

**BARAC-HEATH, Joy**

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**From:** Marlene Keese  
**Sent:** Tuesday, 16 July 2013 5:17 PM  
**To:** TGA Info  
**Cc:** Cara-Lee Rake; Tony Gill  
**Subject:** Re: Fw: Fluorides put into potable drinking water supplies [DLM=Sensitive]

Hi Cara

Here is a copy of the signed Ministerial on fluoridation. Also note the FOI decision in relation to fluoridation with a slight change on the text about the Excluded Goods Order. Please do not circulate this document and only use this for this purpose



img-716171151-...

Best regards  
Marlene

*Marlene Keese*

Marlene Keese | Principal Legal Officer | Office of Legal Services | Therapeutic Goods Administration | ☎ (02) 6232 8398 | 📠 (02) 6232 8426 | ✉ [marlene.keese@tga.gov.au](mailto:marlene.keese@tga.gov.au) | 🌐 <http://www.tga.gov.au>

**From:** TGA Info/TGA/Health  
**To:** Marlene Keese/TGA/Health@TTRA  
**Date:** 16/07/2013 04:01 PM  
**Subject:** Re: Fw: Fluorides put into potable drinking water supplies [SEC=UNCLASSIFIED]  
**Sent by:** Cara-Lee Rake

Hi Marlene

That would be great if you could!

Many thanks  
Cara

**Public Contact Team**  
Therapeutic Goods Administration

Phone: 1800 020 653  
Email: [info@tga.gov.au](mailto:info@tga.gov.au)

Therapeutic Goods Administration  
Department of Health and Ageing  
PO Box 100  
Woden ACT 2606

From: Marlene Keese/TGA/Health  
To: TGA Info/TGA/Health@TTRA  
Cc: Anthony Gill/TGA/Health@TTRA, Cara-Lee Rake/TGA/Health@TTRA  
Date: 15/07/2013 05:22 PM  
Subject: Re: Fw: Fluorides put into potable drinking water supplies [SEC=UNCLASSIFIED]

hi Cara

Please do not use the exemption referred to below. We have modified our response. I'll send you a copy of Ministerial that has been signed by our new Parliamentary Secretary.

Best regards  
Marlene

*Marlene Keese*

Marlene Keese | Principal Legal Officer | Office of Legal Services | Therapeutic Goods Administration | ☎ (02) 6232 8398 | 📠 (02) 6232 8426 | ✉ [marlene.keese@tga.gov.au](mailto:marlene.keese@tga.gov.au) | 🌐 <http://www.tga.gov.au>

From: TGA Info/TGA/Health  
To: Anthony Gill/TGA/Health@TTRA  
Cc: Marlene Keese/TGA/Health@TTRA  
Date: 15/07/2013 04:39 PM  
Subject: Fw: Fluorides put into potable drinking water supplies [SEC=UNCLASSIFIED]  
Sent by: Cara-Lee Rake

Dear Dr Gill

The PCT has received the below enquiry regarding fluoride in water.

I would appreciate your advice and clearance on the below response.

Many thanks  
Cara

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Dear [REDACTED]

Thank you for your email of 12 July 2013 to the Therapeutic Goods Administration (TGA).

We appreciate that you are concerned about the impact that fluoride in water may have had on your health. The most appropriate government agency to respond to your queries is your State Health Department. You might like to contact Queensland Health. They can be contacted on 07 3234 0111.

**Role of the TGA**

The TGA's primary consideration of a particular product is a consideration of whether or not it should be subject to regulation as a therapeutic good under the provisions of the *Therapeutic Goods Act 1989* (the Act). The Act provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in

Australia. The definitions provided in section 3 of the Act are used to determine whether or not a particular product is a therapeutic good for the purposes of regulation under the Act.

### **TGA's regulatory status for fluoride in water**

The Secretary of the Department of Health and Ageing may (under section 7 of the Act), by order published in the *Gazette*, declare that the goods, or the goods when used, advertised, or presented for supply in that way, are or are not, for the purposes of the Act, therapeutic goods. In accordance with this provision of the Act, the Secretary has declared that certain products are not therapeutic goods for the purposes of the Act (Therapeutic Goods (Excluded Goods) Order No. 1 of 2011, available at [www.tga.gov.au/industry/legislation-excluded-goods-order-1101.htm](http://www.tga.gov.au/industry/legislation-excluded-goods-order-1101.htm)). This declaration relevantly declares that oral hygiene products for care of the teeth are not therapeutic goods if:

- any benefits claimed to result from use are directly related to improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and
- other benefits in relation to diseases or ailments, e.g. gum or other oral disease or periodontal conditions are not claimed to result from use.

