

Legal update - High Court rejects anti-fluoride bid

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The High Court has dismissed an application to classify hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) as medicines when those substances are used to fluoridate water.

The judgment did not address issues relating to the efficacy and safety of fluoridation. However, the decision should provide comfort to councils and District Health Boards about the current rules relating to the fluoridation of water supplies.

The case, which New Health New Zealand brought against the Ministry of Health, had its origins in an earlier case that New Health lost against the South Taranaki District Council. In rejecting New Health's arguments in that earlier case, the High Court observed that: "*although the addition of fluoride [to water] does no more than to elevate it to levels which often occur naturally, it is nevertheless a process undertaken for the purpose of preventing or arresting a disease... the process of fluoridation is undertaken for a therapeutic purpose*".

Relying on that observation in its case against the Ministry of Health, New Health argued that HFA and SSF, when used for community water fluoridation, are "medicines" within the meaning of the Medicines Act 1981 (the Act) and therefore must be regulated as medicines by the Ministry.

However, the High Court ruled that when HFA and SSF are used to fluoridate water they are not medicines within the meaning of the Act. Justice Collins' decision focused on the definition of "medicine" in the Act, the relevant part of which provides that "medicine":

"(a) means any substance or article that-

(i) Is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and

(ii) Achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means..."

In light of the definition, Justice Collins said that three questions were central to deciding whether HFA and SSF are medicines under the Act when used to fluoridate water supplies:

- Is fluoride added to domestic water supplies for a therapeutic purpose?
- Is fluoride "administered" to a human being when it is added to domestic water supplies?
- Does the context of the Act "otherwise require" the conclusion that fluoride, when added to domestic water supplies, is not a medicine within the meaning of the Act?

The Court found that because HFA and SSF are added to water in order to prevent, alleviate and treat tooth decay, water fluoridation is done for a "therapeutic purpose". Justice Collins was also satisfied that fluoride is "administered" to people when it is added to community water supplies.

New Health's application therefore turned on whether there was anything in the legislative context that meant that fluoride, when added to water, should not be considered a medicine for the purposes of the Act. In this case the surrounding context includes the Medicines Regulations 1984 (the Regulations), which state that a substance will only be considered a "medicine" if the concentration of that substance exceeds 10 milligrams per litre (mg/L) (see the introduction to Schedule 1 of the Regulations).

The maximum allowable level of fluoride in domestic water supplies in New Zealand is 1.5mg/L (as provided for by New Zealand's Drinking Water Standards) - well below the concentration threshold required for a fluoride to be a medicine according to the Regulations. In light of that, Justice Collins concluded that when HFA and SSF are added to domestic water supplies at the maximum acceptable level (ie 1.5mg/L) HFA and SSF are not medicines for the purpose of the Act. He did, however, state that HFA and SSF would be medicines if they were added to water supplies in concentrations of 10mg/L or more.

Interestingly, the Crown was not entitled to costs because, according to Justice Collins, New Health advanced legitimate arguments in the public interest. It remains to be seen whether the decision not to award costs will encourage other groups to pursue similar actions in the future.

New Health has said that it will file an appeal in the next few weeks.

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