Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health

Submission on proposed amendment to the regulations (Medicines Regulations 1984) made under the Medicines Act 1981, that Fluoride-containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purposes of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.

Submitter: Fluoridegate Legal Action NZ (FGLANZ)

Prepared by: BSc, LLB(Hons) (Founder)

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Position: FGLANZ is opposed to proposal Question 1.

FGLANZ notes that Proposal Question 2 is a non-sequitur, as fluorine-containing compounds are not added to public water supplies to treat the water; they are added to treat human beings, hence are used as medicines. FGLANZ would be opposed to the use of fluorine compounds to treat public water supplies, due to fluorine compounds' inherent toxicity and risk to human health, and that there are already substances available to treat water for biological safety.

Fluoridegate Legal Action NZ

The organisation's role is to:

1. Pursue legal remedy to prohibit the use of the public water supply to deliver a medicine (viz. fluorides)
2. Pursue legal remedy for those harmed by water fluoridation against those responsible for implementing or promoting water fluoridation.

As such, FGLANZ represents the interests of all New Zealanders subject to, or proposed to be subject to, water fluoridation.

Note: due to the short timeframe, and bad faith timing of the submissions over the Christmas break, not all points have scientific references listed. These can be supplied upon request.

Summary

We are opposed to the proposal on the following grounds:

1. The proposal has been made in bad faith, being nothing more or less than an attempt to circumvent legal action before the Court, at the ongoing risk of the public health.
2. In making this proposal the Ministry is in breach of its obligations under section 3A of the Health Act 1956, by putting perpetuation of its failed fluoridation policy ahead of protecting the public health:

   "... the Ministry shall have the function of improving, promoting, and protecting public health."
3. The proposal undermines the purpose of the Medicines Act 1981, which is to protect the public from the inappropriate use of medicines, and to ensure the purity of medicines used to treat people (105(1)(k)).
4. The Medicines Act does not provide for exempting substances only when delivered by a certain mechanism – a substance is exempt or not, and an exempt substance's use cannot be restricted to a specific mode of delivery. Once exempt, the chemicals, with their heavy metal contaminants could be used in fluoride tablets, for example, and be exempt from the Medicines Act. We consider this totally inappropriate.
5. Fluoridating chemicals cannot be exempted unless they are first accepted as being medicines. This proposal carries the inherent admission that they are, contrary to Collins J's ruling.
6. Water fluoridation fails to meet the minimum standards of proof of effectiveness, proof of safety, proportionality of infringement on human rights and the lack of seriousness of the disease it is supposed to treat (in only about 50% of the population) to justify its practice, let alone exempting chemicals used in its practice from the Medicines Act.

The Proposal's Discourse on Water Fluoridation

Before addressing the proposal itself, it is appropriate to address the claims made in relation to fluoridation in the proposal, since the sole purpose of the proposal is to enable the Ministry of health to continue its practice of water fluoridation, against the overwhelming weight of scientific evidence, and is breach of all precepts of modern pharmacology.

The consultation document is incorrect, misleading, and a gross misrepresentation of what the Ministry is seeking to do.

I refer specifically to the misrepresentative statement:

"The benefit of the proposed amendment is that it would preserve the status quo and provide legal clarity about the regulatory status of fluoride compounds used to treat community water supplies."

Fluoride chemicals are not added to the water supply to treat the water – they are added to treat human beings for a disease – dental caries. This has been accepted since the 1940s, and was confirmed in New Health NZ v STDC.

As such they are medicines – general sale medicines under the current regime.

Proposal statement:
In New Zealand, the addition of fluoride compounds to community drinking water supplies for the purpose of preventing and reducing tooth decay is a common practice. It is supported by the Ministry of Health as well as by public health authorities, medical science bodies and international organisations such as the New Zealand Medical Association, the New Zealand Dental Association, the World Health Organization and the World Dental Federation.

Our Response:
While fluoridation affects, directly, about 50% of NZ's population, it is a practice believed in by only a tiny minority of countries and scientists around the world. As such, it is the 'fringe', not the norm.
No quorum of the WHO General Assembly has ever endorsed water fluoridation. In fact such an assembly rejected it. Fluoridation was only adopted by being surreptitiously added to an omnibus bill at the end of a WHO General Assembly session, and voted through without a quorum. This was manipulated by vested interests, as has WHO fluoridation policy ever since. It is controlled by a now four person committee, three of which are known political fluoridation promoters. Other parts of WHO disagree with fluoridation policy. For example

In a letter written as an outcome of the November 2000 "*3rd International Workshop on Fluorosis Prevention and Defluoridation of Water*", the participants agreed that their shared consensus should be presented to WHO as a basis to seriously reconsider certain parts of the "*WHO draft publication WSH/DRAFT/99.9 Fluoride in Drinking Water*" before its mass publication: "Theoretically as well as empirically, the figure [of 1.5 ppm MAV] seems to be far above the proven safety level... one can often notice that, as far as the issues of fluoride are concerned, different publications and different chapters within a publication of WHO seemed to go in different directions."

Of the 194 member states of the WHO General Assembly, only 24 practice any level of fluoridation, and only 14 fluoridate more than 20% of their population. There are more fluoridated people in the USA than the rest of the world combined. So, contrary to the proposal's claims, those who believe in

and practice fluoridation are a tiny, by powerful and vocal, minority on the world stage.

FDI (the World Dental Federation) is an industry lobby group. It promotes fluoridation in the commercial interests of its membership: superphosphate manufacturers who get paid for the toxic waste that would otherwise be costly to dispose of; fluoridation equipment manufacturers; and, in the USA and Canada at least, dentists, who make more money out of treating dental fluorosis caused by fluoridation than they make out of filling teeth, which latter they are doing increasingly in fluoridated communities. In NZ tooth decay is decreasing in unfluoridated communities while it increases in fluoridated ones (OHS 2010).

UNICEF questions both the claimed effectiveness and safety of water fluoridation. It cites fluoride as the single greatest water-borne health risk facing humanity.

The NZDA's position is controlled by its unrepresentative committee, which harasses and victimises dentists who question water fluoridation into silence. This has been demonstrated recently regarding Dr Lawrie Brett and Dr Stan Litras. Water fluoridation is NOT universally accepted by NZDA membership.

In all, endorsements are political, not scientific. Plunket, for example, point blank refuses to look at the science, stating "we support fluoridation because it is Ministry of Health policy, and will continue to support it as long as it is their policy. We are not interested in the science."

Proposal statement

There is no universal acceptance of the positive health effects of the addition of fluoride to drinking water supplies.

Response

We concur. The York Review made it clear that fluoridation is based on poor quality science. There is no demonstrable benefit of fluoridation to those over 18 years old (*Our Oral Health*, Ministry of Health, 2010, p171).

Further, information obtained under the Official Information Act from the Hawke's Bay DHB, conforms there is no benefit to the poor, as confirmed by the York Review and much subsequent research. The background to be noted here is that here was no difference in decay rates between Napier and Hastings for 50 years, until a sudden spike in Napier in 2006. The HBDHB cannot explain this. Hence the slightly higher levels of decay today in the unfluoridated areas is not due to lack of fluoride, but some other factor that appeared in 2006.

Also, these figures do not allow for a temporary delay in tooth decay, as acknowledged as a possibility by both the York Review and the 2007 NHMRC Review. If this were to be allowed for, it is unlikely there would be any differences at all.

5 yr old – European
Approximately 90% of children have 3 dmft or less, whether fluoridated or not. Only 5% have 6 dmft or more. Extreme dental decay typically equates to 10 dmft or more. The number of caries-free children is not significantly different between fluoridated and unfluoridated communities (64.18% vs 69.95% respectively)

Amongst Maori, 75% have 4 dmft or less, and 90% have 6 dmft or less. The number of caries-free children is not significantly different between fluoridated and unfluoridated communities (37.6% vs 35.2% respectively)

Year 8 figures.
These are essentially similar to the 5 year old figures. Only 1-2% of Europeans and 3 – 5 % of Maori have 6 DMFT or more.

These figures show that the real issue with oral health is focussed in a small percentage of the population, as has been confirmed by international research, and by Cuttress, de Liefde, et al *NZ Dental Journal*, September 2009, p109.

> More than 50 percent of five-year-old children in New Zealand are caries-free. For the majority of the remainder, caries affects only a few teeth, mainly small lesions. Only a very small proportion of New Zealand preschool children suffer from the rampant caries illustrated. Such cases may, however, be clustered geographically due to underlying factors such as socio-economic status and parental education.

Fluoridating the entire community to (fail to) address the problems with this tiny group is a clear waste of resource. The opportunity cost, in terms of deploying the massive political resources currently being thrown at defending this failed policy, this proposal being just one case in point, could be spent on effective programmes to address this group. These include those programmes run by the Waikato, Canterbury, and Canterbury DHBs; and the Scottish National Health Service's Childsmile programme. I am aware that a review of the NZ programmes has claimed they fail because those involved in delivering them lose interest in a relatively short time. Perhaps this is because the achievements are deliberately downplayed (thereby disheartening participants) so that fluoridation can continue to be promoted as the 'silver bullet'. Whatever the reasons, the effectiveness of these programmes shows that the issue is to keep participants motivated; not give up because it is 'too hard'. Again, if fluoridation promoters applied the same rationale they would have given up promoting fluoridation long ago.

The figures also show there is less of a gap between Maori and Europeans in the unfluoridated communities. (4% less absolute [10.5% relative] difference in 5 yr olds and 7% less absolute [44% relative] difference in year 8). This shows that, for whatever reason, fluoridation INCREASES social inequalities

in oral health, rather than decreasing them as falsely claimed by the Ministry of Health. This is also confirmed by the data in the Oral Health Survey Report 2010.

Fluoridation Policy and Practice Challenged on Scientific and Ethical grounds

A number of public health law scholars have suggested that existing public health laws be continually reevaluated in light of current scientific knowledge and evolving public notions of personal liberty and bodily integrity.

Under one proffered system of evaluation, public health laws are only justified when public health authorities are able to demonstrate: (1) a significant risk to the public health based on scientific evidence; (2) the intervention's effectiveness by showing a reasonable fit between means and ends; (3) that economic costs are reasonable; (4) that human rights burdens are reasonable; and (5) that benefits, costs, and burdens, are fairly distributed.

"[It is arguable] that under this systematic approach, compulsory water fluoridation is no longer a justifiable public health measure, and continued fluoridation schemes veer dangerously close to ongoing human research experiments without informed consent."[1]

Responses to further points in the proposal

Proposal statement

In the recent case *New Health New Zealand v Attorney-General*[1] ... the High Court dismissed the plaintiff's claim that HFA and SSF properly come within the definition of "medicine" and recommended use of regulation-making powers under the Act to exempt HFA and SSF from being medicines for the purposes of the Act.

Response

This judgment is under appeal – a fact you were obliged to disclose, since it is not a final judgment until the appeal is decided. As you are well aware, the judgment was unsound. In fact, under the medicines Act, the Minister cannot exempt a product unless it is subject to the Act in the first place. Until this unsound judgment is overturned, fluoridation chemicals cannot be exempted.

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[1] Rita F Barnett "COMPULSORY WATER FLUORIDATION: JUSTIFIABLE PUBLIC HEALTH BENEFIT OR HUMAN EXPERIMENTAL RESEARCH WITHOUT INFORMED CONSENT" 23 January 2014
Chapman University: Fowler School of Law
Available at: http://works.bepress.com/rita_barnett/3

Proposal statement

This would serve to provide greater clarity about the issue by removing any possible ambiguity and would also regularise the status quo as regards the use of HFA and SSF in water fluoridation.

Response

There is no ambiguity – fluoride supplied for a therapeutic purpose, acting pharmacologically, is a medicine. We do not understand what you mean by "regularise" in this context: the fact is the exemption is designed to create an irregularity by allowing an unapproved, untested, contaminated medicine to be administered to the population via the public water supply.

Report of the Office of the Chief Science Advisor to the Prime Minister on Fluoridation

We expect those supporting fluoridation, and the proposal, will refer to the report by the Royal Society and the Office of the Chief Science Advisor to the Prime Minister. We note that this report has received unfavourable international review, and exposed as an unscientific, unreliable, politically motivated document. Most importantly, emails obtained under the Official Information Act reveal that no analysis was done on health risks from fluoridation, as the literature was considered "too vast and complex". The Report simply regurgitated the denials of international reviews conducted by pro-fluoridation organisations such as the NHMRC of Australia, while ignoring the NRC Review, and denying or artificially downplaying major research and reviews such as that of Bassin and Choi. Accordingly, this report cannot be relied on for scientific evidence. It was produced for political reasons to a political timeframe, as those emails show.

The Proposal

We therefore oppose the proposed misuse of regulatory authority to exempt fluoridation chemicals from being medicines under the Medicines Act purely to enable the Ministry of Health to pursue this unproven (as the proposal document admits) policy of water fluoridation.

There is no medical or scientific justification for exempting silicofluorides from being medicines under the Medicines Act 1981.
The only reason this is being proposed is political – the Ministry wants to continue to add contaminated industrial waste grade product to the water supply for the purpose of mass medication. This is a 'bad faith' proposal.

The problem with the proposed amendment is that it will allow the indiscriminate application of a medicine to the public to continue, using toxic, contaminated waste products.

Water fluoridation breaches all tenets of modern pharmacology, which are to give the right dose to the right person at the right time. It is axiomatic that the water supply should never be used to deliver a substance for a therapeutic purpose. This is why the Netherland amended its Constitution to ban such a practice in the 1970s.

There is no precedent for exempting a substance intended to be ingested from being a medicine. All current exemptions are for topical application or mouth rinses.

Of key importance is the requirement under the Medicines Act that a medicine meet certain purity standards. Exemption of silicofluorides would be completely contrary to the intention of the Medicines Act unless the chemicals added to the public water supply were required to meet the normal purity standards as a requirement. This, of course, would make them too expensive to use in water fluoridation. Allowing these industrial waste grade products to be used under an exemption would establish that the Ministry is more concerned with protecting fluoridation policy than it is with protecting the public's health and safety, contrary to its statutory duty under section 3A of the Health Act 1956.