Fluoridated water satisfies this requirement and is therefore not a therapeutic good for the purposes of the therapeutic goods regulatory scheme.

Yours sincerely

Cara

**Public Contact Team**  
Therapeutic Goods Administration

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

From: [REDACTED]  
To: <[info@tga.gov.au](mailto:info@tga.gov.au)>  
Date: 12/07/2013 08:29 PM  
Subject: Fluorides put into potable drinking water supplies

Dear Sir/Madam,

**Fluoride is listed by the Therapeutic Goods Administration (TGA) under “Substances that may be used in listed medicines” (Dec 2007), used as a “component” and with the following restrictions:-** “In dental products, the concentration from all ingredients must not exceed 15 mg/kg or 15 mg/L or 0.0015%. In other products, the concentration from all ingredients must not exceed 1000 mg/kg or 1000 mg/L or 0.1% “

This TGA document also states “Importantly, as a result of a safety concern, substances may be subject to new restrictions or may be removed from the list.” (page 3).

The TGA definition of *medicine* means:

- (a) therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal; and
- (b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of *therapeutic device*, not to be therapeutic devices.

By the TGA's own definition it still has not listed the "fluorides" put into public potable water supplies as a medicine when there is a therapeutic use proclaimed for its inclusion in the water supply ie to prevent tooth decay.

**I have searched the Excluded Goods Order No. 1 of 2011 and can find no relevant category that would cover these "fluorides" being excluded from TGA assessment.**

Table 1 Item 10 refers to Substances used for the purification or treatment of drinking water but are restricted to those substances which claim no therapeutic use.

As the "fluorides" put into drinking water are there to treat the body and not the water and as a therapeutic use is intended, this Section does not apply.

Table 2 Item 7 refers to Oral hygiene products for care of the teeth and the mouth (e.g. dentrifices, mouth washes and breath fresheners) If:

- a. any benefits claimed to result from use are directly related to improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and
- b. other benefits in relation to diseases or ailments, e.g. gum or other oral disease or periodontal conditions are not claimed to result from use.

This section appears to cover "over-the-counter" products one might find at a supermarket for example, but does not cover the "fluorides" in public potable drinking water supplies.

Could you please clarify:-

**Why would the TGA not require a risk assessment of the "fluorides" put into the drinking water supply as they are listed as Poisons, are not pharmaceutical grade and as far as I know have never been tested for human consumption, yet the authorities including these substances do so by claiming a therapeutic use?**

Individuals consuming these "fluorides" are not under the supervision of any clinician or dentist; there is no dose to weight or age relationship; no advice on potential overdosing, no contra-indications; or who should not be taking these "fluorides", **yet the TGA on its own website has the following guidance:-**

#### **Fluoride supplements**

Fluoride supplements (drops, tablets) should not be taken during pregnancy. The labelling of fluoride supplement products should include advice consistent with the following:

- *\*This product should only be used on the advice of a dentist.*
- *\*Do not use if pregnant.*

**What guidance does the TGA have for pregnant women drinking the "fluorides" in the public potable water supply?**

**Why is it that fluorides put into the drinking water supply are not regarded as a therapeutic good when other oral hygiene products with the same or lower dosage of Fluoride are listed on the ARTG?**

**What manner of risk assessment is carried out to differentiate what is or is not a therapeutic good or an excluded good?**

Based on the above findings, "Fluorides" included in the public potable water supply are not Excluded Goods by any TGA definition, but by definition are a therapeutic good., and as the regulatory authority I believe the TGA has a duty of care to the public to assess the safety of these "fluorides" for human consumption..

I would very much appreciate your response at your earliest opportunity.

Yours faithfully,

[REDACTED]

[REDACTED]

Email: [REDACTED]  
Ph: [REDACTED]

This email is sensitive information because it includes information about a request made under section 9C of the Therapeutic Goods Act 1989 for a copy of an entry in the Register that was supplied in confidence by a third party



Internal Review  
Decision FOI 1...



