3.3 contains a list of chemical substances, which are permitted for use as processing aids in packaged water and water used as an ingredient. Several of these chemical substances are listed in the WHO GDWQ e.g. chlorine, copper, epichlorohydrin, fluoride, acrylamide, nitrate, styrene and EDTA. Of these substances, only a few are listed with a higher maximum permitted level in Standard 1.3.3 compared to the WHO GDWQ, e.g. fluoride (1.5 mg/kg vs 1.0 mg/L (FSANZ recommendation)) and styrene (0.03 mg/kg vs 0.02 mg/L). Moreover, a number of the chemical substances may be used at GMP that theoretically could result in higher levels of use than that indicated by the WHO GDWQ. However, the expectation is that usage following GMP will not conflict with the numerical maximum levels in the WHO GDWQ and is likely to be lower. Epichlorohydrin, for example, is a component of many ion exchange resins, including carboxymethyl cellulose ion exchange resin, quaternary amine cellulose ion exchange resin, diethyl aminoethyl cellulose ion exchange resin and agarose ion exchange resin which have specifications in Standard 1.3.4 and the Table to clause 8 of Standard 1.3.3. The resins, in general, are likely to use the specifications found in 21 CFR § 173.25[2] – which includes diethylenetriamine, triethylene-tetramine, or tetraethylenepentamine cross-linked with epichlorohydrin. These specifications have requirements for maximum levels of extracted organics, plus requirements for specified conditions of use.

2.4 Costs associated with compliance and testing under the WHO GDWQ

Testing under the ABWI Model Code is a costly process. Currently the Model Code specifies limits for 49 chemical substances. If the WHO GDWQ were adopted, a total of 90 chemical substances would require testing. Furthermore, a number of chemical substances that are currently tested under the ABWI Model Code will require compliance and testing to lower limits. SD2 outlines the various chemical substances and limits that would be required if the WHO GDWQ were adopted, compared to the current Model Code and the Table to subclause 2(2) of Standard 2.6.2 of the Code.

The Applicant has indicated the following testing regimen and associated costs over a twelve year period could be adopted by industry with ABWI support (Table 1). The Applicant has recommended that all the chemical analytes listed in the WHO GDWQ should be assessed every four years after two years compliance has been demonstrated. There would be an annual cost of $7200 for this. The testing frequency for inorganic chemicals would continue annually at a cost of $800pa.

[2] The Code of Federal Regulations, USA.

Table 1: ABWI sampling plan and cost estimate per water source for the proposed WHO GDWQ analyses

Year	Cost (AUD)
1	$7200
2	$7200
3	$800
4	$800
5	$800
6	$7200
7	$800
8	$800
9	$800
10	$7200
11	$800
12	$800

These costs would be carried by the bottler for each water supply/site. The Applicant has indicated that there could be a minimal cost passed to consumers. The testing regime could however be varied by different suppliers, including those who export to Australia and New Zealand. These costs therefore are indicative, but provide sufficient information to show the cost of analysis of the total analytes which would be covered by the proposed changes to the Code.

While the WHO GDWQ are a scientifically credible set of values for chemical substances, it should be remembered that they have been prepared not for bottled water but for drinking water delivered by the potable, municipal water supply. It is questionable whether all the chemical substances identified in the WHO GDWQ are relevant for: (i) packaged water *per se*, or (ii) the Australian and New Zealand environment in particular.

Firstly, a number of chemicals used in the treatment of potable water may not be used for water derived from natural mineral springs where there is limited or no treatment required. Secondly, a number of industrial chemicals or pesticides may not be in use or have never been used in either country. Thus, there would be a disproportionate cost impost from adopting the WHO GDWQ on domestic packaged water suppliers/bottlers to test for chemicals that are not of a health and safety consequence for domestic (Australia and New Zealand) consumers.

Considering the overall cost of testing for the extra chemical substances that are listed in the WHO GDWQ, it is possible that a number of packaged water suppliers/bottlers will find the cost of testing to be an unacceptable burden on business with little to suggest improved domestic market access. From a compliance perspective, enforcement agencies will also face an increase in water testing for packaged water, where before the selection of chemicals was limited under the Code.

Nonetheless, there were no submissions from the packaged water industry (regional or imported) to suggest that the burden on business was an unacceptable consequence of adopting the WHO GDWQ. Concerns raised by enforcement agencies about the effect on small business or products currently in the market, were not echoed by industry. Further comment in response to these and other concerns raised in the submissions was prepared and made available in Appendix 1 of the Approval Report.

2.5 Industry support for the adoption of the WHO GDWQ

The adoption of the WHO GDWQ is sought by the industry for several reasons. It would support Hazard Analysis and Critical Control Points (HACCP) requirements and prevent confusion on safety issues for bottled water compared to potable water.

It is arguable that such an action would promote fair trading in food by having a uniform, comprehensive safety standard for packaged water. Currently, consumers would be unaware of the differences between various packaged water products in Australia and New Zealand with respect to the level of scrutiny applied to chemical analyses in their water. The Applicant has noted that:

> "Consumers both local and overseas are becoming increasingly conscious of the impact of chemical residues in food and beverages. As a premium beverage, a high level of purity is an expectation of consumers. Having a testing regime which provides safety and confidence for consumers is necessary for today's discerning market."

