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.

Application A1043

World Health Organization Limits for Packaged Water

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# Executive summary

FSANZ has considered three regulatory options with respect to this Application. Option 1 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. Option 2 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 3 considered the merits of replacing the current chemical specifications with one of a number of alternative specifications associated with drinking water or packaged water for human consumption.

FSANZ's analysis concluded that the preferred approach was to adopt Option 2, i.e. to replace the current Table to clause 2 of Standard 2.6.2 with a reference to the WHO guidelines. Two exceptions would be made to adopting the WHO guidelines 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. The maximum level for styrene would be set at 0.03 mg/L so as to be consistent with the permitted use of styrene as a processing aid in packaged water (Table to clause 11, Standard 1.3.3).

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# 1. Options considered

The following three regulatory options were considered as part of this Application.

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

*Option 2:* 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, to limit the use of fluoride to 1.0 mg/L and to permit the use of styrene at a higher maximum level of 0.03 mg/L.

*Option 3:* 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 another authority, to limit the use of fluoride to 1.0 mg/L and to permit the use of styrene at a higher maximum level of 0.03 mg/L.

The costs and benefits of these options have been considered from various perspectives, such as the protection of the health and safety of consumers, monetary and regulatory impacts, reputational outcomes and market access.

# 2. Option 1

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

## 2.1 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 is difficult to prove conclusively that there are 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 is 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 guidelines[1]

[1] In this document, Annex 3 Chemical summary tables, Table A3.3 Guideline values for chemicals

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.

## 2.2 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 is 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."

## 2.3 Consideration by Codex

The current Table to subclause 2(2) has 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

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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 guidelines'.

recent “Guidelines for Drinking Water Quality” published by the World Health Organization’ for its health-related limits for chemical and radiological substances.

## 2.4 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 guidelines. 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.

## 2.5 Summary of Option 1

Overall, there is 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.

# 3. Option 2

**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, to limit the use of fluoride to 1.0 mg/L and to permit the use of styrene at a higher maximum level of 0.03 mg/L.**

## 3.1 The WHO Guidelines for Drinking Water Quality

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

The WHO guidelines 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 of drinking water.”

The WHO guidelines provide an extensive risk analysis of various microbiological, physical and chemical contaminants for drinking water. The WHO guidelines 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 guidelines.

## 3.2 The use of the WHO guidelines

The Guideline 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 Guidelines 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). "

## 3.3 Comparison to the Code

The WHO guidelines 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 guidelines 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 guidelines 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 guidelines 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 guidelines, 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 guidelines. However, the expectation is that usage following GMP will not conflict with the numerical maximum levels in the WHO guidelines 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.

## 3.4 Costs associated with compliance and testing under the WHO guidelines

Testing under the ABWI Model Code is a costly process. Currently the Model Code specifies limits for 49 chemical substances. If the WHO guidelines 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 guidelines 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 guidelines 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.

**Table 1: ABWI sampling plan and cost estimate per water source for the proposed WHO guidelines 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 guidelines 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 guidelines are relevant for: (i) packaged water

[2] The Code of Federal Regulations, USA.

*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 Guidelines 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 guidelines, 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.

## 3.5 Industry support for the adoption of the WHO guidelines

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

By having a uniform, comprehensive safety standard for packaged water, it is arguable that such an action would promote fair trading in food. 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 guidelines:

> "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 guidelines 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].

## 3.6 Importation of packaged water

This option impacts imported waters entering the Australian and New Zealand markets. A number of imported bottled waters that are derived from natural springs, bores or other earth-bearing sources may contain naturally high levels of dissolved salts, i.e. inorganic chemicals. These imported bottled waters may have had a long history of consumption in the country of origin and/or Australia and New Zealand. The possible consequence of adopting the WHO guidelines for packaged water, and in the absence of any specific exemption for spring water or alternative chemical limits in the Code, is the loss of those affected waters from the domestic market. Thus there may be a loss in consumer choice and/or the potential for creating a technical barrier to trade.

## 3.7 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.

## 3.8 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. To ensure that there is no discordance within the Code with respect to chemical limits in packaged water, FSANZ recommends 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 is justified on the basis that the limit for styrene in the Code for packaged water has already been established by a prior risk assessment.

## 3.9 Summary of Option 2

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 guidelines represent a credible risk analysis that has been based on contemporary scientific data by experts to ensure the safety of drinking water. The WHO guidelines 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 two exceptions. Firstly, that the total fluoride content of packaged water would be limited to 1.0 mg/L based on FSANZ's own risk assessment. Secondly, that the

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

limit for styrene be raised from 0.02 to 0.03 mg/L based on an existing limit for the use of styrene as a processing aid in packaged water in Standard 1.3.3 of the Code. The adoption of the WHO guidelines has industry support with claims that it would also support access to export markets. Cost estimates have been provided against a proposed testing regimen. The adoption of this option would provide regulatory certainty and consistency for Australian and New Zealand producers/bottlers and importers of packaged water.