Allowing these industrial waste grade products to be used under an exemption would establish that the Ministry is more concerned with protecting fluoridation policy than it is with protecting the public's health and safety, contrary to its statutory duty under section 3 of the Health Act 1956. Paragraph a repeat of previous paragraph

The arsenic contamination of the chemicals used will, on the currently accepted and internationally listed cancer risk factor for Arsenic result in 1.1 cancer deaths per year in New Zealand.
The calculation is as follows:

0.645µg/l x 1.5 litres/day x 3.5 x 10^{-5} x 4.4 x 10^{6} x 52% / 70 years = 1.1 deaths/year

Using cancer risk factors for Arsenic supplied by the Ministry of Health the situation is even worse. The Ministry refers to the WHO document "Arsenic in Drinking-water - Background document for development of WHO *Guidelines for Drinking-water Quality*" World Health Organization 2011, which cites the combined risk factor for skin and bladder cancers from Arsenic at the MAV of 10 µg/litre, as 12 – 18 per 10,000 in males and 14 – 23 per 10,000 in females. These are lifetime risk figures.
If we use 15/10,000 as a representative figure and apply this to NZ, we get 94 deaths per year at the MAV (15/10,000/70 yrs * 4.4 million = 94/yr).

Dr Mackie, who supplied this information, tries to deny this risk factor by citing Section 13.4.7 of its *Guidelines for Drinking-Water Quality, 2nd edition,* which gives the estimated excess lifetime risk of skin cancer associated with exposure to the MAV as 6 x 10^{-4}. But this was only for skin cancer, not both

cancers combined. Do deaths from bladder cancer not count, while deaths from skin cancer do?

On this basis the expected cancer deaths per year from Arsenic contamination of fluoridation chemicals would be 3.2:

$15 \times 10^{-4} \times 4.4 \times 10^{6} \times 52\% / 70/10 \times 0.645 \mu g/l = 3.2$ deaths per year

The Ministry cannot deny this, as Dr Mackie admits the Ministry has never calculated the cancer risk from Arsenic in water supplies.

Silicofluorides are also contaminated with lead. As reported in the NZ Listener, research (initially conducted overseas but repeated in NZ) shows that following the removal of lead from petrol (a move opposed by the NZ Ministry of Health and the Royal Society) crime rates decreased. Lead's neurotoxicity is known specifically to be related to crime, and especially violent crime. The influence was shown to be Lead neurotoxicity during infancy, when bottle-fed infants will be exposed to elevated lead levels from fluoridated water, resulting in criminal behaviour in early adulthood, 20 years later.

Not only are silicofluorides contaminated with Lead, but they cause increased absorption of Lead through the digestive system[2] – a double risk.

The form of the proposed exemption

Key point: the way the exemption is proposed simply identifies a class of chemicals. It does not, and under the legislation cannot, restrict the exemption to the use of water fluoridation.

PROPOSAL: Fluoride-containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silicofluoride (SSF) are not medicines for the purposes of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies (emphasis added).

We turn first to the wording, which is incorrect and ambiguous

"when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies"

This is badly worded. It can have alternate interpretations:

1. Manufactured for the purpose of fluoridating community water supplies

And either

a. Supplied for the purpose of fluoridating community water supplies; or
b. distributed for the purpose of fluoridating community water supplies

[2] Masters and Coplan 1999

2. Manufactured

And either

c. Supplied for the purpose of fluoridating community water supplies; or
d. distributed for the purpose of fluoridating community water supplies

While HFA is manufactured, it is not manufactured for the purpose of fluoridating community water supplies. It is a spontaneously occurring waste product of the fertiliser industry that is manufactured whether it is subsequently used in water fluoridation or not. Consequently, depending on interpretation, it does or does not fall within the proposed exemption.

Under this proposal, a manufacturer could theoretically manufacture Prozac 'for the purpose of water fluoridation', and it would be exempt from the Medicines Act. The fact that it is not used in water fluoridation would not matter, as the proposal is worded.

Regulation 105(i) states: specifying, by name or description, substances or articles, or kinds or classes of substances or articles, that are, or are not, medicines or medical devices for the purposes of this Act:

1. This does not allow for a substance to be a medicine in some circumstances but not in others - a substance is either a medicine under the Act or it is not.

2. This does not allow for a substance already classified as a medicine to be exempted from being a medicine when put in the public water supply – a substance is either a medicine under the Act or it is not.

Discussion

The regulatory power exempts the substance itself. It does not exempt a substance based on it mode of delivery.

Consequently, Sodium Fluoride, which is currently a regulated (pharmacy only) medicine when used to make fluoride tablets, recommended to be used by dissolving in water, will not be a medicine either when added to the public water supply for the same purpose – to treat human beings for dental caries – and no longer a medicine when used in fluoride tablets, if the term "chemicals used to fluoridate public water supplies" is used.

If HFA and SSF are specifically named, this will avoid the issue of Sodium Fluoride. But, once SiFs are exempt, they can be used in fluoride tablets and not be medicines. Sodium Fluoride tablets would still be medicine. Such an anomaly is clearly preposterous.

Inconsistency with current exemptions

The current exemptions apply to products intended to contact the surface of the body only; not be ingested. These are products that would not normally be thought of as medicines.

This exemption would be the first for a medicine intended to be swallowed, with a pharmacological exposure to the whole body. Firstly, for the Ministry to meet its obligations under Section 3A of the Health Act 1956, such a product would have to have been proven safe by the highest standard of science (double blind, random control studies), to all members of the community regardless of age, health, or daily dosage (some people drink 10 – 12 litres of water a day, or 7 – 8 mg fluoride per day, well into the level that can cause Stage I or Stage II, and possibly Stage III skeletal fluorosis, not to mention other adverse effects identified by the NRC Review 2006). Such studies have never been conducted, despite the rhetoric of the Ministry of Health.

There would have to be proof that no one was hypersensitive to fluoride – yet there are well-documented medical case histories as well as random control and epidemiological studies showing that there are hypersensitive individuals, who suffer extreme health distress from fluoride exposure through the drinking water.

In reviewing the basis for the previous exemptions, we see that (quotes from relevant briefing papers):

- These were 'related products' under the Act, not medicines:
  > "A number of products are currently regulated as 'related products' under the Medicines Act. This results in an overly rigorous assessment of products that are relatively low risk."
- The safety of the products used was not a concern (unlike fluoride compounds used in water fluoridation)
- NZ was unique in classifying the products as medicines, leading to unwarranted compliance costs and delays in bringing new products to market (there is no proposal to bring new fluoridation chemicals to market)
  > "Pre-market approval of new products and notification of changes to existing products is required for related products. Product manufacturers and distributors find the requirements onerous, particularly given the low-risk nature of the products, the number of different variants marketed and the rapidity with which changes are made."
  >
  > "This legislative framework is nearly 30 years out of date and is in need of updating to ensure that it safeguards consumers while not placing unnecessary barriers in the way of innovation in the health sector."
- One of the reasons was increased workload for the regulator, with no significant impact on public health and safety

Note that fluoride toothpaste as a product was exempted; not the fluoride chemicals used in the toothpaste. The equivalent in relation to the current

proposal would be to exempt fluoridated water. That would be an acceptance that fluoridated water is a medicine (that needs exempting).

In contrast to the exemption of 'related products', fluorides added to the water supply are medicines, not 'related products'. For example, in the USA, under the Food, Drug, and Cosmetic Act (FD&C Act), the Department of Health and Human Services, which includes the Food and Drug Administration (HHS/FDA) are responsible for regulating drugs – which include any substances designed to treat, prevent or mitigate disease. Under this Act HHS and FDA are required to regulate such drugs for both safety and effectiveness when they are deliberately added to public drinking water. This is confirmed by the US EPA, which sets MAVs for drinking water contaminants. The FDA has consistently refused to perform this statutory duty. The US is still operating under the unprotective MCLG and MCL, determined in 1986, as the EPA has failed to update these with the latest science in spite of commissioning the NRC review, which reported in 2006.

Under EU legislation, fluoridated water is a 'functional food', hence a medicine.

Further, there appears no possible rationale under the purposes of the Medicines Act to exempt fluorides. The purpose of the Act is to safeguard the population from the improper use of medicines, and ensure their safety, efficacy, and purity. The proposal seeks to remove all those safeguards by allowing a contaminated industrial waste product to be used indiscriminately as a medicine by placing it in the public water supply without any of those safeguards applying. The only reason for this proposal is to bypass all safety standards, and all principles of modern pharmacology, to enable the Ministry to pursue its failed policy of water fluoridation.

Low Risk a Key Factor in Current Exemptions

In the briefings to the Minister of Health proposing the current exemptions, one of the key themes was the importance of the fact that the products formed no risk to the public health, and that the key purpose of the medicines Act was to protect the public health from the improper use of medicines. These two points are repeated in a number of places.

Silicofluorides have never been tested for human health safety. While the Ministry promotes the overly-simplistic position that the silicofluorides break down completely to give free fluoride ions, this is rejected by the US EPA. Further, the ions are still present to act synergistically, and to recombine into the molecular form, which they do in the acid conditions of the stomach. WHO states that 40% of ingested fluoride is absorbed in the stomach as molecular hydrofluoric acid. Research by Westendorf; and Masters, Coplan, and others, show that silicofluoride have a different physiological effect than Sodium Fluoride or Calcium Fluoride.

As discussed above, one of the key issues with fluorides, and especially silicofluorides, is that not only do the chemicals themselves pose a real risk to

the public health, but the technical grade industrial waste product used in water fluoridation contains heavy metal impurities that also pose health risks.

So the current proposal is to exempt a dangerous chemical being used indiscriminately as a medicine by dosing the public water supply with it, thereby exempting it from the normal purity requirements designed to protect the public health, so that the Ministry can continue to promote the addition of toxic waste products contaminated with heavy metals to the public water supply when they would never, in that form of impurity, be allowed to be sold as medicines under the Act. This is called 'normalising" the practice in the proposal – doublespeak if there was ever a classic example of it.

Proposal Regarding Prescribing Medication

At the same time as the exemptions were proposed, there was also a proposal that for a doctor to prescribe a medicine, not only should the patient be 'under the care' of that doctor, but that the patient should be in New Zealand at the time of prescription, or normally resident but temporarily overseas at that time.

Submissions included a requirement for a face-to-face consultation, and adherence to the Medical Council's rules in relation to prescribing. There was also a suggestion that such requirement might need to be reviewed where telemedicine enabled remote physical examination of the patient to occur.

All these suggestions focus on the need for a personal connection between the prescribing medical professional and the patient. This is in stark contrast to the situation with water fluoridation, where:

- There is NO face-to-face examination of the patient
- The patient's history is not known
- There is no monitoring of side effects (because the Ministry claims fluoride is the only substance in the world that does not produce side effects in anyone, in spite of compelling evidence to the contrary.)

The proposal was not proceeded with, as the Ministry decided to do more policy work on this. However, the real concerns show how inappropriate it is to deliver a medicine indiscriminately through the water supply, and how it would be equally inappropriate to exempt such medicine from the Medicines Act in light of the key purpose of protecting the public health from such abuses.

Appendix 1 – Current Exemptions

Part 12
Miscellaneous

58ASubstances that are not medicines or related products for purposes of Act

- (1)The following classes of substances are not medicines or related products for the purposes of the Act:
  - (a)dentifrice products, provided that—
    - (i)the dentifrice product does not contain a medicine specified in Schedule 1; and
    - (ii)the dentifrice product is not claimed to be for use in relation to any therapeutic purpose other than one or both of the following:
      - (A)preventing dental decay:
      - (B)improving oral hygiene:
  - (b)anti-dandruff hair products, provided that—
    - (i)the hair product does not contain a medicine specified in Schedule 1; and
    - (ii)the hair product is not claimed to be for use in relation to any therapeutic purpose except controlling dandruff; and
    - (iii)the hair product is claimed to be effective through cleansing, moisturising, exfoliating, or drying the scalp and not through any other process:
  - (c)anti-acne skin care products, provided that—
    - (i)the skin care product does not contain a medicine specified in Schedule 1; and
    - (ii)the skin care product is not claimed to be for use in relation to any therapeutic purpose except preventing acne; and
    - (iii)the skin care product is claimed to be effective through cleansing, moisturising, exfoliating, or drying the skin and not through any other process:
  - (d)barrier cream products, provided that—
    - (i)the barrier cream product does not contain a medicine specified in Schedule 1; and
    - (ii)the barrier cream product is not claimed to be for use in relation to any therapeutic purpose except preventing nappy rash; and
    - (iii)the barrier cream product is claimed to be effective through providing a barrier to the transmission of moisture and not through any other process:

- (e)anti-bacterial skin products, provided that—
  - (i)the product does not contain a medicine specified in Schedule 1; and
  - (ii)the product is not claimed to be for use in relation to any therapeutic purpose except preventing the spread of bacteria (but not a named bacterium); and
  - (iii)the product is not presented as being for use in connection with—
    - (A)any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or
    - (B)either of the procedures specified in subclause (2); and
  - (iv)the product is not recommended for use in connection with the provision of health services (as defined in section 2 of the Health and Disability Commissioner Act 1994).

(2)The procedures referred to in subclause (1)(e)(iii)(B) are—

- (a)piercing the skin or mucous membrane for any purpose; and
- (b)venipuncture, or the delivery of an injection.

Appendix 2 – Extracts from Previous Exemption Briefing Documents (attached)

Regulations under the medicinces Act 1981 Consultation
: askmedsafe 04/01/2015 08:24 p.m.

History: This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:

Email:

Address:

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission.

Fluoride

⁄: askmedsafe 04/01/2015 08:30 p.m.

History: This message has been replied to.

Hi, This is for the Fluoride Submission:

I do give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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Name
Email
Address

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak for my submission.