The Applicant has also highlighted the value to Australian and New Zealand packaged water for export which would accrue from the adoption of the WHO GDWQ:

> "Australian manufacturers of bottled water export to the USA and Asia including Singapore, Hong Kong, United Arab Emirates, India, China and Japan.
>
> Members of the International Council of Bottled Water Associations (ICBWA) in these countries regard Codex and WHO Drinking water Guidelines as a safety guideline for bottled water production in addition to model codes for quality, for which the ABWI Code is based.
>
> Requirements for import into these countries are equivalent to the Australian requirement, this being importer ensures the product meets local requirements for physical, chemical and microbiological criteria which are most often based on the WHO Drinking Water Guidelines."

These remarks suggest that the adoption of the WHO GDWQ as a regulatory measure in Australia and New Zealand would be concordant with the promotion of consistency between domestic and international food standards; and the desirability of an efficient and internationally competitive food industry.

Advice from the Applicant indicates that its members, representing 80% of the Australian and 27% of the New Zealand markets, are supportive of the adoption of the chemical limits from the WHO Guidelines as a regulatory measure. The Applicant also indicated that it has the support of the Chair of the New Zealand Juice and Beverage Association (NZJBA) Technical Committee for this Application. The NZJBA members represent over 95% of all juices and beverages sold at a retail level in New Zealand[3].

[3] NZJBA, http://www.nzjba.org.nz/ (accessed 10 April 2012).

2.6 Importation of packaged water

This option is unlikely to have any significant adverse impacts on the bottled/packaged water imported into either Australia or New Zealand. FSANZ considered that the universality of the WHO GDWQ to drinking water guidelines around the world ensures that most bottled/packaged water would meet the safety limits for chemicals in the GDWQ. FSANZ noted that from a collation of over twelve hundred packaged water products produced in different parts of the world only a few have been reported to exceed the level of 1.0 mg/L for fluoride (See discussion in SD3). A small ad hoc survey of bottled/packaged water imported into Australia and New Zealand revealed that all eight brands identified in supermarkets had levels of fluoride below 1.0 mg/L.

No objections to the adoption of the new chemical limits from the WHO GDWQ into Standard 2.6.2 were received during either the pubic consultation period or the WTO notification period. FSANZ did not receive any comments from packaged water producers, bottlers, marketers or importers during targeted discussions to suggest that the new chemical limits would unduly affect the supply/sale of imported or domestically bottled/packaged water. Advice from the Food and Beverage Importers Association (FBIA) (Australia) also indicated that no objections have been raised from its members with respect to the new chemical limits. This organisation represents about 50% of the major importers of bottled/packaged water in Australia. Most of the bottled/packaged water imported into Australia is from Italy and France based on the value of the imported product. The FBIA indicated that most of the bottled water producers would be members of a bottled water association that would require compliance with safety and quality parameters. In Europe, this is the European Federation of Bottled Waters (EFBW), which is the regional representative of the International Council of Bottled Water Associations (ICBWA). ICBWA members are required to meet Codex Alimentarius Commission, national, regional, and industry standards for bottled water. Another condition of bottler membership within each Member Association is they must pass an annual water analysis administered by an independent laboratory covering more than 150 possible compounds. FSANZ considers that this evidence and support from the FBIA indicates that adverse effects on the majority of imported bottled water is unlikely from the imposition of the proposed limit for fluoride, or for the adoption of the WHO GDWQ. The maximum level for fluoride in bottled/packaged water proposed by FSANZ is also consistent with other international regulators.

2.7 Fluoride concentration in packaged water

In considering this option, FSANZ is of the opinion that the total concentration of fluoride should be limited to 1.0 mg/L in packaged water. This conclusion is based upon FSANZ's risk assessment for fluoride that was conducted as part of its consideration of Application A588 – *Voluntary Addition of Fluoride to Packaged Water*. The justification for this position is detailed in SD3.

2.8 Use of styrene as a processing aid in packaged water

Standard 1.3.3 (Processing aids) of the Code contains permission for a variety of processing aids for use in packaged water and water used as an ingredient in other foods (Table to clause 11, Standard 1.3.3.). The maximum permitted level for styrene is 0.03 mg/kg as a processing aid. Previous consideration by FSANZ (A1043, Call for Submissions document) had recommended that the maximum level for styrene be raised from 0.02 mg/L (as in the WHO guidelines) to 0.03 mg/L (as in Table 11 to clause 11, Standard 1.3.3) for packaged water. This higher limit was initially justified on the basis that the limit for styrene in the Code for packaged water had already been established by a prior risk assessment.

However, after consideration of the submissions received during the assessment of this Application, and an investigation for the basis of the maximum permitted level in Standard 1.3.3 (Table to clause 11), FSANZ reversed its initial recommendation and instead has reduced the limit for styrene in Standard 1.3.3 from 0.03 mg/kg to 0.02 mg/kg, to be equivalent to the WHO GDWQ limit for styrene at 0.02 mg/L.

