

## BARAC-HEATH, Joy

---

**From:** Bill Turner  
**Sent:** Monday, 17 March 2014 10:28 AM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Draft TGA web statement re regulation of fluoride used in water [SEC=UNCLASSIFIED]

[REDACTED] thank you both for the clarifying comments.

[REDACTED] - thank you also for the NZ document, it has proven to be a fascinating read. Many of the issues canvassed within it, we have struggled with here at the TGA. Some of the conclusions don't necessarily fit well into the Australian legal framework (we don't have any bill of rights or similar document, for example), but they illuminate some of the core issues.

As to the background to the statement, I am going to be frank and open with colleagues here and I trust that some of the sensitivities that I am about to disclose will be treated appropriately.

Unfortunately, the issue that we are addressing is not simply a case of anti-fluoridationists interpreting in their own way various pieces of TGA legislation and other documents. The TGA has inadvertently actively fed into an interpretation that fluoride and fluoridated water are therapeutic goods under our Act and therefore within our regulatory control. This has led to threats to councils that they face prosecution from us because the goods are not registered. It has also led to repeated requests from activists that we take such action, which we have fended off. If that was all there was, we would not now be considering this statement.

However, in December 1012, we provided very inaccurate advice to an activist regarding the status of fluoride under our Act. The origin of this advice has been traced and it was given in good faith; however, it was substantially incorrect. We referred the activist to the Excluded Goods Order, Item 7 of Table 2 'Oral hygiene products for care of the teeth and the mouth (e.g. dentrifices, mouth washes and breath fresheners)'. As you will see, it is a stretch to call fluoridated water an 'oral hygiene product' and to confound the matter further, there is a condition that it would also have to meet the definition of 'cosmetic' in the Industrial Chemicals Notification and Assessment Act 1989, which it clearly doesn't.

In responding to a ministerial from another correspondent, this error was identified and, unfortunately, compounded when we referred the correspondent to Item 10 of Table 1 - substances for use in the purification or treatment of drinking water. Again, fluoride is not for the 'purification' or 'treatment' of drinking water; the meaning of these words was to cover chemicals like chlorine and, in particular, colloidal silver, that are used to make drinking water safe. Colloidal silver is a therapeutic good in some circumstances, so, to make sure it wasn't inadvertently excluded in circumstances where it needed to be regulated by us, there is a condition that no claims for therapeutic use could be made. [REDACTED] I note your recommendation to remove this item or explicitly redraft - will take on board the redrafting suggestion, however, it may not play well into plans for the future - there are misunderstandings about the EGO that I will clarify below).

This precipitated two events:

1. Firstly, the activist in question 'went, ah ha, gotcha - the councils are making therapeutic claims so therefore they are in breach of the order and the TGA has to prosecute'.
2. The ministerial circulated among the activists and the first activist (whom we had referred to the oral hygiene products item) noticed that the advice in the ministerial was substantially different from the advice we had given him and he made a complaint to the Commonwealth Ombudsman.

Which leads us to where we currently are - after his investigation, the Commonwealth Ombudsman concluded that we needed to write to the complainant and advise him of the status of fluoride under our legislation, and make a public statement about the legal status of fluoride.

The intent of the statement is to step through three main points: 1. Fluoride is safe, 2. Fluoride is regulated by the states and territories, 3. Fluoride is not regulated by the TGA.

[REDACTED] - I thank you for your suggested edits - I will have to consider about whether we delete the history and safety part at the front; but I don't think we can delete the bit about the regulation by states and territories. A statement that merely said 'Fluoridated water is not a therapeutic good' begs too many questions. I know it is addressed a bit at the end, but I think we need to retain an explicit statement about this.

[REDACTED]

With regard to the Excluded Goods Order, I make some points that are not well understood (sadly, even internally).

1. It is not a legislative instrument and has no direct legal effect. Under section 7 of the Act, it is merely a declaration by the secretary that she has determined something isn't a therapeutic good within the definition set out in the Act.

2. The term 'excluded' is poorly used; it suggests a positive action to exclude a therapeutic good - we are looking to change this language in a future edition. (We now have a new power specifically to allow us to exclude therapeutic goods from the operation of our Act).

3. Just because something isn't in the EGO doesn't mean it is a therapeutic good - i.e. no part of the EGO currently covers fluoride, but that doesn't put it in the therapeutic goods basket.