Thanks

This email has been checked for viruses by Avast antivirus software.
www.avast.com

654

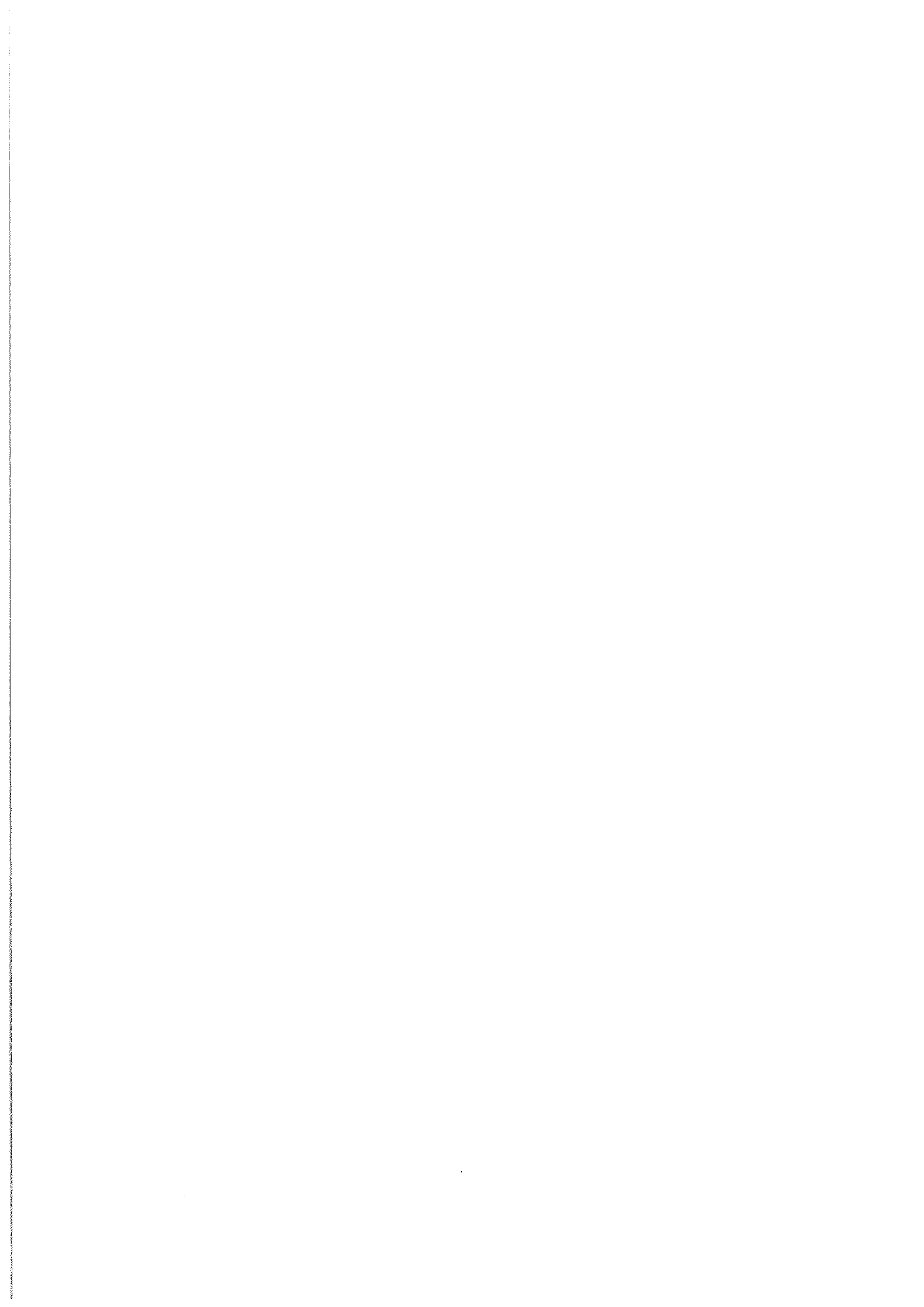
SUBMISSION FORM

Regulations regarding Fluoride

Consultation on Proposed Amendment to Regulations under the Medicines Act 1981.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer of community drinking water and tax payer.
Question 1 *Do you support the proposed amendment? If not, why not?*	Yes. I support enabling fluoride treatment of drinking water for public health benefits.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	No comment.

◉ I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.



Fluoride
): askmedsafe 04/01/2015 09:10 p.m.
Cc: j.coleman

History: This message has been replied to.

Dear Medsafe

SUBMISSION ON PROPOSAL THAT HFA AND SSF ARE NOT MEDICINES FOR THE PURPOSES OF THE MEDICINES ACT WHEN THEY ARE MANUFACTURED AND SUPPLIED OR DISTRIBUTED FOR THE PURPOSE OF FLUORIDATING COMMUNITY WATER SUPPLIES

QUESTION 1: DO YOU SUPPORT THE PROPOSED AMENDMENT? IF NOT, WHY NOT?

ANSWER TO QUESTION 1

I oppose the proposed amendment for the following reasons:

1 = No Regulation should be made exempting HFA and SSF from being medicines until the Court of Appeal has determined whether or not HFA and SSF are medicines under the Medicines Act.

2 = If HFA and SSF are medicines they should not be exempt from the Medicines Act.

3 = If HFA and SSF are not medicines there is no need for the exemption.

4 = The Medicines Act is designed to ensure the safety, quality and efficacy of medicines. HFA and SSF should be subject to these controls.

5 = These controls will ensure that people are not exposed to uncontrolled doses of fluoride from an industrial grade and heavy-metal contaminated fluoride substance.

6 = If fluoride tablets are not recommended for babies, toddlers and pregnant women, these sub-populations should not be ingesting fluoridated water.

7 = No protection against dental decay is provided by swallowing fluoride; consequently HFA and SSF should not be swallowed.

8 = Those people who believe there is a benefit in ingesting fluoride can buy sodium fluoride tablets from a pharmacy.

QUESTION 2: ARE THERE ANY OTHER FLUORIDE-CONTAINING COMPOUNDS USED TO TREAT COMMUNITY WATER SUPPLIES THAT SHOULD BE SPECIFICALLY IN THE REGULATION? IF SO, WHAT ARE THEY?

ANSWER TO QUESTION 2: NO.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

Although this is a pasted response, it states what I wish and that is that water supplies should not have added fluoride, those who desire and are able to tolerate fluoride can purchase their own supply so those of us who cannot tolerate ingesting this substance are able to continue to consume water from our taps without negative impact on our health.

Yours faithfully

656

Fluoride Submission on Proposed Amendment to Regulations under the Medicines Act 1981

to: askmedsafe

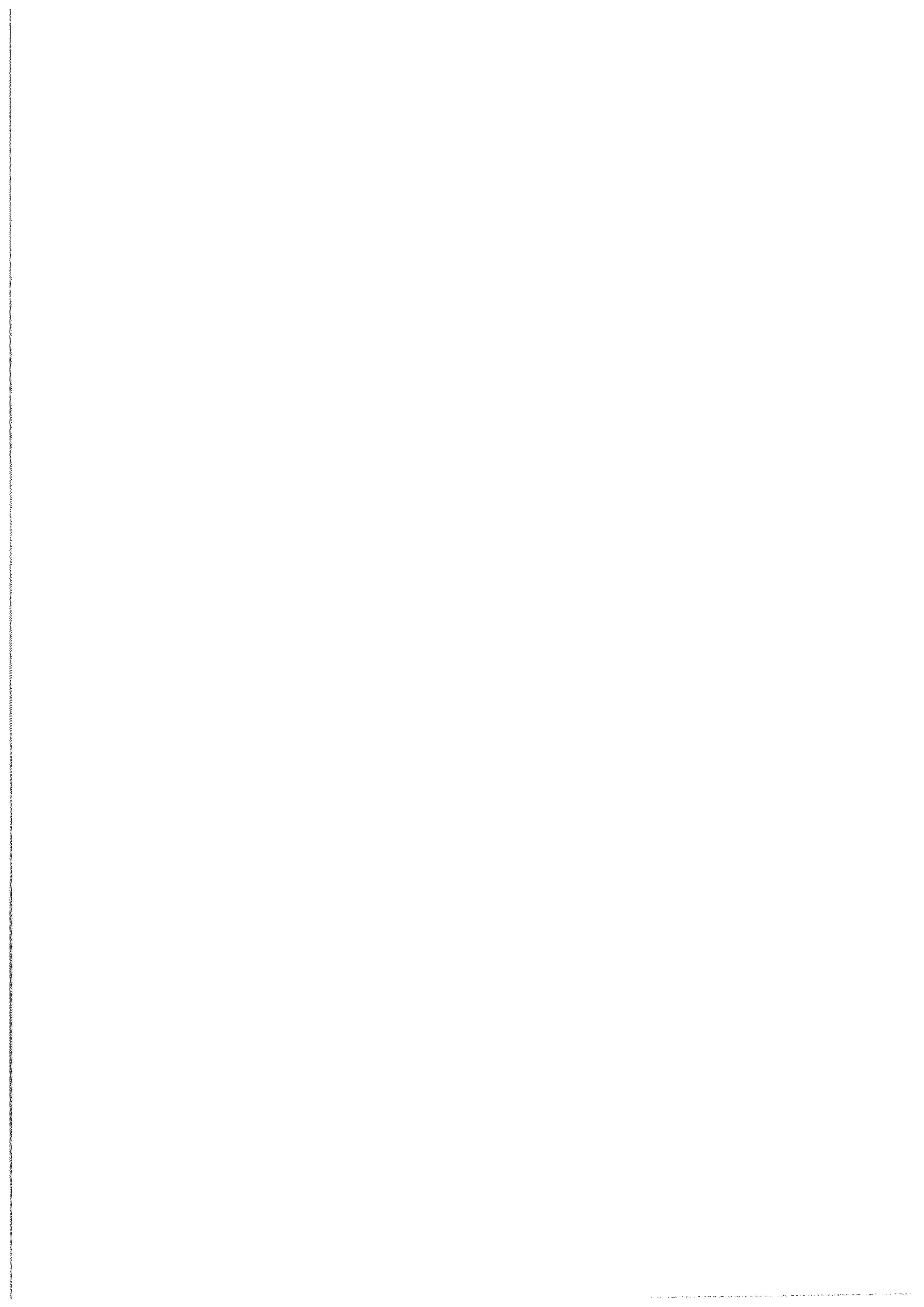
04/01/2015 09:37 p.m.

History: This message has been replied to.

Question 1: I do not support the proposed amendment. People should not be forced to drink additives where it is not proven that it is safe to do so. You could be forcing diseases on the whole of the population just because of the small minority of fizzy drinkers who are suffering from tooth decay. This in fact represents a failure from the Ministry of Health in educating the population on the danger of sweetened drinks which are not only causing tooth decay but an obesity and diabetes epidemic. It would be a much better idea to fluoridate fizzy drinks as the heavy drinkers of fizzy do not even drink water so wouldn't even receive any perceived benefit of water fluoridation. A sugar tax would be another good option which would not endanger the entire population. The revenue could be used to promote better nutrition education such as the previous government's healthy tuck shops in schools campaign.

Question 2: No fluoride-containing compounds should be added to public water supplies.

Thank you for your consideration of my submission.



SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer
Question 1 *Do you support the proposed amendment? If not, why not?*	Yes.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	Please word the regulation to allow other fluoride-containing compounds with similar properties, perhaps as approved by the FDA , UK and Aus testing bodies as well as NZ.

Please note that all correspondence may be requested by any member of the public under

the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

✓ ☐ I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Submission on HFA and SSF

askmedsafe, j.coleman 05/01/2015 07:54 a.m.

History: This message has been replied to.

Dear Medsafe

SUBMISSION ON PROPOSAL THAT HFA AND SSF ARE NOT MEDICINES FOR THE PURPOSES OF THE MEDICINES ACT WHEN THEY ARE MANUFACTURED AND SUPPLIED OR DISTRIBUTED FOR THE PURPOSE OF FLUORIDATING COMMUNITY WATER SUPPLIES

QUESTION 1: DO YOU SUPPORT THE PROPOSED AMENDMENT? IF NOT, WHY NOT?

ANSWER TO QUESTION 1

I oppose the proposed amendment for the following reasons:

1 = No Regulation should be made exempting HFA and SSF from being medicines until the Court of Appeal has determined whether or not HFA and SSF are medicines under the Medicines Act.

2 = If HFA and SSF are medicines they should not be exempt from the Medicines Act.

3 = If HFA and SSF are not medicines there is no need for the exemption.

4 = The Medicines Act is designed to ensure the safety, quality and efficacy of medicines. HFA and SSF should be subject to these controls.

5 = These controls will ensure that people are not exposed to uncontrolled doses of fluoride from an industrial grade and heavy-metal contaminated fluoride substance.

6 = If fluoride tablets are not recommended for babies, toddlers and pregnant women, these sub-populations should not be ingesting fluoridated water.

7 = No protection against dental decay is provided by swallowing fluoride; consequently HFA and SSF should not be swallowed.

8 = Those people who believe there is a benefit in ingesting fluoride can buy sodium fluoride tablets from a pharmacy.

QUESTION 2: ARE THERE ANY OTHER FLUORIDE-CONTAINING COMPOUNDS USED TO TREAT COMMUNITY WATER SUPPLIES THAT SHOULD BE SPECIFICALLY IN THE REGULATION? IF SO, WHAT ARE THEY?

ANSWER TO QUESTION 2: NO.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

Yours,

--

659

Fluoride

askmedsafe@moh.govt.nz 05/01/2015 08:49 a.m.

History: This message has been replied to.

Dear Sir/Madam,

SUBMISSION TO 'Regulations under the Medicines Act 1981 Consultation' by Medsafe, Ministry of Health

Q1: I support the proposed changes to clarify that -
Fluoride-containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purposes of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.

Q2: Not that I am aware of.

Thank you for considering my submission.

Yours sincerely

Sent from my iPhone

Fluoride

ɔ: askmedsafe 05/01/2015 09:12 a.m.

Cc: j.coleman

History: This message has been replied to.

Dear Medsafe

SUBMISSION ON PROPOSAL THAT HFA AND SSF ARE NOT MEDICINES FOR THE PURPOSES OF THE MEDICINES ACT WHEN THEY ARE MANUFACTURED AND SUPPLIED OR DISTRIBUTED FOR THE PURPOSE OF FLUORIDATING COMMUNITY WATER SUPPLIES

QUESTION 1: DO YOU SUPPORT THE PROPOSED AMENDMENT? IF NOT, WHY NOT?

ANSWER TO QUESTION 1

I oppose the proposed amendment for the following reasons:

1 = No Regulation should be made exempting HFA and SSF from being medicines until the Court of Appeal has determined whether or not HFA and SSF are medicines under the Medicines Act.

2 = If HFA and SSF are medicines they should not be exempt from the Medicines Act.

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4 = The Medicines Act is designed to ensure the safety, quality and efficacy of medicines. HFA and SSF should be subject to these controls.

5 = These controls will ensure that people are not exposed to uncontrolled doses of fluoride from an industrial grade and heavy-metal contaminated fluoride substance.

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7 = No protection against dental decay is provided by swallowing fluoride; consequently HFA and SSF should not be swallowed.

8 = Those people who believe there is a benefit in ingesting fluoride can buy sodium fluoride tablets from a pharmacy.