**The Hon Shayne Neumann MP**  
**Parliamentary Secretary for Health and Ageing**

Mr Anthony Shorten MP  
Member for Algeester  
PO Box 854  
ARCHERFIELD QLD 4108

27 MAY 2013

Dear Mr Shorten

Thank you for your representations of 11 January 2013 to Dr John Skerritt, National Manager, Therapeutic Goods Administration (TGA), on behalf of [REDACTED] regarding fluoridated water. As Parliamentary Secretary for Health and Ageing with responsibility for this matter, I am responding on behalf of the Australian Government. I apologise for the delay in responding.

As you are aware, the TGA received an email from [REDACTED] on 17 October 2012, and representations from the Hon Bernie Ripoll MP, on behalf of [REDACTED] on 6 December 2012, regarding her concerns with fluoridated water. In responding to both [REDACTED] and Mr Ripoll, the TGA explained the circumstances under which fluoridated reticulated drinking water is not a therapeutic good for the purposes of the therapeutic goods regulatory scheme.

The Secretary of the Department of Health and Ageing, or her delegate, has the power under section 7 of the *Therapeutic Goods Act 1989* (the Act) to declare some products not to be therapeutic goods. Once a product is declared not to be therapeutic goods, that product is no longer regulated under the Act. The Therapeutic Goods (Excluded Goods) Order 2011 ('Excluded Goods Order') is the most current written instrument under section 7 of the Act.

As reflected in our previous response, the TGA initially considered that fluorides and fluoridated reticulated drinking water are not therapeutic goods because of item 7 under section 6 of the Excluded Goods Order (being oral hygiene products). However, our records show that it was the TGA's intention that chemicals added to water for the purposes of fluoridation should be excluded goods under the Excluded Goods Order. The specific item that was intended to cover fluorides was an item excluding substances for use in the purification or treatment of drinking water. This is currently Item 10 of section 5 of the Excluded Goods Order and is subject to the condition that no claims must be made about therapeutic use. Regulation of reticulated drinking water, including its fluoridation, has always been the jurisdiction of the states, territories and local councils.

To allay any more confusion about the regulation of substances for fluoridation of water or fluoridated water, the TGA agrees that the Excluded Goods Order or any other appropriate legislative instrument under the Act should make it clear that these substances and products are not therapeutic goods.

Another form of regulation which is set out in the Act is scheduling of medicines and poisons. Scheduling is a national classification system that controls how medicines and poisons are made available to the public. The Schedules and the list of substances per Schedule are set out in the current Poisons Standard (also known as the Standard for the Uniform Scheduling of Medicines and Poison) accessible on the ComLaw website at [www.comlaw.gov.au](http://www.comlaw.gov.au).

The requirements mandated by the Schedules are generally given legal effect through state and territory legislation. The listing of a substance in a particular Schedule is determined according to the level of regulatory control over the availability of the medicine or poison required to protect public health and safety. The listing of a substance in a particular Schedule takes into account a number of factors such as the toxicity of the substance, the purpose of the use, potential for abuse, safety in use and the need for the substance. Information in relation to these criteria can be accessed from the TGA website at [www.tga.gov.au](http://www.tga.gov.au).

'Fluorides' for human use, which are for dental products, medicines and the like, are listed in Schedules 2, 3 and 4. Fluorides whose concentrations are 15mg/kg and less are not covered by the scheduling requirements. Fluorides are not listed in Schedule 7 of the current Poisons Standard.

Fluoride scheduling was first considered in 1956 and since then fluoride has been considered on numerous occasions. In 2007, a Fluorides Working Party was established to address the issues of concern in relation to contemporary human exposure to fluoride (acute toxicity in children and adults and fluorosis in children and adolescents). The acute oral toxicity of fluoride is generally recognised as 5mg/kg and the acceptable daily intake for fluoride in children one to three years of age, in relation to the incidence of dental fluorosis, is 0.7mg.

In 2011, the National Health and Medical Research Council (NHMRC) published the latest version of the *Australian Drinking Water Guidelines* which can be accessed on the NHMRC website at [www.nhmrc.gov.au/guidelines/publications/eh52](http://www.nhmrc.gov.au/guidelines/publications/eh52). The Guidelines contain a specific chapter on drinking water treatment chemicals, including fluoride. The NHMRC's website advises that the Guidelines undergo rolling revision to ensure it represents the latest scientific evidence on good quality drinking water. Ms Haines may wish to contact the NHMRC about having her views considered in the next update of its Guidelines.