4. The item about chemicals for purification and treatment above was originally framed to cover fluoride, but when it was amended to cover colloidal silver, it ended up leaving it out and this wasn't noticed. For this reason, which was fundamental to the confusion in the first place, we do not wish to issue an excluded goods order that covers fluoride because of the problems of future changes losing the intent. This public statement is meant to stand as our forever viewpoint on the matter.

Thank you once again for all your input and I trust that this provides background and fills in some gaps for you.

Regards,

**Bill Turner**  
Branch Head  
Office of Scientific Evaluation

Phone: 02 6232 8187  
Email: [bill.turner@tga.gov.au](mailto:bill.turner@tga.gov.au)

Therapeutic Goods Administration  
Australian Government Department of Health  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

[REDACTED]

From: [REDACTED]  
To: "Anthony.Gill@tga.gov.au" <Anthony.Gill@tga.gov.au>, "Bill.Turner@tga.gov.au" <Bill.Turner@tga.gov.au>  
Cc: [REDACTED]

Date: 14/03/2014 06:38 PM  
Subject: RE: Draft TGA web statement re regulation of fluoride used in water [SEC=UNCLASSIFIED]

Hi Tony/Bill,

Could you please clarify what TGA is intending to achieve here, in the sense of the legal meaning of placing a “web statement re the regulation of fluoride used in drinking water” on the web site of a regulatory agency.

We all recall that the original issue is that anti-fluoridationists (based in NSW or Qld mainly) appear to be interpreting, in their own way, schedules and tables on various TGA web sites for info on fluoridation of drinking water, thereby making claims about fluoridation of drinking water being “therapeutic” or “medication” in the TGA sense and querying the legitimacy of State health agencies’ statements about the efficacy of fluoridation of drinking water.

Accordingly, it would seem to me that the key purpose of any TGA “web statement” is to nullify/quash these misinterpretations as effectively as possible and in a manner consistent with the core goals of TGA.

Unfortunately, most of the proposed text is a reinterpretation of material re fluoridation which is not directly relevant to TGA.

I am suggesting that the proposed TGA web statement does not need to go into the early history of fluoridation or the role of the NHMRC or reinterpreting ADWG (and unfortunately introducing errors in doing so, which is covered later), all it needs to do is point to this subject being managed by NHMRC and pointing to suitable info on a NHMRC web site.

It is suggested that the proposed TGA web statement should focus on the Word document version as attached to this email (please note yellow highlighted comments and additions).

As background, NHMRC recommends fluoridation of drinking water via this instrument:

[www.nhmrc.gov.au/guidelines/publications/eh41](http://www.nhmrc.gov.au/guidelines/publications/eh41)

... not via ADWG, which is now at the 2013 update.

It is important to note that your statement that “These guidelines recommend an optimal level of fluoride in drinking water of between 0.7 mg per litre and 1 mg per litre” is incorrect. ADWG merely records (on page 720) the fact that “*In fluoridated supplies, the target fluoride concentration is between 0.7 and 1 mg/L*”.

The recommendation sits in the document on the above URL and, as Northern Territory pointed out, the correct statement is:

*“It is recommended that water be fluoridated in the target range of 0.6 to 1.1 mg/L, depending on climate, to balance reduction of dental caries and occurrence of dental fluorosis.”*

[there are bands of +/- 0.1 mg/L on either side, hence 0.6 to 1.1 is more correct as a range.]

That was reiterated in the 2013 update of this statement, as advised by Northern Territory below. It would be simpler if TGA just referred to these NHMRC statements/web sites directly.

Similarly, your statement that ADWG 2006 [sic] states that “... in areas where the naturally occurring levels exceed this amount [i.e. 1.5mg per litre] , recommend reducing the concentrations to the optimal level for the public health benefits by dilution or by using activated aluminium or bone char” is also incorrect.

ADWG certainly generically states that “*Fluoride concentrations in drinking water can be reduced by dilution with other sources, or by using activated alumina or bone char*”, but nowhere does it recommend or link this generic statement to being a specific action starting or required at a level of 1.5 mg/L, nor does it specifically recommend these actions as a means of “reducing the concentrations to the optimal level”.

In closing, and I circulate this for all parties too, please find attached a copy of a recent New Zealand judgment (Taranaki PDF file attached) that responds to, and effectively demolishes, all anti-fluoridation arguments that were raised in that specific case.

Whilst the legislative instruments in question are of course peculiar to NZ, the anti-fluoridation arguments that were raised are familiar and wide ranging, and therefore much of the context is highly relevant to the Australian situation. In particular, please note the judge's comments re fluoridation of drinking water being "medication".

