

Draft Web Statement

The issue of fluoridated water has been in the media recently, as well as being the topic of representations to state and territory governments, local councils and the Therapeutic Goods Administration.

Much of the correspondence has centred on the scope of the *Therapeutic Goods Act 1989* and whether or not fluorides and fluoridated water are regulated under that Act by the TGA.

The records of the TGA demonstrate that, when the Act was enacted in 1989, there was a clear intention to exclude fluorides and fluoridated water from the operation of the Act and leave the control and regulation of fluoridated water with the states and territories. Drinking water in various parts of Australia has been fluoridated since at least 1956, more than 30 years before national regulation of therapeutic goods commenced.

However, during the period since 1989, there have been a number of changes to the Act and subsidiary legislative instruments that mean it has become unclear how the intent to exclude fluorides and fluoridated water from the operation of the Act is expressed.

As a result, the TGA has inadvertently provided advice to members of the public and others that inaccurately reflect the operation and intention of various parts of the Act and those supporting instruments. This was unintentional and the advice given reflected the best understanding available at that point.

The TGA is currently reviewing the legislation and will develop a more definitive position as soon as possible. In the meantime, the status quo persists, with states and territories remaining responsible for whether to fluoridate drinking water supplies. Where they do fluoridate, the TGA does not believe that they are committing an offence against the Act.

Fluoridated water is safe and there are no known health consequences associated with its consumption. Where fluoride is added to Australian drinking water supplies, it is done so in amounts so as not to exceed the safe levels recommended in the National Health and Medical Research Council Drinking Water Guidelines 2011 (<http://www.nhmrc.gov.au/guidelines/publications/eh52>), and the higher end of the spectrum of naturally occurring fluoride found in potable water supplies.

Scheduling of fluoride

Part of the information around water fluoridation focuses on the 'scheduling' of fluorides, as recommended in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

Scheduling is a process of classifying medicines, chemicals and poisons in accordance with their potential to cause harm if there is unrestricted access. Scheduling in relation to substances for use in humans determines whether a prescription is required to access the substance (Schedule 4); whether the substance can only be supplied through a pharmacist (Schedule 3); whether the substance can only be supply through a pharmacy, but not directly from the pharmacist (Schedule 2); or whether the substance is freely available (exempt from scheduling).

Various substances may appear in different schedules, depending on their use, concentration and packaging size. This recognises the different levels of risk.

Fluoride appears in 5 of the 9 schedules - Schedules 2, 3, 4 for human use and schedule 5 and 6 for agricultural, domestic and industrial use. Fluoride in concentrations lower than 15mg/kg is exempt from scheduling as a consequence of the wording in Schedule 2 which says in part:

...except in preparations containing 15 mg/kg or less of fluoride ion or preparations for supply to registered dental professionals or by approval of an appropriate authority.

Scheduling is a process of determining classification for medicines and poisons when used in different amounts for different purposes. The schedule a substance is placed in determines the access conditions that would apply to products containing that medicine or poison in the defined amounts. For example, Schedule 4 medicines can only be attained with a prescription; Schedule 2 medicines can only be sold in pharmacies; and Schedule 5/6 poisons are used for agricultural or industrial uses, such as pesticides.

Any given substance can conceivably appear in two or more schedules, based on its potential formulation, use and concentration. Substances can also be exempt from scheduling, where their safety is such that it doesn't require access control.

Thus, fluoride appears in the SUSMP in 5 of the 9 schedules — schedules 2, 3, 4, 5 and 6 — in various concentrations and for various uses. It is also exempt from scheduling where used in concentrations below 15mg/kg.

This doesn't mean, just because fluoride is considered a poison when used for agricultural pest control in comparatively high concentrations (schedule 5 and 6) that it is unsafe when added to drinking water to in concentrations that conform with to the NHMRC drinking water guidelines (exempt from scheduling).

The father of modern toxicology, Paracelsus, wrote in the 16th century that 'all things are poison, and nothing is without poison; only the dose permits something not to be poisonous.' This is more commonly quoted as 'the dose makes the poison'.

The dose of fluoride ingested through fluoridate drinking supplies is at a concentration around 1 part per million and is safe not enough to make fluoridated water poisonous.

NOTE do we need to add something about states and territories providing information on their websites is not against the TG AC, if it isn't!

Comment [gillan1]: Suggest words I have added which are directly from latest version of Ombudsman response