QUESTION 2: ARE THERE ANY OTHER FLUORIDE-CONTAINING COMPOUNDS USED TO TREAT COMMUNITY WATER SUPPLIES THAT SHOULD BE SPECIFICALLY IN THE REGULATION? IF SO, WHAT ARE THEY?

ANSWER TO QUESTION 2: NO.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

Yours sincerel:

PS 1. I am very careful of my personal water supply and what I am ingesting. I do not want to be the subject of indiscriminate mass medication, thank you!

2. I am equally concerned at undemocratic government behaviour in attempting to circumvent a due legal process.

Canterbury
District Health Board
Te Poari Hauora ō Waitaha

Submission from

Canterbury District Health Board

January 2015

Consultation on Proposed Amendment to Regulations under the Medicines Act 1981

Introduction:

The Canterbury District Health Board (CDHB) welcomes the opportunity to comment on the proposed amendment to regulations under the Medicines Act 1981. The reasons for making this submission are to promote the reduction of adverse environmental effects on the health of people and communities and to improve, promote and protect their health pursuant to the New Zealand Public Health and Disability Act 2000 and the Health Act 1956. The CDHB's vision is to promote, enhance and facilitate the health and wellbeing of the people of the Canterbury District.

Specific comments and recommendations:

It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride-containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purposes of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.

Question 1

Do you support the proposed amendment?

The Canterbury District Health Board supports the proposed amendment to the Medicines Regulations.

The Board recognises that water fluoridation has been carried out in New Zealand since 1954, there have been recent reviews of the safety and effectiveness of community water fluoridation, and the proposed amendments remove ambiguity and would regularise the status quo as regards the use of fluoride compounds in community water fluoridation.

Question 2

Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

The Canterbury District Health Board notes that the proposed amendments do not specifically list sodium fluoride as a compound that may be used to treat community water supplies.

The Board understands that sodium fluoride is not the preferred compound for use in community water fluoridation but that it may be used in small water systems. As such, the Board recommends that it should be specifically named in the amendment for the sake of completeness and clarity.

Conclusion

Any further clarification on this submission is welcomed. We would also welcome the opportunity to work in partnership with the Ministry of Health on health issues that arise from the proposed amendment to regulations under the Medicines Act 1981.

Details of Submission

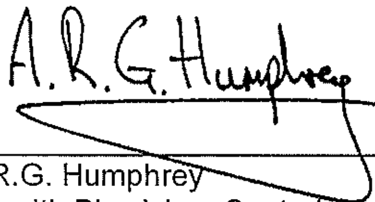
Person Making Submission
Dr. Alistair Humphrey MPH FAFPHM FRACGP
Public Health Physician

Postal Address
Community and Public Health
Canterbury District Health Board
PO Box 1475
Christchurch 8140

Phone (03) 379 9480 **Fax** (03) 379 6125

Contact Person for this application: Emma Kenagy

Email: emma.kenagy@cdhb.health.nz



Date: 22nd December 2014

Alistair R.G. Humphrey
Public health Physician, Canterbury District Health Board

FLouride

L , to: 'askmedsafe@moh.govt.nz' 05/01/2015 10:27 a.m.

History: This message has been replied to.

Totally agree with new proposed amendment, as a dental therapist/hygienist I see the benefits of fluoride for a greater population in my everyday work. I

Legal Disclaimer

SUBMISSION FORM
to: askmedsafe 05/01/2015 11:02 a.m.

History: This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name: I
Email: i

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission.

1~~407~~
6604

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

~~I do~~ / do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

~~I do~~ / do not (delete whichever does not apply) wish to speak to my submission

"It is proposed that a new regulation be made under section 105(1)(i) that:
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Name:

Email:

Address:

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NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

Post to:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz

665

Regulations under the Medicines Act 1981 Consultation
to: askmedsafe 05/01/2015 11:34 a.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
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Name: '

Email: |

Address:

Question 1. Do you support the proposed amendment? If not why not?

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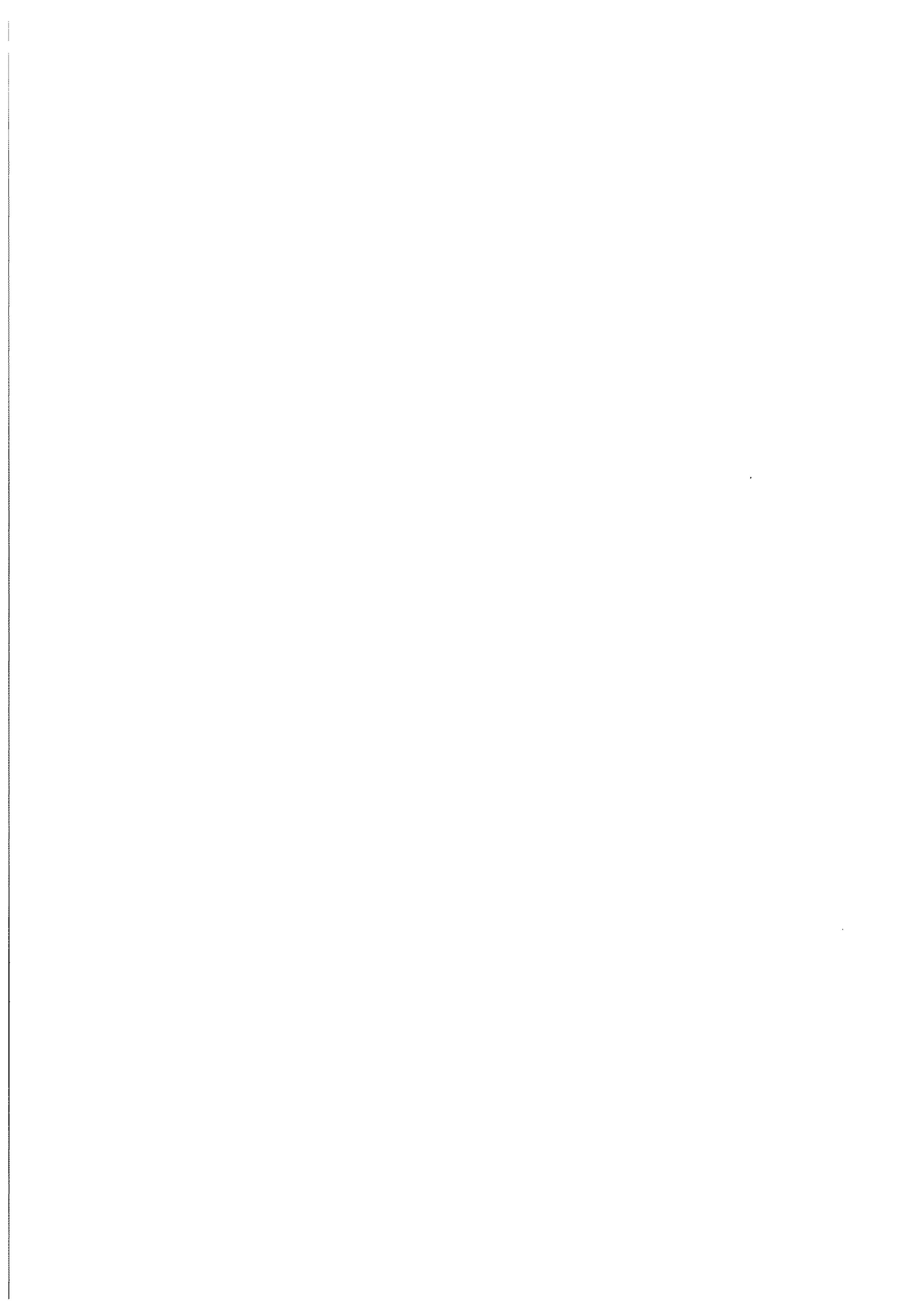

data on Fluoride
C skmedsafe@moh.govt.nz 05/01/2015 11:59 a.m.
Please respond to
History: This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982
Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)
"It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe
Name:
Email:
Address:
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1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines
Fluoride in the body rises constantly with age and there is even one excellent book named for this effect: "Fluoride The Aging Factor" by Dr. John Yiamouyiannis [ISBN 0-913571-03-2]. Fluoride increases in the bones with age and all the effects of aging leading to immune system dysfunction and death track the retention of fluoride in the human body. Yianouyiannis and others have picked up on this effect.

The industrial age has brought on a huge rise in the levels of fluoride in the air, water, and food supplies. Persons like German doctor Waldbott were some of the first to begin to point out the problems of fluoride. One of his books even presents the issue as the Dilemma: "Fluoride The Great Dilemma" by George Waldbott, MD [ISBN 0-87291-097-0] with foreword by Alton Ochsner, MD. .

Fluoride has been used as a pesticide for centuries and when looks for the method of which it kills bugs one quickly discovers the mechanism involves the upsetting of trace metal metabolism within cells. In insecticide uses, higher concentrations are applied, but when these same poisons enter the human food chain these same effects happen, only more slowly. Every human on the face of planet Earth is affected by this fluoride effect, some more that others depending on geographic, food consumption, industry, and water pollution. Fluoride is cumulative from even the subtlest levels taken in by human consumption.

The key to understanding the most damaging effect of fluoride is to know about these trace metal upsets that control enzyme repairs and other processes within cells. Upsets in these trace metals occur due to the fact that fluorine is the most electronegative element and when present within the body will cease onto trace metals spontaneously. This effect keeps these trace metals from being able to do their essential uses with the body and cells. This effect leads to rise in cell damages, higher levels of oxidation like damage to DNA, rises in the cytokine levels, loss of immune system tolerance in detection and elimination of varied pathogens, etc.

The problems associated with fluoride don't stop with the metals-complex issues, as fluoride damage thyroid hormone due to iodine like valence effects, it damages the pineal gland and the melatonin / serotonin hormones, it contributes to arterial plaque, it upsets many of the immune cells like macrophage energy, it associates to heart attacks, kidney damage, and etc. If there were one element that was associated with the God of the Underground, Death, and Hell; it would be fluorine.

Fluoride effects are directly related to loss of IQ in children and the dumbing down of the population that makes them easier to lead. Fluoride effects linked to aluminum are linked to the passage of aluminum across the blood-brain-barrier that is linked with Alzheimer's effects. Fluorides complex with aluminum to form G-protein like substances that are able to permanently upset cell bonding sites. Fluorides increase the retention of toxic metals in the body and lower the retention of beneficial trace metals, and this is a death keel to essential enzyme processes.

Fluoride taken into the stomach is converted by the stomach acid to hydrofluoric acid, which is highly absorbed into the body and highly retained. It is a cumulative effect. The effect is most pronounced in rodents that consume bones that highly concentrate fluorine from the environment.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

askmedsafe 05/01/2015 12:33 p.m.

History: This message has been replied to.

0 NOT

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 . Fluoride (2014)

I DO NOT give permission for my personal details to be released to persons under the Official Information Act 1982

.It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.. Medsafe

Name

Email:

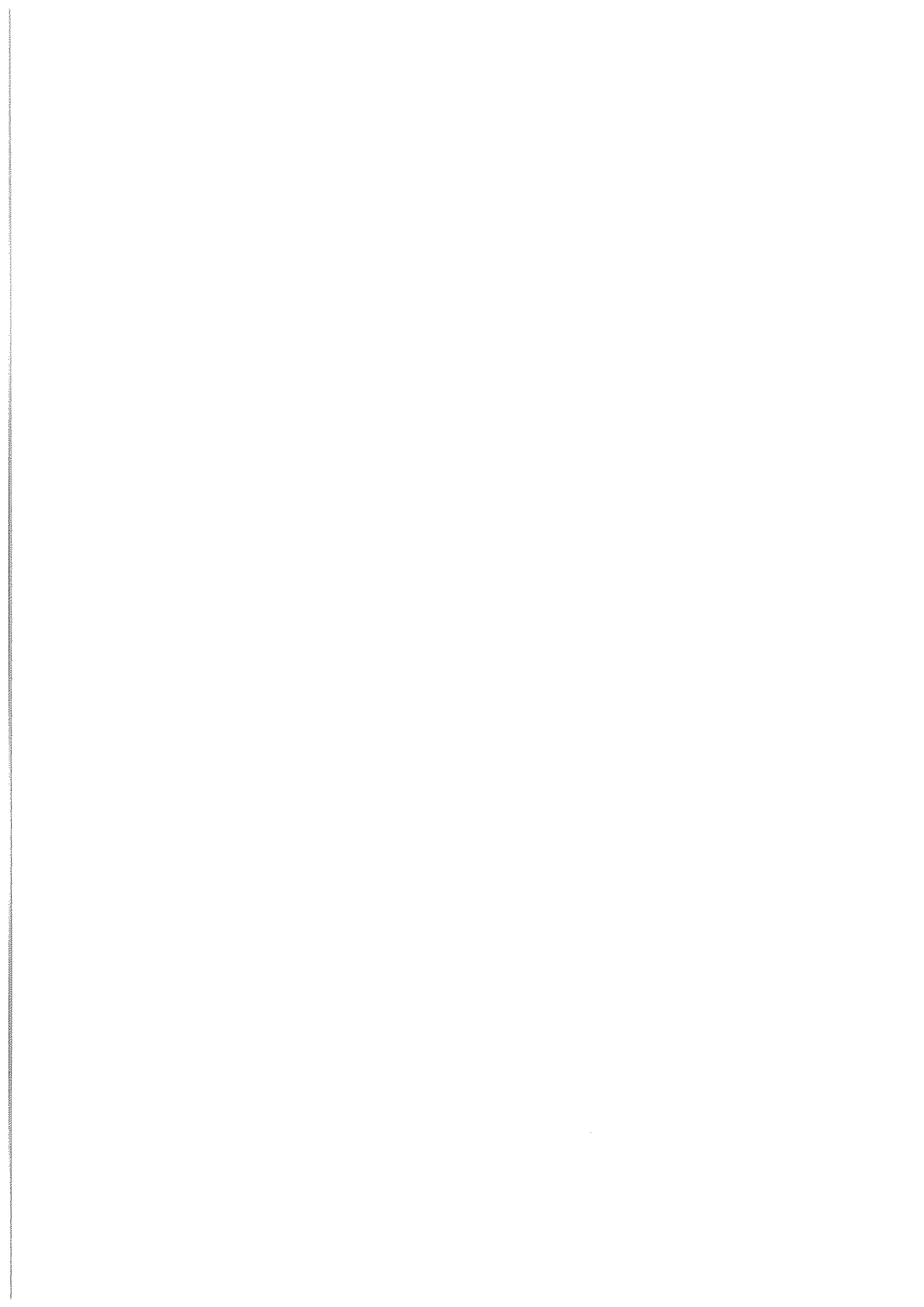
Address:

Question 1. Do you support the proposed amendment? If not why not?