# 4 Option 3

**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 another authority, to limit the use of fluoride to 1.0 mg/L and to permit the use of styrene at a higher maximum level of 0.03 mg/L.**

## 4.1 Other guidelines for drinking water

This option is based on the assumption that the current Table to subclause 2(2) is inadequate for all the same reasons considered in support of Option 2, but considers the merits of adopting limits for specific chemicals as outlined by other competent authorities with respect to drinking water. Any regulatory outcome should be based on a risk analysis using the best available scientific evidence. The alternative sets of chemical limits that have been considered in this option have been developed by Codex Alimentarius, the NHMRC (Australian Drinking Water Guidelines) and the NZMOH (Drinking-water Standards for New Zealand).

### 4.1.1 Codex Alimentarius

There are two Codex standards that may be more applicable to packaged water than the WHO guidelines: The *Codex Standard for Natural Mineral Waters* (CODEX STAN 108-1981) and the *Codex Standard for Bottled/Packaged Waters (other than natural mineral waters)* (CODEX STAN 227-2001).

The *Codex Standard for Natural Mineral Waters* could be considered an appropriate standard for adoption into the Code, as it relates to chemical constituents/contaminants in packaged/bottled water that has traditionally been prepared from a natural water source, such as a spring or artesian waters. Limits are given for inorganic chemicals only (16 analytes). SD2 lists the various chemicals and their respective limits for the *Codex Standard for Natural Mineral Waters*. The table to subclause 2(2) of Standard 2.6.2 was originally based on the Codex list of chemical substances and limits, and represents safety consideration for inorganic contaminants.

If this option was adopted, there would be little or no impact on domestic or imported packaged waters compared with Option 1, with lower costs for industry and regulatory/enforcement agencies than for Option 2. Domestic suppliers/bottlers would continue to be free to use the ABWI Model Code to enable claims relating to adherence to international levels for their products. Consumers would continue to be safeguarded by the protection afforded by voluntary use of an international standard by many packaged water suppliers.

However, the *Codex Standard for Natural Mineral Water* was specifically established for naturally occurring spring water. Packaged water in Australia and New Zealand is not only derived from spring water, but may also include water derived from other sources including

potable/municipal sources. Therefore, if a Codex standard was being considered for packaged water, the most appropriate standard for Australia and New Zealand would be the *Codex Standard for Bottled/Packaged Waters*. The latter document references the WHO guidelines in its chemical limits. Hence if the latter Codex standard was adopted instead, this would result effectively in adopting the WHO guidelines.

### 4.1.2 Australian and New Zealand Drinking Water Guidelines

The NHMRC Australian Drinking Water Guidelines (2011) contains an extensive list of 212 organic and inorganic chemical substances. The NZMOH Drinking-water Standards for New Zealand (2005, revised 2008) also contains an extensive list of 140 organic and inorganic chemical substances. One hundred of the chemicals in the NZDWS are also found in the Australian Drinking Water Guidelines. The Drinking-water Standards for New Zealand and the Australian Drinking Water Guidelines also note limits for radioactive constituents.

In contrast to the WHO guidelines, the lists of contaminants in the Australian and New Zealand guidelines/standards account for those contaminants that are *realistically* expected to affect water supplies in these particular countries. By utilising the same guidelines/standards in each country respectively, there would be concordance for chemical analyses for all water used for human consumption, i.e. potable and packaged. This would remove the regulatory inconsistency for packaged water, where compliance testing for chemical contaminants is much less comprehensive than for potable water. This would ensure a consistent application of health and safety standards for all drinking water for the benefit of consumers and industry.

From a compliance perspective, testing facilities and test methods for the chemical substances in each guideline/standard have already been established. This option would bring all water suppliers (potable and packaged) under the same testing regimens of each particular jurisdiction. Moreover, compliance testing costs for enforcement agencies would therefore not be considered too onerous in regards packaged water.

Of the 90 chemicals in the WHO guidelines, 21 chemicals are not listed in the Australian Drinking Water Guidelines and 4 chemicals are not listed in the Drinking-water Standards for New Zealand. The values for the various limits in both sets of guidelines/standards are not completely consistent with the WHO guidelines, but this reflects slight differences in the calculation of risk based on human body weight. The WHO guidelines use an adult reference body weight of 60 kg, whereas both the NHMRC and NZMOH use an adult reference body weight of 70 kg. This difference may affect the reference limit by up to 17%. Nonetheless, the toxicological basis from which the limit is derived e.g. animal-based NOAEL[4], is consistent with the WHO guidelines where applicable.

