BARAC-HEATH, Joy

From: Tony Gill
Sent: Monday, 5 August 2013 3:38 PM
To: TGA Info
Subject: Re: Fw: Your reply to enquiry dated 26/7/13 [DLM=For-Official-Use-Only]

Cara

Happy for this initial response to go.

Thanks

Tony
Dr Tony Gill | MBBS MPH FAFPHM AFACHSM | Senior Medical Adviser | Office of Scientific Evaluation | Therapeutic Goods Administration | PO Box 100, WODEN ACT 2606 | Ph: 02 6232 8395 | Fax: 02 6232 8239| Mob: 0432 758 162 I Email: anthony.gill@tga.gov.au

From: TGA Info/TGA/Health
To: Anthony Gill/TGA/Health@TTRA
Date: 05/08/2013 02:57 PM
Subject: Fw: Your reply to enquiry dated 26/7/13 [DLM=For-Official-Use-Only]
Sent by: Cara-Lee Rake

Dear Dr Gill

Please find attached a draft response to [redacted] request.

Your consideration/ clearance would be greatly appreciated.

Many thanks
Cara

Dear [redacted]

Thank you for your email of 30 June 2013 to the TGA.

Please find attached the copies of the Excluded Goods Order publications as requested.

Your subsequent email has been forwarded to the relevant area of the TGA for response.

I hope that this information is useful.

Yours sincerely
Cara

Public Contact Team
Therapeutic Goods Administration

Phone: 1800 020 653
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606
www.tga.gov.au

[redacted]
[attachment "EGO 2002-1.pdf" deleted by Anthony Gill/TGA/Health] [attachment "EGO 2004-1.pdf" deleted by Anthony Gill/TGA/Health] [attachment "EGO 2005-1.pdf" deleted by Anthony Gill/TGA/Health]

From: [redacted]
To: <info@tga.gov.au>
Date: 30/07/2013 12:25 PM
Subject: RE: Your reply to enquiry dated 26/7/13

Hi Cindy – TGA

Thanks for your reply. With regard to some information you supplied, I've tried to locate the Excluded Goods Orders No. 1 of 2002, No. 1 of 2004 and No. 1 of 2005 through the TGA website but they're not coming up.

I wonder whether you could give me the link to these documents or provide me with a copy.

Thanks a lot.

[redacted]

-----Original Message-----
From: cindy.chan@tga.gov.au [mailto:cindy.chan@tga.gov.au] **On Behalf Of** info@tga.gov.au
Sent: Friday, 26 July 2013 11:49 AM
To: [redacted]
Subject: Re: Fluorides put into potable drinking water supplies [SEC=UNCLASSIFIED]

Dear [redacted]

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

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.

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. It is the legislation in these jurisdictions that sets out which chemicals may be used in the water supply and the standards of purity that must be met by those chemicals.

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) which is accessible on the ComLaw website.

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.

'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 and are not classified as Poisons at or below this concentration.

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 fluoride 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 (NMHRC) published the latest version of the *Australian Drinking Water Guidelines* which can be accessed on the NHMRC website. 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.

I hope that this information is useful.

Yours sincerely

Cindy Chan

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Therapeutic Goods Administration

Phone: 1800 020 653
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Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
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From: [redacted]
To: <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 thereaputic 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 woment 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]

[redacted]

[redacted]

Email: [redacted]

Ph: [redacted]

[attachment "EGO 2002-1.pdf" deleted by Anthony Gill/TGA/Health] [attachment "EGO 2005-1.pdf" deleted by Anthony Gill/TGA/Health] [attachment "EGO 2004-1.pdf" deleted by Anthony Gill/TGA/Health]