NO. I DO NOT support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to .first do no harm.
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines.
5. Fluoride is an industrial wast product and has not place in the drinking water supply.
6. There is no possible moral or ethical basis for mass medication. Why should I be forced to take this "medication" because other people rot their teeth with sugary drinks and food?

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people.



***Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)**

n to: askmedsafe@moh.govt.nz 05/01/2015 12:34 p.m.

History: This message has been replied to.

*I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:

Email: f

Address:

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NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people.

Thank you

Submission on Proposed Medicines Act 1981 - Fluoride
to: askmedsafe 05/01/2015 12:44 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

"It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:

Email:

Address:

Question 1. Do you support the proposed amendment? If not why not?

1. **I do not support the proposed amendment because:**

   1. Fluoride is not a water treatment like chlorine

   2. Fluoride is added to the water as treatment for the disease of dental caries, therefore it is a medicine

   3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

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Email to: askmedsafe@moh.govt.nz

Submission on Proposed Medicines Act 1981 - Fluoride.docx

Fluoride

, ..._..... .o: askmedsafe 05/01/2015 12:57 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
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1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name

Email:

Address:

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
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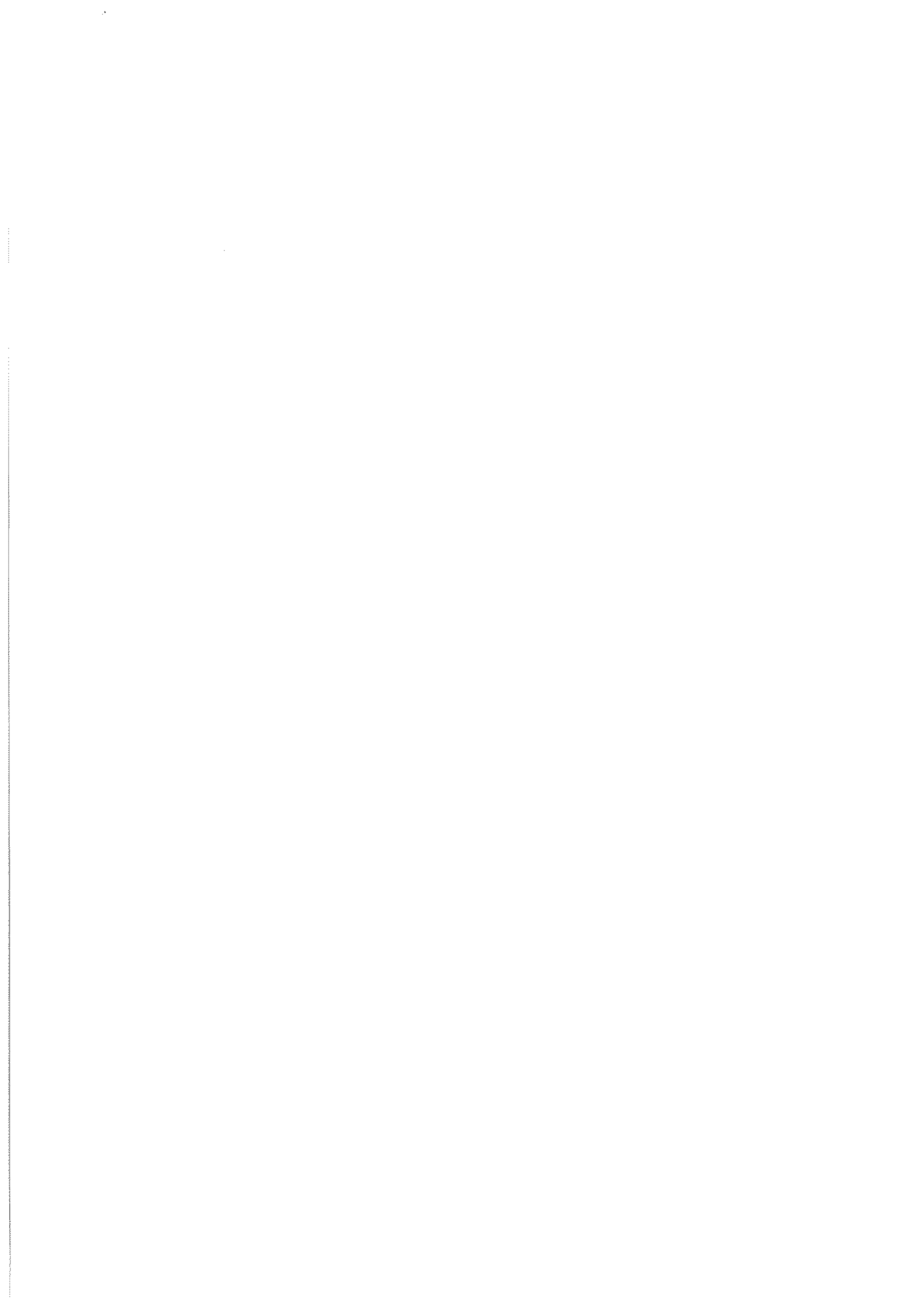
NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

Post to:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz



Fluoride

to: askmedsafe 05/01/2015 01:14 p.m.

History: This message has been replied to.

Dear Medsafe

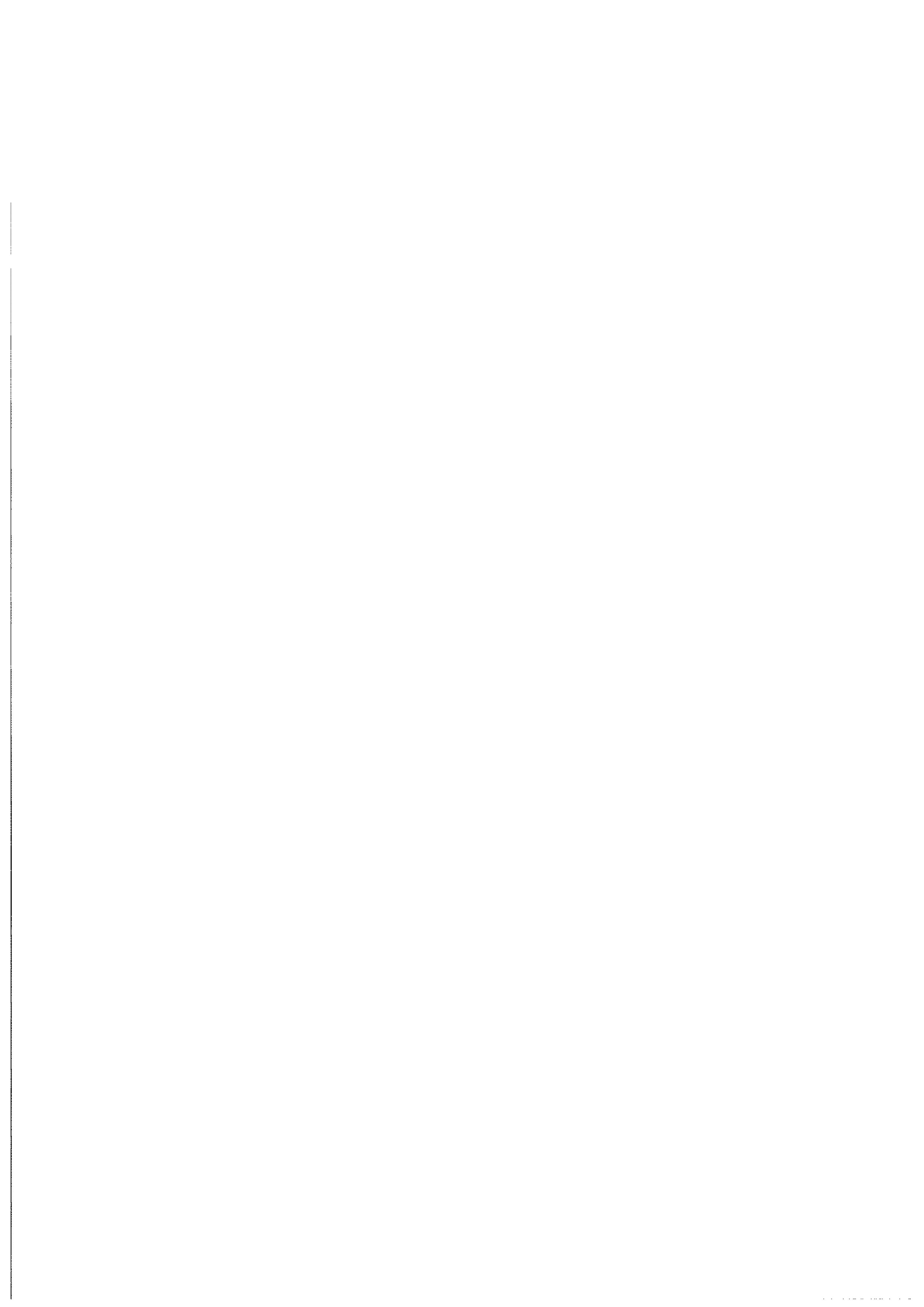
I do not support the proposed amendment

Forgive me, but I feel it is pigheaded dogmatic madness, though no doubt well-funded and with plenty of bombast, to add one of the most toxic chemicals known to what should be sancrosanct - the public water supply! Most European countries steer well clear and they're wrong? I think not.

Its introduction and attempted whitewashing ever since evidently owes to the nuclear industry and we all know how much us kiwis love snuggling up to nukes, radiation and the bomb. A classic case of might making right. It's disgusting. If humanity is to survive, heartless ignorant politics of this kind must be abandoned for good.

http://fluoridealert.org/news/rethinking-water-fluoridation-for-the-economically-disadvantaged/

Regards



Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)
to: askmedsafe 05/01/2015 01:15 p.m.

History: This message has been replied to.

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do / do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:

Email:

Address:

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
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Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	·
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	My interest is as a retired natural health practitioner and consumer.
Question 1 *Do you support the proposed amendment? If not, why not?*	I do not support the proposed amendment. The sole purpose of adding fluoride to drinking water is as a perceived preventative and treatment of dental caries. As fluoride is not a water treatment chemical it can only be considered as a medicine as the intention of adding it to water is to medicate anyone who ingests it.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	There are no fluoride- containing compounds that can treat community water supplies because, as previously stated, fluoride does not treat water, i.e. it does not purify it or make it safe to drink in any way.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you

consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

☐X I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Fluoride
to: askmedsafe 05/01/2015 01:30 p.m.

History: This message has been replied to.

Consultation on Proposed Amendment to Regulations under the Medicines Act 1981

Regarding the proposed changes:

Question 1

Do you support the proposed amendment? If not why not?

I DO **NOT** SUPPORT THIS. Fluoride is a toxin that has dubious benefit, as has been articulated by hundreds of scientists and researchers. Regardless of how this is presented, addition of fluoride is mass medication, and has serious negative impacts on those who are medically susceptible. If people desire to take fluoride in the belief that it will help their dental health, make it available at the pharmacy.

Question 2

Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO fluoride compounds should be added to the water supply. Other than to minimally treat water to make it potable, no substances should be added to the water.

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer
Question 1 *Do you support the proposed amendment? If not, why not?*	No i do not support the proposed amendment. Having spent literally hundreds of hours studying the addition of Fluoride or hydrofluorosilicic acid and having read all the studies, It is 100% clear to me that this is absolutely preposterous to be adding this to the water supplies. Please consider the following comments from some of the planet's brightest minds on this subject: "If someone were to tell you that you were being subjected to a known poison, without your consent, that the substance could lead to an increased risk of cancer and osteoporosis, and that it was used as a

	commercial rat poison, you would probably think they were mad. And if they discovered that this medication was being administered with the full knowledge and cooperation of government and the medical profession, you would be sure they were mad. Yet this is exactly what is happening to well in excess of a million New Zealanders today, for that poison is fluoride!" – adapted from the introduction to the book Fluoride – Drinking Ourselves to Death by Barry Groves. "Fluoride is more toxic than lead and only marginally less toxic than arsenic" – Clinical Toxicology of Commercial Products, 5th Edition. "Fluoridation is the greatest case of scientific fraud of this century, if not of all time." – Dr Robert Carton, formerly US Environmental Protection Agency. "No laboratory test has ever shown that 1 part per million fluoride in the drinking water reduces tooth decay" – Chief Dental Officer, UK Ministry of Health and Social Security, (11 December 1980.) "To my horror, they showed that fewer fillings had been required in the unfluoridated part of Auckland than in the fluoridated part" – A quote from the late Dr John Colquhoun who was the chief dental officer of the Department of Health for Auckland and president of the New Zealand Fluoridation Society. When he received the figures and data for his study they came with a warning that they were not to made public. Coloquhoun realized why and I quote, "They showed that in most Health Districts the percentage of children who were free of tooth decay was greater in the unfluoridated parts of the district." It was a great and courageous step on Dr Coloquhoun's part when he came out against fluoridation. He was "retired" from his post in 1990.