However, the adoption of the country-specific potable water guidelines/standards for packaged water in Standard 2.6.2 would be problematic and raises a number of issues.

Foremost, such an option would be inconsistent with the Trans-Tasman treaty (*Trans-Tasman Mutual Recognition Act 1997*). Having different standards for each country is not desirable and could affect trade between both countries without a credible, scientific basis regarding safety. Furthermore, having different standards will pose issues for industry and regulatory agencies where the same chemical substance has a different limit or is not included in each other's guideline/standard (as noted above).

It is important to bear in mind, that there is no evidence to suggest that consumers of

[4] No Observed Adverse Effect Level (NOAEL)

packaged water in Australia or New Zealand are currently exposed to unsafe drinking water, in the absence of the adoption of either guideline/standard.

From an export market perspective, it is unknown whether the adoption of either potable water guideline/standard would facilitate industry accessing foreign markets even if both are based on WHO guidelines values. On the other hand, the Applicant has indicated that adoption of the WHO guidelines for domestic production would "provide guidelines for the changing chemical criteria for best practice of production of bottled water".

Compliance costs for the packaged water industry could be considerable even if packaged water suppliers are already testing against the ABWI Model Code or obtaining test results from potable water suppliers if that is the relevant source. For industry members currently testing compliance to the Code only, the increase in compliance testing may be too onerous to ensure business survivability. It is questionable whether consumers would derive any further benefit, i.e. safety, from packaged water suppliers testing to 212 (Australian Drinking Water Guidelines) or 140 (Drinking-water Standards for New Zealand) compared to 90 (WHO guidelines) chemical analytes.

For imported packaged/bottled water, compliance testing against either guideline/standard may also be too onerous and financially unviable to supply either market. Thus, in a similar criticism to that made for Option 2, the potential consequence of adopting these guidelines/standards for packaged water could result in the loss of those affected waters from the domestic market. Moreover there may be a loss in consumer choice and/or the potential for creating a technical barrier to trade. The latter would be more so than for Option 2, because they are a set of highly regionally specific guidelines/standards without any significant benefit over either the Codex Standard or the WHO guidelines.

## 4.2 Consideration of limits for fluoride and styrene

In considering this option, FSANZ is also of the opinion that the total concentration of fluoride should be limited to 1.0 mg/L. 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. Furthermore, FSANZ recommends that the maximum level for styrene be raised from 0.02 mg/L to 0.03 mg/L for packaged water. This higher limit of 0.03 mg/L is equivalent to the current maximum permitted level for styrene as a processing aid for use in packaged water in the Table to clause 11 of Standard 1.3.3.

## 4.3 Summary of Option 3

Various sets of chemical limits have been developed for drinking water i.e. the Codex *Standard for Natural Mineral Waters*, the Codex *Standard for Bottled/Packaged Waters*, the Australian Drinking Water Guidelines and the Drinking-water Standards for New Zealand. For the purposes of regulating packaged water in Australia and New Zealand, the Codex *Standard for Bottled/Packaged Waters* would appear to be the most appropriate, international standard. However, the basis for the chemical limits in this standard is actually the WHO guidelines. Furthermore, the WHO guidelines have also been used in the development of the Australian and New Zealand guideline/standard for potable drinking water. The adoption of regionally specific guidelines/standards for packaged water that parallel those used for potable water, would appear to have merit from the perspective of reducing the current discordance for chemical limits in packaged and potable water. Nonetheless, adoption of the Australian Drinking Water Guidelines and Drinking-water Standards for New Zealand into Standard 2.6.2 would be problematic from a regulatory perspective and would be inconsistent with the intent of the FSANZ Act and the Trans-

Tasman treaty. FSANZ does not recommend this option for the adoption of either the Australian Drinking Water Guidelines or the Drinking-water Standards for New Zealand into Standard 2.6.2.

FSANZ does not consider adoption of a separate set of chemical limits for Natural Mineral Waters is needed as the WHO guidelines are protective of human health. The Codex *Standard for Natural Mineral Waters* has lower values for some analytes, but these may reflect quality parameters which are not an appropriate consideration for inclusion in the Code. Only in the case of boron are there higher limits in the standard for Mineral Waters and this probably reflects an older WHO risk assessment. Therefore packaged Natural Mineral Waters are adequately covered by the proposed approach to adopt the WHO guidelines and manufacturers of these products should not be adversely impacted.