I trust that the above information is of assistance.

Yours sincerely



Shayne Neumann



**Australian Government**

**Department of Health and Ageing  
Therapeutic Goods Administration**



**FREEDOM OF INFORMATION REQUEST FOI 156-1213  
Notice of Internal Review Decision**

I refer to your request dated 14 May 2013 under the *Freedom of Information Act 1982* (the FOI Act) for internal review of the decision by Mr Pio Cesarin on 16 April 2013 to release all documents identified by him as relevant to your request of 20 January 2013, as follows:

*"...the TGA has apparently made a decision that both fluoridated water and water containing water fluoridation chemicals are to be excluded from being therapeutic goods. I believe the TGA advises that both fluoridated water and the fluoride chemicals are Excluded Therapeutic Goods.*

*Through FOI I seek a copy of the total TGA file on how and why this decision was made.*

*I particularly am seeking the justification (statement of reasons or similar) why fluoridated water and water containing water fluoridation chemicals should not be considered as therapeutic goods, who made this decision and when.*

*I seek a copy of Minutes of all relevant meetings, all reports, all documentation of any kind and all relevant internal and external correspondence. I do not seek correspondence to or from private individuals."*

On 1 February 2013 you confirmed that the scope of your request included "... anything from 1990 onwards to present".

On 6 February 2013, during a telephone conversation with TGA officers, you clarified that the scope of your request related to correspondence, meetings, or any other documents leading to the making of the decisions to exclude fluoridated water and water containing fluoridation chemicals from being therapeutic goods.

In your request for internal review, you expressed the view that not all documents within the scope of the request were provided to you. Specifically, you asked for the following:

*"Please now supply any missing information ( emails, letters, memos, Minutes of meetings, etc ) that shows when / how / who in the TGA determined that fluoridation chemicals are Excluded goods, as this information is missing".*

**Decision maker**

I am authorised under section 23 of the FOI Act to make this decision on internal review.



## **Decision**

I have decided to affirm Mr Cesarin's decision. For reasons set out below, I am satisfied that all reasonable steps have been taken to find the documents relevant to your request and that no further documents can be found or exist.

## **Background**

In Mr Cesarin's initial decision on 16 April 2013 he identified thirty-three (33) documents falling within the scope of the request, of which he has released eighteen (18) documents to you in full and fifteen (15) documents to you with deletions made under subsection 22(1) of the FOI Act on the basis that the deleted material was not within the scope of your request.

On 14 May 2013, the TGA received a request from you for an internal review of Mr Cesarin's decision.

On 20 May 2013, the TGA wrote to you acknowledging your request for internal review.

## **Material considered in decision making**

In coming to my decision I had regard to the following:

- your request for internal review dated 14 May 2013;
- your initial FOI request dated 20 January 2013 and subsequent clarifications dated 1 February and 6 February;
- all relevant documents on the TGA processing file including those identified in the original search for documents;
- the documentation of further searches conducted on internal review (see below);
- the provisions of the FOI Act; and
- correspondence between the TGA and you.

## **Reasons for decision**

The initial search and retrieval was sent to relevant offices in the TGA and the rest of the Department of Health and Ageing (DoHA) that were considered may have documents within the scope of your request. Specifically, within the TGA, the search and retrieval was sent to the Office of Medicines Authorisation, the Office of Devices Authorisation, the Office of Scientific Evaluation, the Office of Complementary Medicines, the Office of Legal Services and the Office of Parliamentary and Support Services. Also, within DoHA, the search and retrieval was sent to the Office of Chemical Safety and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

Following receipt of your request for internal review on 14 May 2013, all relevant offices within the TGA and DoHA which were sent the initial search and retrieval were requested to conduct a further search for documents. In addition TGA Records Management was asked to conduct a search and retrieval of all records on the TGA's document management system (TRIM) and to advise if they found any files or documents that might relate to your request. TGA Records Management was also asked whether there were any old TGA Executive files that could contain documents about fluoride during the relevant time period from 1990 to 1992, or otherwise. Long serving employees of the TGA, including those present at the TGA or the Department of Health, Housing and Community Services during the relevant period, were consulted in searching for the records.

None of these searches above was able to locate any further documents relevant to your request.