	"Hydrofluorosilicic acid (HFA) is the predominant fluoridation agent used in New Zealand." –quoting Graeme Colquhoun, Product Manager Water Chemicals, Orica Chemnet, Auckland. (Now please keep that in mind when I read you this next quote.) "Hydrofluorosilicic acid is derived from toxic gases produced in the manufacture of phosphoric acid and phosphate fertilizers; it contains lead, mercury, arsenic and high concentrations of radionucloides; it is also the chemical agent most used for water fluoridation in the United States" – George Classer. "Fluoride does not need to be swallowed to be effective. It is not an essential nutrient. Nor should it be considered a desirable "supplement" for children living in non-fluoridated areas.....Even if there were a systemic benefit from the ingestion of fluoride, it would be miniscule and clinically irrelevant. The notion that systemic fluorides are needed in non-fluoridated areas is an outdated one that should be abandoned altogether." – Hardy Limeback, Associate Professor and Head of Preventive Dentistry, University of Toronto. "After 55 years of artificial water fluoridation it is time for opening the scientific debate on this subject. Dentists' dogma and their doctrine that water fluoridation is safe and effective public health measure can no longer be defended in science." – Professor Rudolf Ziegelbecker, 5 August 2000. "This is against all principles of modern pharmacology… I think those nations that are using it should feel ashamed of themselves. It's against science." – Dr. Arvid Carlsson, Swedish neuropharmacologist, 2000 Nobel Laureate

	for Medicine "I am appalled at the prospect of using water as a vehicle for drugs. Fluoride is a corrosive poison that will produce serious effects on a long range basis. Any attempt to use water this way is deplorable." – Dr Charles Gordon Heyd, Past President of the American Medical Association. "…fluoride damages bone even at levels added to public drinking water" – American Journal of Epidemiology, October 1999. "Hundreds of millions of dollars may be wasted annually on children's fluoride treatments by dentists. Typically given once or twice a year at routine checkups, the treatments do nothing to reduce cavities in kids, says a study of insurance records." Journal of Public Health Dentistry. And I will leave you with this closing quote from a comment made in 1982 by Professor Albert Schatz, the co-discoverer of streptomycin. He stated: "Indeed fluoridation is the greatest and potentially the most dangerous medical hoax not only of the present century but of all time. In other words, it is the greatest fraud that has ever been perpetrated and it has been perpetrated on more people than any other fraud has."
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	No.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

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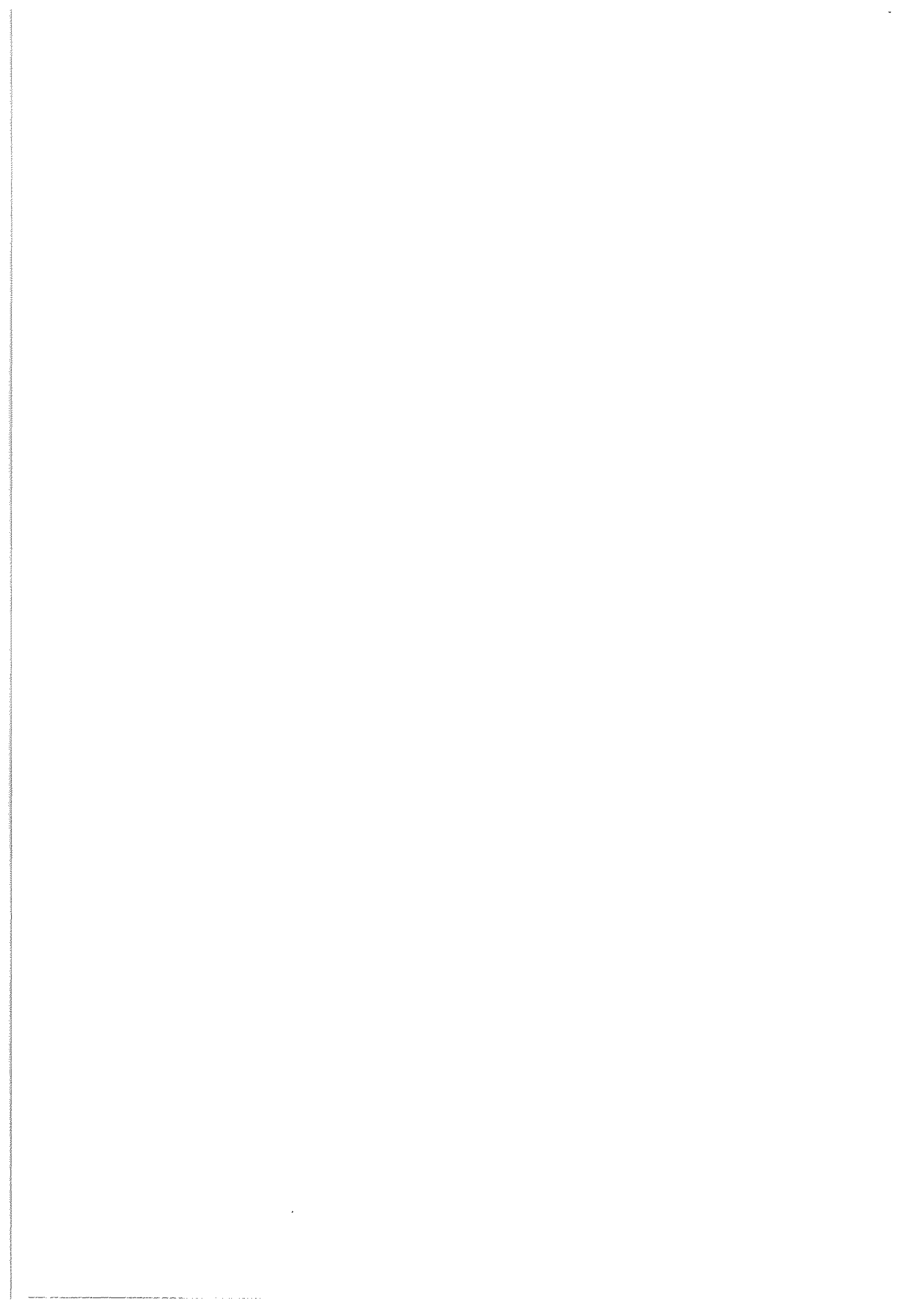

Water Fluoridation
to: askmedsafe 05/01/2015 03:59 p.m.

History: This message has been replied to.

I do not support the fluoridation of our water supply. I do not feel that such mass medication is warranted, as I feel there are many other factors affecting the health of children's teeth. I would suggest a strong education campaign directed towards parents,especially those who might not have genuinely understood previously the damage caused by sugary drinks, biscuits, sweets etc.

I would urge that our water supplies remain fluoride free, and that other alternatives be considered.

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This email is free from viruses and malware because avast! Antivirus protection is active.
http://www.avast.com

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)
): askmedsafe 05/01/2015 01:47 p.m.

History: This message has been replied to.

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name: I

Email

Address: :

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride

to: askmedsafe 05/01/2015 01:49 p.m.

History: This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:

Email·

Address: I

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

Post to:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz

F

.o: askmedsafe@moh.govt.nz 05/01/2015 02:26 p.m.

History: This message has been replied to.

Please record my objection to the proposal. to exclude fluoride from the Medicine's Act.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

I to: askmedsafe 05/01/2015 02:41 p.m.

Name:
Email:
Address:

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)
I do not give permission for my personal details to be released to persons under the Official Information Act 1982
"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe
Question 1. Do you support the proposed amendment? If not why not?

1. I do not support the proposed amendment because:
   1. **Fluoride is not a water treatment like chlorine**
   2. **Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine**
   3. **The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"**
   4. **The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines**

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

1. **Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people**

Submission

.o: askmedsafe 05/01/2015 02:44 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:
Email
Address:

Question 1. Do you support the proposed amendment? If not why not?

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   1. Fluoride is not a water treatment like chlorine
   2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
   3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
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Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

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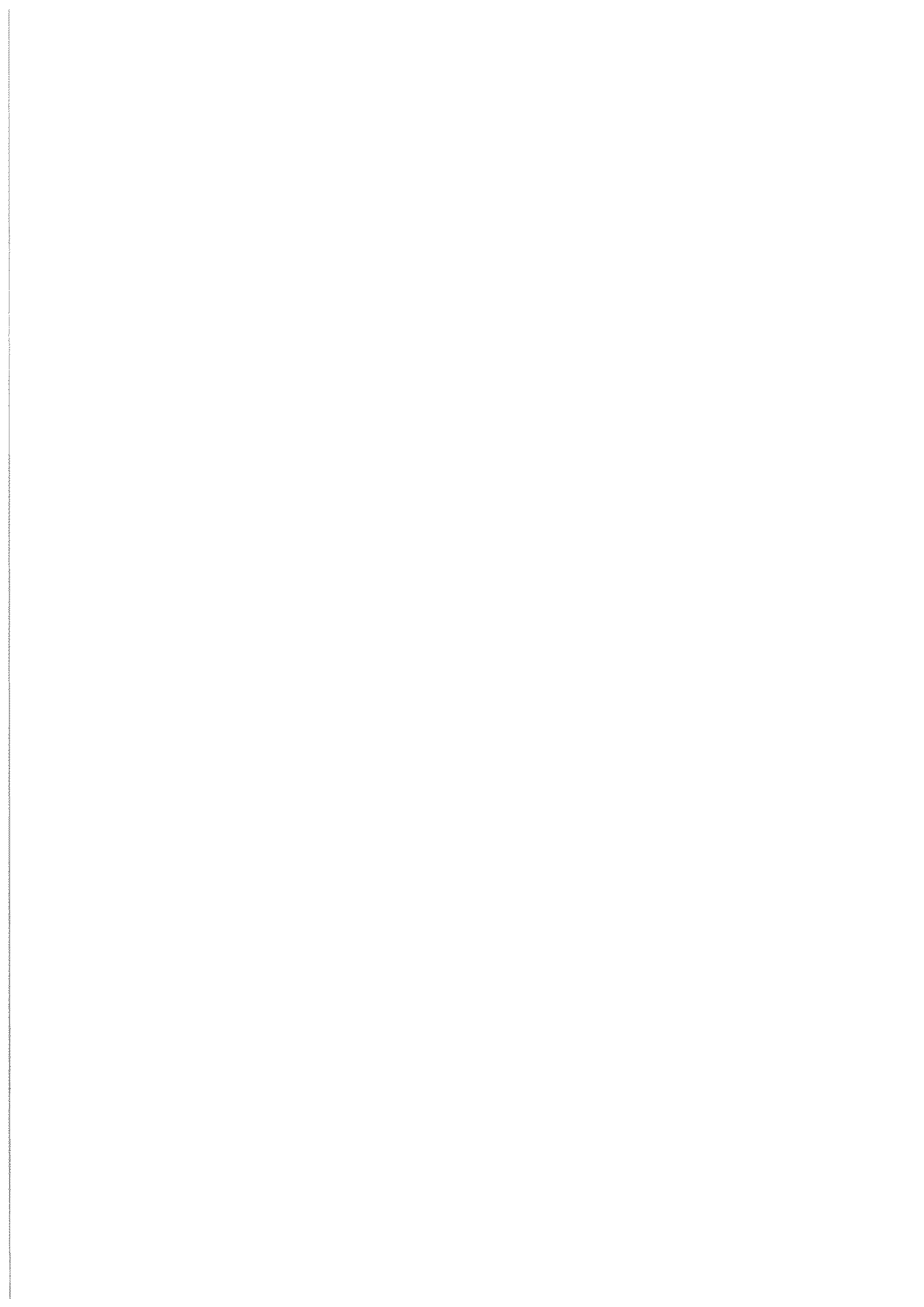

fluoride submission

o: askmedsafe 05/01/2015 02:50 p.m.

History: This message has been replied to.

To Medafe

Fluoride submission

Date: 5 January 2015

From: health professional and former school dental nurse

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V

Fluoride-containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) must remain classed as medicines.

My concern is the indirect effect of fluoride on the thyroid gland.

Fluoride is one of a group of halogens. Unfortunately when fluoride is picked up by the receptor sites, fluoride will block iodine's uptake by the thyroid gland. As noted below by Sir Peter Gluckman and Sir David Skegg, iodine deficiency can affect IQ.
Unfortunately there is a great deal of misinformation about fluoride.

In 2014 Sir Peter Gluckman, chief scientific advisor to the Prime Minster of New Zealand and Sir David Skegg published "Health Effects of Water Fluoridation: a Review of the Scientific Evidence."
Below are some excerps:
"Recently there have been a number of reports from China and other areas where fluoride levels in groundwater are naturally very high, that have claimed an association between high water fluoride levels and minimally reduced intelligence (measured as IQ) in children.
"In addition to the fact that the fluoride exposures in these studies were many (up to 20) times higher than any that are experienced in New Zealand or other CWF communities, the studies also mostly failed to consider other factors that might influence IQ, including exposures to arsenic, iodine deficiency, socioeconomic status, or the nutritional status of the children.
"Further, the claimed shift of less than one IQ point suggests that this is likely to be a measurement or statistical artifact of no functional significance."
A critique of the above statements by Sir Peter and Sir David has appeared on the Dr Mercola website. Just a portion of that critique has been reproduced below:
http://articles.mercola.com/sites/articles/archive/2014/12/09/fluoridation-hollow-men.aspx?e_cid=20141209Z3_DNL_art_1&utm_source=dnl&utm_medium=email&utm_content=art1&utm_campaign=20141209Z3&et_cid=DM62068&et_rid=756562286
"Gluckman and Skegg mistakenly claim "a shift of less than one IQ point" in the 27 studies reviewed by Choi et al. (2012). What they have done here is to confuse the drop of *half of one standard deviation* reported by the authors with the actual drop in IQ, which was 6.9 points. Such an elementary mistake would not have been made by Gluckman and Skegg if they had actually read the report.

"Gluckman and Skegg's claim that "fluoride exposures in these studies were many (up to 20) times higher than any that are experienced in New Zealand or other CWF communities" again indicates that they didn't read the report (or read it carefully). Only two out of the 27 studies had the "high-fluoride" village concentrations going up to 11 and 11.5 ppm respectively (Yao, 1996, 2-11 ppm, and Wang, 2007, 3.6-11.5 ppm). More relevant to NZ (and other countries with water fluoridation programs in the range of 0.6 to 1.2 ppm) is the fact that 8 of the reviewed studies had concentrations in the "high-fluoride" village of *less than 3 ppm*.
"Moreover, when harm is found, toxicologists do not normally focus on the *highest* level but on the Lowest Observable Adverse Effect Level (LOAEL). In one of the studies (Xiang et al., 2003 a,b) the authors sub-divided the children in the "high-fluoride" village into 5 groups with increasing fluoride concentrations in their well water from 0.75 to 4.3 ppm. They found that as the fluoride concentration increased, the mean IQ was lowered in a linear fashion. The lowest level at which IQ lowering occurred was 1.26 ppm. This offers no adequate margin of safety to protect all children drinking artificially fluoridated water between 0.6 and 1.2 ppm.
"This lack of an adequate margin of safety gets worse when one notes that in two respects, NZ children are likely to get higher fluoride doses than the rural Chinese children in this study, because a) they are more likely to use fluoridated toothpaste and b) more likely to be bottle-fed, with levels of fluoride about 200 times more than breast milk (0.004 ppm)."

The most extensive independent research has been done by Christopher Bryson. An interview (28 minutes) appears here:
http://articles.mercola.com/sites/articles/archive/2014/12/13/fluoride-deception.aspx?e_cid=20141213Z3_DNL_art_1&utm_source=dnl&utm_medium=email&utm_content=art1&utm_campaign=20141213Z3&et_cid=DM62072&et_rid=760820652
In the above interview, at 23 minutes 54 seconds, Bryson covers research on the neurotoxicity of fluoride.