Before finalising the TGA web statement, I recommend that all interested parties look through this judgment – apart from reading is entirety, best to scan it for the word "therapeutic", as there are numerous references to the therapeutic purpose of fluoridation therein.

I hope this clarifies and assists.

Regards

[REDACTED]  
**Environmental Health Directorate | Public Health and Clinical Services Division**  
**Department of Health**  
Grace Vaughan House, 227 Stubbs Terrace SHENTON PARK WA 6008  
PO BOX 8172 | Perth BC | WA 6849

[REDACTED]  
[www.public.health.wa.gov.au](http://www.public.health.wa.gov.au)

promoting health | preventing disease | managing risk

**From:** [REDACTED]  
**Sent:** Thursday, 13 March 2014 14:09  
**To:** [REDACTED]

[REDACTED] 'Anthony.Gill@tga.gov.au'; 'Bill.Turner@tga.gov.au'

**Subject:** FW: Draft TGA web statement re regulation of fluoride used in water [SEC=UNCLASSIFIED]

Hi All,

Please see the comments below from the Director of Environmental Health in the NT.

Many Thanks

[REDACTED]  
Oral Health, Territory Wide Services | Department of Health  
9 Scaturchio St, Casuarina, NT 0810 | PO Box 40596, Casuarina, NT 0811

**Department of Health is a *Smoke Free Workplace***

If you are not the intended recipient of this message, any use, disclosure or copying of the message or any attachments is unauthorised  
If you have received this message in error, please advise the sender. No representation is given that attached files are free from viruses or other defects.  
Scanning for viruses is recommended.

Hi

I might be missing something or maybe it's simply just a typo, but any reason they are not referring to the more recent 2011 ADWG version. Ironically the page number of the fact Sheet which has the footer: *Australian Drinking Water Guidelines Version 2.0 Updated December 2013*, is page 720.

Its ironic though as NHMRC 2013 statement said 0.6 – 1.1mg/L (below) and the Fluoride fact sheet target at page 720 is 0.7 – 1mg/L, which is what TGA are advocating too.

### 2013 Council consideration regarding the status of the Public Statement

NHMRC Council considered the NHMRC Public Statement on The Efficacy and Safety of Fluoridation at its meeting on 21 June 2013. Council reaffirmed its position that "Fluoridation of drinking water remains the most effective and socially equitable means of achieving community-wide exposure to the caries prevention effects of fluoride. It is recommended that water be fluoridated in the target range of 0.6 to 1.1 mg/L, depending on climate, to balance reduction of dental caries and occurrence of dental fluorosis".

Nonetheless, would suggest they change to 2011 ADWG version if it is an updated TGA statement (in unison now with *Fluoride* Fact Sheet) as optimum levels still the same. They could also simply just drop the year of publication and quote the ADWG, although former preferred.

Regards

[REDACTED]  
Environmental Health Branch | Territory Wide Services  
Department of Health

 258 Trower Road, Casuarina NT 0810  
 PO Box 40596 Casuarina NT 0811

[REDACTED]  [www.nt.gov.au/health](http://www.nt.gov.au/health)

If you are not the intended recipient of this message, any use, disclosure or copying of the message or any attachments is unauthorised. If you have received this message in error, please advise the sender. No representation is given that attached files are free from viruses or other defects. Scanning for viruses is recommended.

*Department of Health is a Smoke Free Workplace*

 Please consider the environment before printing this email

**From:** [Anthony.Gill@tga.gov.au](mailto:Anthony.Gill@tga.gov.au) [<mailto:Anthony.Gill@tga.gov.au>]

**Sent:** Thursday, 13 March 2014 8:49 AM

**To:** [REDACTED]

**Cc:** Bill Turner

**Subject:** Draft TGA web statement re regulation of fluoride used in water [SEC=UNCLASSIFIED]

Dear all

After significant internal discussion the TGA has drafted the attached web statement re the regulation of fluoride used in drinking water. Before we put it on our website I am circulating it to you so you are aware of what we will be saying and getting any comments you might have on it. As you will note it is not lengthy.

If any of you have the contact details of the appropriate people in SA, NSW and the ACT so I can send it to them it would be appreciated if you could provide them to me.

Regards

Tony

**Dr Tony Gill** MBBS MPH FAFPHM  
Senior Medical Adviser  
Office of Scientific Evaluation  
Phone: 02 6232 8395 Fax: 02 6232 8329  
Mobile: 0432 758 162