




Australian Government
Department of Health
Therapeutic Goods Administration



By email: 

Our Reference: R13/844848

Dear 

Subject: Your letter dated 17 September 2013 regarding alleged non-compliance with the *Therapeutic Goods Act 1989* with regard to the fluoridation of water

Thank you for your letter of 17 September 2013, which was a response to my letter of 3 September 2013. I apologise for the delay in responding to you. I am also responding to your email to the Queensland Minister of Health who has referred your emails to the TGA for response.

I thank you for correcting the record for us on the correspondence you have had with the former Minister for Health and Ageing, the former Parliamentary Secretary for Health and Ageing, the TGA and the Complaints Resolution Panel.

In your most recent letter and previous correspondence, you have shared a view that there has been a non-compliance with the *Therapeutic Goods Act 1989* in the act of fluoridating water supplies in Australia.

With respect to whether state water authorities are in breach of the therapeutic goods legislation, I can advise you that it has always been the TGA's position that fluoride used for the fluoridation of water and fluoridated water are not therapeutic goods, regardless of the claims that might be made about the fluoridated water by state and territory governments or water authorities. It has also always been the TGA's position that the regulation of fluoride in drinking water is a matter for the states and territories, as it was at the time the Act was enacted.

This remains the TGA's position. As such, there is no non-compliance on which the TGA could or would take action.

However, I recognise that we have provided conflicting information to you in the past, which may have led you to form an incorrect view that the Act covers fluoride used in drinking water and the resulting fluoridated water and I apologise for this confusion. It is clear from the historical record that it was the intent of the legislative drafters to ensure it was understood that fluoride used to fluoridate drinking water and the drinking water itself were not covered by the Act (for example, I would refer you to documents 10 and 15

in FOI 156-1213-19, which discuss how the Excluded Goods Order of the time was to handle this matter).

I note that you have also asked some unanswered questions about risk assessments of fluoride. As fluoride for use in drinking water does not, in our opinion, come within the operation of the Act, the TGA has no role in carrying out such risk assessments. I would refer you to two documents (one of which I know you have previously been referred to) published by the National Health and Medical Research Council (NHMRC):

- The Australian Drinking Water Guidelines 2011 (http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/eh52_aust_drinking_water_guidelines_update_120710_0.pdf), which state that 'based on **health considerations** [my emphasis], the concentrations of fluoride in drinking water should not exceed 1.5mg/L'.
- Nutrient Reference Values for Australian and New Zealand (<http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/n35.pdf>), which states that 'because of its role in the prevention of dental caries, fluoride has been classified as essential to human health' and sets 'adequate intake' levels for fluoride.

I trust this is useful to you.

Yours sincerely



Bill Turner
Head of the Office of Scientific Evaluation

18 November 2013