I have a further concern about fluoride quality. When working as a school dental nurse I used (concentrated) laboratory quality fluoride. This is not what is added to our water supply.

Regards,

Raf Manji talk to Kim Hill, National Radio, about our debt-based money supply, and how Christchurch can be rebuilt without creating more government debt.

"One of the most fundamental insights is that banks simultaneously create new credit and new money ex nihilo [from nothing]. And that is one of the most fundamental, important things for people to be taught, which economic undergraduates should be taught about the nature of how monetary economy with banks works." Lord Adair Turner, former Chairman of Financial Services Authority, United Kingdom.

fluoride

ɔ: askmedsafe 05/01/2015 05:55 p.m.

History: This message has been replied to.

To Medsafe

Fluoride is far too potent to be removed from the Medicines Act and regulations.

hydrofluorosilicic acid
This is a compound of: fluoride, cadmium, arsenic, lead, and polonium 210.
There is no safe level of lead.
There are no studies to show that hydrofluorosilicic acid is safe.
Fluoride kills bacteria. This is useful for bacteria in the mouth that produce acid. However, the gut is the centre of the immune system and we need a great deal of good bacteria. Ingesting fluoride involves the gut bacteria.
Fluoride is also found in the pituitary gland. In another submission I pointed out that fluoride affects the thyroid gland.

Regards,

Raf Manji talk to Kim Hill, National Radio, about our debt-based money supply, and how Christchurch can be rebuilt without creating more government debt.

"One of the most fundamental insights is that banks simultaneously create new credit and new money ex nihilo [from nothing]. And that is one of the most fundamental, important things for people to be taught, which economic undergraduates should be taught about the nature of how monetary economy with banks works." Lord Adair Turner, former Chairman of Financial Services Authority, United Kingdom.

Fluoride

askmedsafe 05/01/2015 03:07 p.m.

History: This message has been replied to.

Dear Medsafe,

First, I am a retired American dentist who has been involved in fluoridation politics for the past 16 years. I have visited your beautiful country twice and have met some wonderful dentists along the way. I am very happy to see that your Health Ministry recognizes fluoridation as sound, public health policy. To answer your questions:

1) Yes, I support your proposed amendment. Once any of these additives are added to water (in the case of HFSA: 16.66 liters into 3,785,412. liters = 1 ppm or mg/l), these additives completely hydrolyse or dissociate into their ionic components. Our Center for Disease control discribes it in this manner:

HFSA + H2O = H2O & silica & F-

Fluoride Additives Are Not Different From Natural Fluoride

Some consumers have questioned whether fluoride from natural groundwater sources, such as calcium fluoride, is better than fluorides added "artificially," such as HFSA or sodium fluoride. Two recent scientific studies listed below demonstrate that the same fluoride ion is present in naturally occurring fluoride or fluoride drinking water additives and that no intermediates or other products were observed at pH levels as low as 3.5. In addition, fluoride metabolism is not affected differently by the chemical compounds nor are they affected by whether the fluoride is present naturally or artificially.

The ionic speciation study conducted in 2006 mentioned previously (Finney WF, Wilson E, Callender A, Morris MD, Beck LW. Re-examination of hexafluorosilicate hydrolysis by fluoride NMR and pH measurement. Environ Sci Technol 2006;40:8:2572)
The pharmacokinetics of ingested fluoride was studied by a 2008 study (G.M. Whitford, F.C. Sampaio, C.S. Pinto, A.G. Maria, V.E.S. Cardoso, M.A.R. Buzalaf, Pharmacokinetics of ingested fluoride: Lack of effect of chemical compound, Archives of Oral Biology, 53 (2008) 1037–1041)

http://www.cdc.gov/fluoridation/fact_sheets/engine...

Put simply: fluoride ion is a fluoride ion is a fluoride ion. All sea water such as found in the Tasmanian Sea contains fluoride at a concentration of 1.2-1.5 ppm. Are the oceans of the world medicated?? Of course not.

2) There is a 3rd fluoride additive that should be included. That is sodium fluoride. Again, when the sodium fluoride additive is dissolved in water, it completely hydrolyses to its ionic components.

In closing, no court of last resort in the U.S. or Canada has ever ruled that fluoridation is mass medication or is a medicine. I hope that this amendment will clarify the same in New Zealand.

Best regards,

684

I do not s[illegible] e proposed amendment
[illegible] askmedsafe 05/01/2015 03:16 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I / do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:

Email:

Address

Question 1. Do you support the proposed amendment? If not why not? No

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they? No

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

Post to:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013

Wellington 6145

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

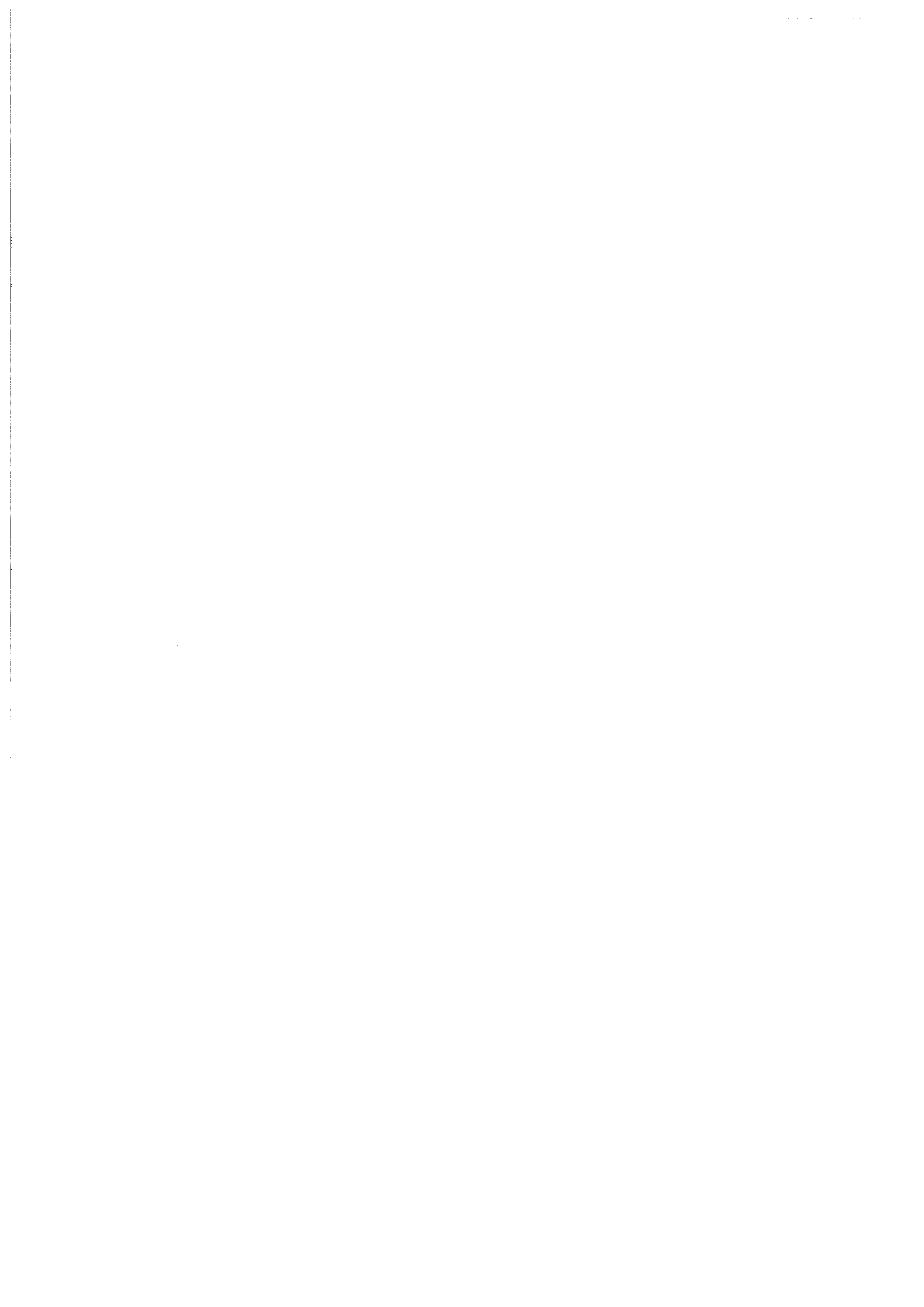
Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	HEALTH PROFESSIONAL. HEALTH PROTECTION OFFICER THAT WORKS FOR PUBLIC HEALTH BUT THIS SUBMISSION IS AS INDIVIDUAL.
Question 1 *Do you support the proposed amendment? If not, why not?*	YES
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	THERE MAY BE BUT I AM NOT AWARE OF THEM AT PRESENT. I SUGGEST A CAREFULLY WORDED CODICIL that would cover all and future compounds (not the usual sloppily drafted grammatically incorrect legislation of recent years). The issue is their purpose not the individual compound. If being used to fluoridate water supplies then which compound (assuming it is safe) is not the issue.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

× I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.



NO to water fluoridation
ɔ: askmedsafe@moh.govt.nz 05/01/2015 03:58 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
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Email:

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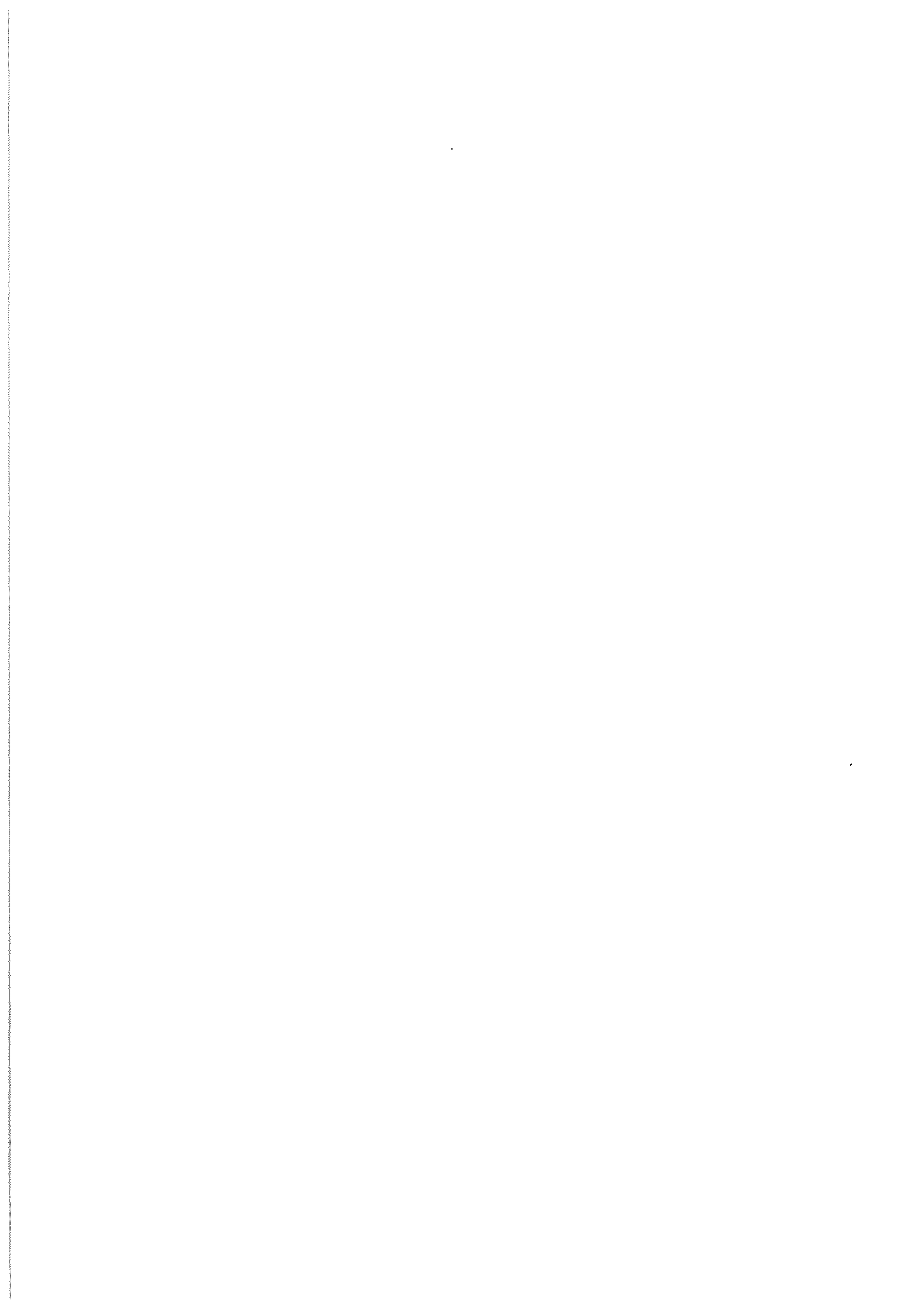
Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people.

Humans have a right to water, and a right to refuse unnecessary additives to that basic right.

