Comments from the Victorian Department of Health.

13 September 2012

The Victorian Department of Health (DH) welcomes the opportunity to provide comments on Application A1043 – World Health Organisation Limits for Packaged Water.

It appears that the proposal to adopt option 2 is to achieve three important goals:

- Ensure that that the range of chemicals to be tested for and their limits is commensurate with best current available evidence;
- That certainty for industry is provided and confusion about safety issues for bottled water compared to potable water is prevented; and
- Promotion of consistency for domestic and international packaged water markets.

However, a review of the assessment report and its supporting documents has raised a series of concerns about the proposal to adopt option 2 and, if the Application progresses, the drafting of the variation to the Standard.

DH understands that the Table to subclause 2(2) of Standard 2.6.2 has not been subject to review since the Food Standards Code was published in December 2000 and that therefore it now may not be in keeping with best current available evidence. However, DH is concerned about the proposal to adopt option 2. That concern stems from the context of there being no evidence to suggest that there has been regulatory failure to date with respect to the application of Standard 2.6.2. This appears incommensurate with the potential burden that will be imposed on parts of the bottled water industry of the Application progresses.

It is understood that the industry currently applies the 'Model Code' which provides additional standards for chemical substances that parallels or supplements Standard 2.6.2 in the Code. It is also understood that that application sees industry participants undertake a risk assessment to determine which hazards and risks may be present and then the chemical monitoring program is tailored accordingly. By adopting a broader range of chemicals which have to be compulsorily tested for or complied with, the likely effect is the imposition of an unnecessary cost burden on small suppliers. This is especially of concern if there is not the ability to tailor the testing program according to an appropriate risk assessment. The FSANZ assessment recognises this impost and that there would be little evidence that a wider testing regime is likely to improve domestic market access. The assessment also questions whether all of the chemical substances identified in the WHO guidelines are relevant for packaged water as well as for the Australian or New Zealand setting.

Further on the issue of cost impact on the industry, FSANZ has relied upon the costings and testing frequency advice provided by the Applicant. While it is acknowledged that FSANZ has accepted that those costings are indicative, there does not appear to be any critical appraisal how those costs have been arrived at nor of the testing regime proposed. In terms of the latter, some commentary is needed about whether the proposed testing regime is reflective of current industry practice and how the introduction of a broader suite of chemicals that must be tested for is likely to impact on all parts of the industry.

It is noted that the Applicant has indicated that there would be a minimal cost passed on to consumers but there does not appear to be any further assessment by FSANZ of the quantum of those costs nor whether those cost increases could be mitigated through appropriate variations to the testing regime. In addition, FSANZ has indicated that from a compliance perspective, enforcement agencies will face an increase in water testing for packaged water but there is no assessment of the likely costs that such agencies will incur.

Before offering some specific technical and drafting comments, DH suggests that FSANZ considers undertaking a more detailed cost benefit analysis with a particular focus on the impact that the effect of the proposed change will have on smaller manufacturers.

Finally, set out below are comments that are of a technical/drafting nature:

(i) Proposal to exclude packaged water from the application of Standard 1.4.2 – MRLs

- In supporting document 1, under 3.3 Comparison with the Code, FSANZ discusses Standards 2.6.2, 1.3.3, and 1.3.4, but is silent on 1.4.2 (and 1.4.1 – see below). Standard 1.4.2 (Australia only – not applicable to product imported from New Zealand) 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.
- Zero tolerance is a significant policy issue currently under consideration by FSANZ and the jurisdictions. DH has already raised concerns about the approach proposed by FSANZ to adopt a default 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.
- DH prefers an approach where this default 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 internationally recognised MRLs) should continue to have a not detectable (zero tolerance) requirement.
- The proposal to exclude packaged water from the current requirements of Standard 1.4.2 appears to be pre-empting the broader consideration of the zero tolerance issue.
- DH appreciates the challenge of drafting an amendment that creates MRLs for agvet chemicals outside the application of Standard 1.4.2, and which moves from an 'Australia only' standard to a Chapter 2, bi-national standard. Should FSANZ require assistance in addressing this issue, DH would be happy to provide that assistance.
- The assessment report implies that businesses will face more onerous testing if the WHO guidelines are adopted and if Standard 1.4.2 no longer applies. It could be argued that the reverse is true as packaged water must currently have no detectable residues of any agvet chemical.

(ii) Standard 1.4.1 – Contaminants and Natural Toxicants

- Standard 1.4.1 includes three listings for 'All Foods' against acrylonitrile, pulegone and vinyl chloride. Vinyl chloride has a maximum level of 0.01 mg/kg, compared with 0.0003 mg/L in the WHO guidelines. This is 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, DH suggests that FSANZ investigates this issue further both in terms of Standard 1.4.1 and Standard 2.6.2.

(iv) Drafting

- The proposed drafting states "Water presented in packaged form must not contain a chemical listed in Table A3.3…, unless the level of the chemical is equal to or less than the guideline value for the chemical specified in that Table". This wording is ambiguous. That is, if the packaged water contains more than the guideline value, it must not contain any of that chemical. This approach varies from other standards where maximum levels for substances are specified. DH recommends that the wording be amended to: "Water presented in packaged form must not contain a chemical listed in Table A3.3…, at a level greater than the guideline value for the chemical specified in that Table".

- DH recommends FSANZ consider amending the Standard 1.4.1 requirement to 'All foods except packaged water'.
- The proposed standard raises issues for consideration under the 'Code Audit' project:
  - Moving elements of Standards 1.4.1. and 1.4.2. into a Chapter 2 Standard gives the appearance of a stand alone or 'vertical' standard. This can create confusion in a Code that is predominantly 'horizontal' in its approach. For example, packaged water has a microbiological standard under Standard 1.6.1. The issue of when and where cross referencing is appropriate must be considered.
  - FSANZ should take this opportunity to review all references to packaged water in the Code and associated guidance material to ensure consistency.