2.9 Summary of Option 1

The adoption of this option would fulfil a number of secondary objectives of the FSANZ Act in addition to the primary objective of protecting public health and safety. The WHO GDWQ represent a credible risk analysis that has been based on contemporary scientific data by experts to ensure the safety of drinking water. The WHO GDWQ are the basis for chemical limits in the *Codex Standard for Bottled/Packaged Waters*, and as the basis for chemical limits in both 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 a single exception that the total fluoride content of packaged water would be limited to 1.0 mg/L based on FSANZ's own risk assessment. The adoption of the WHO GDWQ 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.

3. Option 2

Reject the Application and maintain the *status quo.*

3.1 Consideration of regulatory failure

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in subsection 18(1) of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

It was difficult to prove conclusively that there were any regulatory problems with the current Standard 2.6.2. The Applicant was not able to demonstrate that packaged water in Australia and New Zealand was failing to meet the substance limits set out in the Table to subclause 2(2) of Standard 2.6.2 or that the current specifications were not protective of human health. Furthermore, there was no information to suggest that consumers were unable to make informed choices or that there was misleading or deceptive conduct. Thus in the absence of regulatory failure, there was no proof that there is currently a risk to public health and safety. Nonetheless, it was questionable whether any epidemiological analysis would be powerful enough to identify a chemical in packaged water as a causative agent for an adverse health effect and therefore provide evidence that the current limits are inadequate. This is because the limits for the chemicals listed in the Table to subclause 2(2) and the WHO GDWQ generally refer to long-term exposure, i.e. whole-of-life, and attribution of such adverse effects to dietary intake of food/water consumed by the whole population is unlikely.

3.2 The safety of packaged water

Consumers are protected by the limits prescribed in Standard 2.6.2 and other standards within the Code that control for physical, chemical and microbiological contaminants. Additionally there is relevant Australian state and territory and New Zealand food safety legislation (Food Acts) to ensure that food in general is safe and fit for consumption.

However, 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 was questionable. In contrast, there have been comprehensive revisions of drinking water standards by the WHO (2011), the National Health and Medical Research Council (NHMRC, 2011) and the New Zealand Ministry of Health (NZMOH, 2005). SD2 tabulates the various chemicals and their respective limits for the WHO, NHMRC and NZMOH, and illustrates the scope of the chemicals considered to pose a risk to human health and safety through the consumption of drinking water.

Consequently, the Table to subclause 2(2) has become discordant with respect to the type/variety of chemical substances that may pose a risk to public health and safety, and the maximum levels that should not be exceeded in potable drinking water for human consumption. The Applicant has noted:

> "Since the last revision to [the] Food Standards Code section 2.6.2 subclause 2, limits for chemical, physical and microbiological criteria for bottled water have been re-evaluated both nationally and globally by regulatory authorities. Changes that have occurred are detailed in two revisions to both the WHO Drinking Water Guidelines (WHO DWG) and the Australian Drinking Water Guidelines (Australian Drinking Water Guidelines).
>
> Increasing demands of consumers upon manufacturers to produce a product that is safe and of the highest standard requires adherence to these latest guidelines from both local and imported bottled water sources."

3.3 Consideration by Codex

The current Table to subclause 2(2) had its genesis with the CODEX Standard for Natural Mineral Waters (see SD2 for list of chemicals and limits). However, the Code does not differentiate chemicals or their respective limits based on whether they are derived from natural mineral waters or other sources e.g. artesian, bore or potable water. Standard 2.6.2 does not explicitly define 'packaged water'. On the other hand, the CODEX Standard for Bottled/Packaged Drinking Waters (other than natural mineral waters) (CODEX STAN 227-2001) defines packaged water as:

> Packaged waters, other than natural mineral waters, are waters for human consumption and may contain minerals, naturally occurring or intentionally added; may contain carbon dioxide, naturally occurring or intentionally added; but shall not contain sugars, sweeteners, flavouring or other foodstuffs.

Importantly, the Codex Standard for Bottled/Packaged Drinking Waters refers to the 'most recent "Guidelines for Drinking Water Quality" published by the World Health Organization' for its health-related limits for chemical and radiological substances.

3.4 The ABWI Model Code

The packaged water industry has established a voluntary ‘Model Code’ that members of the ABWI adhere to. This Model Code, effectively a Code of Practice, utilises a number of limits for various organic and inorganic substances for packaged water that have been based on the WHO GDWQ. This Model Code provides additional standards for chemical substances in packaged water for the industry that parallels or supplements Standard 2.6.2 in the Code.

3.5 Summary of Option 2

Overall, there was no explicit information to indicate a demonstrable regulatory failure for packaged water in terms of the three primary objectives of the FSANZ Act. However, the selection of chemicals and their respective limits listed in the Table to subclause 2(2), are now not in keeping with national and international standards/guidelines for drinking water safety and are not based on the best currently available evidence.