## Information regarding regulation of fluoridation chemicals

As noted above, in your request for internal review you state:

*"Please now supply any missing information (emails, letters, memos, Minutes of meetings, etc ) that shows when / how / who in the TGA determined that fluoridation chemicals are Excluded goods, as this information is missing. Only water treatment chemicals are TGA Excluded Goods on the information provided to date".*

In undertaking this review I have become aware that on 11 December 2012 you received an email from the TGA Public Contact Team indicating that 'fluoridated water' is not a therapeutic good as it satisfies the requirement of a provision in the Therapeutic Goods (Excluded Goods) Order No 1 of 2011. In addition, your initial request indicates that 'the TGA has apparently made a decision that both fluoridated water and water containing water fluoridation chemicals are to be excluded from being therapeutic goods'. This information needs to be clarified and the previous advice corrected.

The relevant item in the Excluded Goods Order No. 1 of 2011 (Item 10 in Table 1 in section 5 of the Order) is for '**substances** (my emphasis) for use in the purification or treatment of drinking water', not for the fluoridated drinking water itself.

The documents you received as part of this FOI request (particularly Documents 8, 10, 15 and 16) show that it was the TGA's original intention that chemicals added to water for the purposes of fluoridation should be excluded goods under the Excluded Goods Order. This is demonstrated by:

- Document 8 – TGA internal email dated 8 July 1991 indicating the existing Excluded Goods Order No. 1, under item 15, excludes '*drinking water purification and fluoridation equipment*'. The email author indicates this provision may not be clear that '*this is intended to encompass chemicals (such as water purification tablets) added to water as part of the process.*' The email then further requests '*at the next opportunity, could this be expanded to specifically include any chemicals added to water for the purposes of purification or fluoridation*'.
- Document 10 - in response to the above, the TGA requested the Attorney-General's Department on 1 November 1991 at 3 '(e) *Item 15 of the Order to extend it to cover not only "equipment", but also any chemicals added to water for the purposes of purification or fluoridation*'.
- Document 15 – TGA internal email dated 4 May 1992 confirming recommendation that '*item 15 should be changed to "equipment and substances used in the purification or treatment of drinking water. It would probably be unnecessary to refer specifically to fluoridation.*'
- Document 16 – TGA request dated 9 June 1992 to the Attorney-General's Department to amend the paragraph in the proposed Excluded Goods Order to reference '*equipment, or substances, for use in the purification or fluoridation of drinking water, the word "fluoridation be removed and substituted with "treatment".*'

The specific documents above indicate the TGA substituted the word "fluoridation" with "treatment" with the intent that substances for use in the treatment of drinking water encompassed (as a subset) substances for use in fluoridation and also allowed for other possible chemicals used in the treatment of drinking water to be captured by the amended wording.

The substitution of "fluoridation" with the broader term "treatment" was not intended to remove fluoridation substances from the scope of relevant item as appears to be implied in your internal review application where you state '*There appears no further mention of*

*“fluoridation chemicals’ so it appears that ‘fluoridation chemicals’ are not Excluded Goods according to the TGA, unless extra information that has not been provided to me shows this’.*

Therefore the specific item in the Order that was intended to cover fluorides (as substances added to drinking water for the purposes of purification or fluoridation) is the item excluding substances for use in the purification and treatment of drinking water. As noted above, this is currently Item 10 in Table 1 in section 5 of the Excluded Goods Order.

I appreciate that the formulation of this item may create confusion in relation to fluoridation, especially when the provision was subsequently changed (in 2002) to only exclude substances for purification if no claims are made for therapeutic use. Although it is recognised this provision does not clearly articulate the exclusion of fluoridation substances for the treatment of drinking water when used for the prevention of tooth decay that was clearly, according to the TGA documents referred to above, the intention of this item.

To allay any more confusion about the regulation of substances for fluoridation of water, the TGA agrees that the Excluded Goods Order or any other appropriate legislative instrument under the Act should make it clear that these substances and products are not therapeutic goods. Our intention is to progress these changes to provide clarity in what was originally intended.

Regulation of reticulated drinking water has always been the jurisdiction of the states, territories and local councils.

I trust that the above information is of assistance.

#### **Rights of review**

If you are not satisfied with my decision you can apply to the Office of the Australian Information Commissioner for a review of the decision. A statement of your review rights is at **Attachment A**.

If you have any queries regarding this matter, please contact Paul Shepherd on (02) 6232 8808.

Yours sincerely

Judy Develin  
Head, Market Authorisation Group  
Therapeutic Goods Administration

June 2013