Thank you for accepting this email



Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)
): askmedsafe 05/01/2015 04:05 p.m.
Sent by:

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

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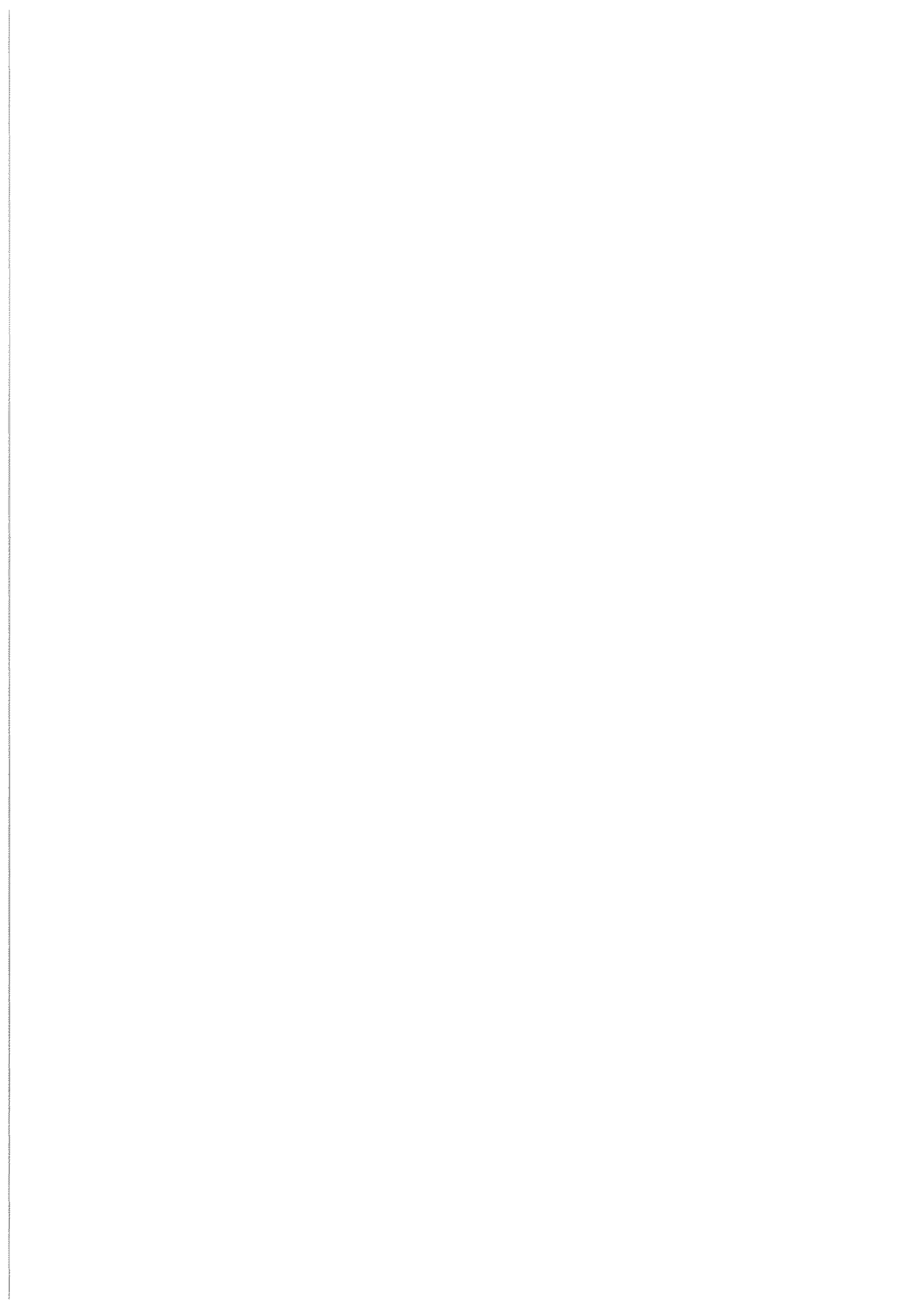

Fluoride
askmedsafe 05/01/2015 05:14 p.m.
Cc:

History: This message has been replied to.

5 January, 2015

Dear Medsafe

SUBMISSION ON PROPOSAL THAT Hydrofluorosilicic acid (HFA) AND Sodium Silico Fluoride (SSF) ARE NOT MEDICINES FOR THE PURPOSES OF THE MEDICINES ACT WHEN THEY ARE MANUFACTURED AND SUPPLIED OR DISTRIBUTED FOR THE PURPOSE OF FLUORIDATING COMMUNITY WATER SUPPLIES

QUESTION 1: DO YOU SUPPORT THE PROPOSED AMENDMENT? IF NOT, WHY NOT?

I oppose the proposed amendment for the following reasons:

Medsafe and the NZ Ministry of Health should be focusing their time, energy and money on educating people about a healthy and varied diet that will provide the fluoride required by our bodies. Further they should be educating people about better oral care and providing at risk individuals with the choice to take sodium fluoride tablets.

HFA and SSF are medicines and should not be forced on people without their consent. It is a basic human right to be allowed to choose whether you take medication/suppliments or not. By adding fluoride to community water supplies you take away this choice.

The Medicines Act is designed to ensure the safety, quality and efficacy of medicines. HFA and SSF should be subject to these controls.

These controls will ensure that people are not exposed to uncontrolled doses of fluoride from an industrial grade and heavy-metal contaminated fluoride substance.

If fluoride tablets are not recommended for babies, toddlers and pregnant women, these sub-populations should not be ingesting fluoridated water.

No protection against dental decay is provided by swallowing fluoride; consequently HFA and SSF should not be swallowed.

Those people who believe there is a benefit in ingesting fluoride can buy sodium fluoride tablets from a pharmacy.

QUESTION 2: ARE THERE ANY OTHER FLUORIDE-CONTAINING COMPOUNDS USED TO TREAT COMMUNITY WATER SUPPLIES THAT SHOULD BE SPECIFICALLY IN THE REGULATION? IF SO, WHAT ARE THEY?

ANSWER TO QUESTION 2: NO.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

Yours sincerely

Submission for Medicines Act - Fluoride

\ ɔ: askmedsafe@moh.govt.nz 05/01/2015 05:35 p.m.
Please respond tc

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
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Email

Address:

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NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

Thank you

Floride!

askmedsafe 05/01/2015 05:46 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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Medsafe
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Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz

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692

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do / do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

I do / do not (delete whichever does not apply) wish to speak to my submission

"It is proposed that a new regulation be made under section 105(1)(i) that:
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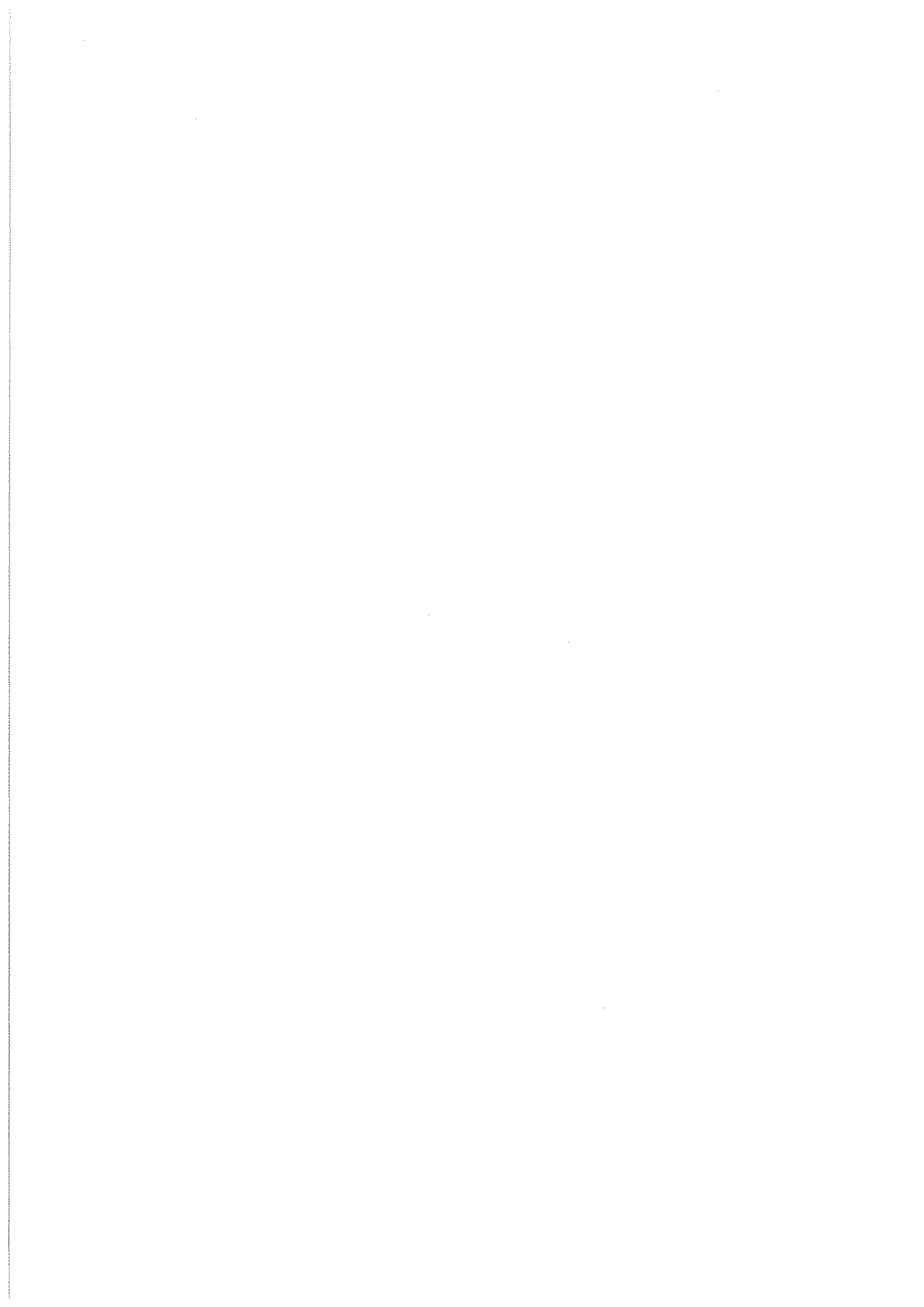
Email to: askmedsafe@moh.govt.nz



Fluoride

): askmedsafe 05/01/2015 06:23 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

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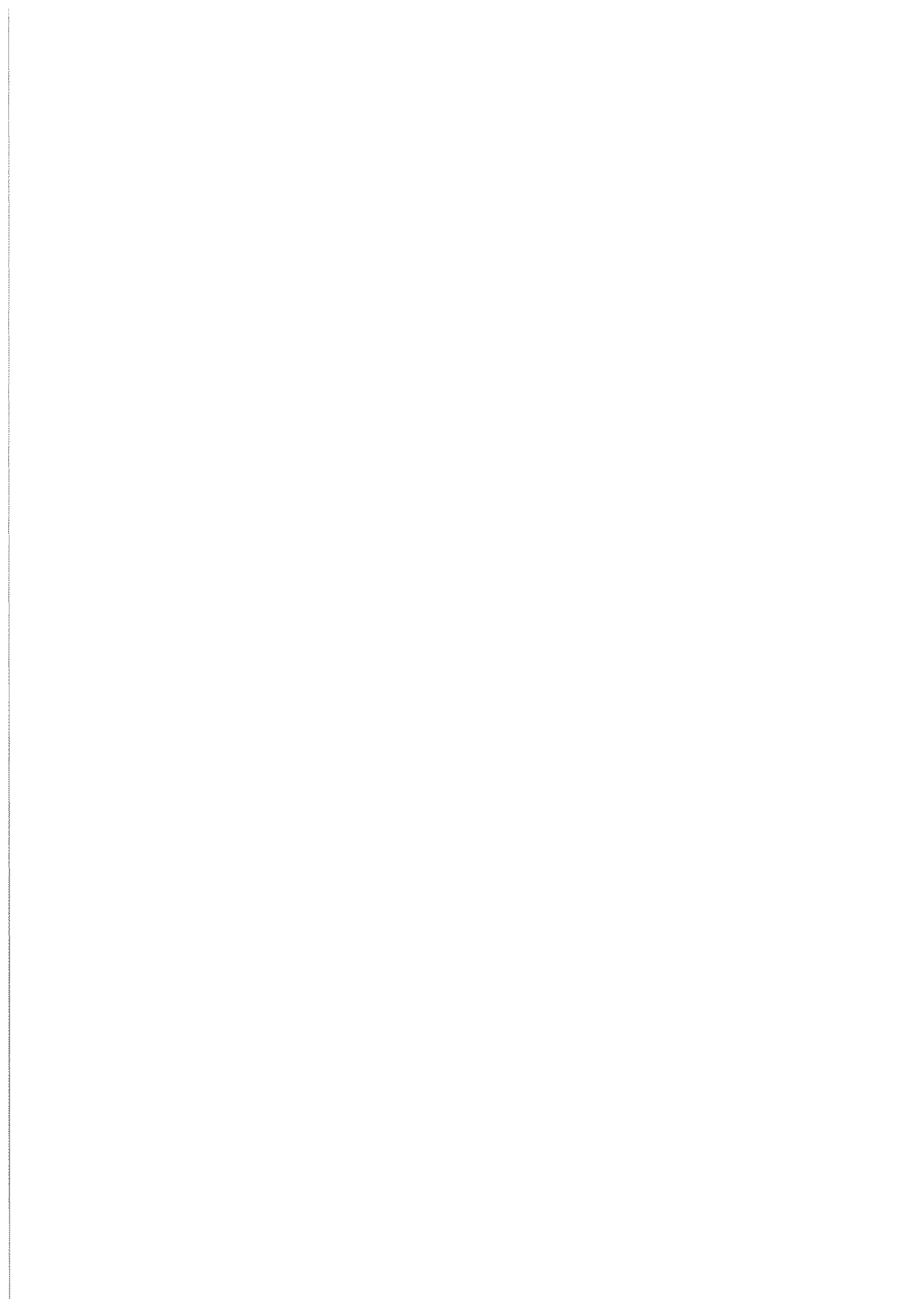

): askmedsafe 05/01/2015 06:25 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
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Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013

Wellington 6145

Fluoride Submission
to: askmedsafe 05/01/2015 07:42 p.m.

History: This message has been replied to.

Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health

Submission to Medsafe

re Consultation on Proposed Amendment to Regulations under the Medicines Act 1981

Question 1

Do you support the proposed amendment?
[to provide legal clarity that the fluoride substances used to treat drinking water are not medicines]

Response: YES

Having made an extensive review of the subject and provided a comprehensive rebuttal to all the objections of the anti-fluoridation campaigners for the South Taranaki District Council [STDC] in 2012, I am concerned that the same unscientific and emotive objections may influence the attitude of decision makers.

My submission to the STDC was motivated by the lack of a thorough scientific and medical response to the anti-fluoridation movement (by the Taranaki District Health Board) which could have prevented the New Plymouth District Council from removing fluoride from the water supply. There needed to be an independent scientific, evidenced based voice which could not be accused of following a political or employer's policy and as an independent (non-PHO) GP who had reviewed all the claims, I was in a position to provide that response and help the STDC make the best decision to improve the health of those most affected by dental caries.

That submission is freely available on-line at:

[please do not reply to the gmail address as I only use this when away from my usual ISP]

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer, parent of consumers, Grandparent of consumers

Question 1 *Do you support the proposed amendment? If not, why not?*	No.

Fluoridation is a bad medical practice

1) Fluoride is the only chemical added to water for the purpose of medical treatment. The U.S. Food and Drug Administration (FDA) classifies fluoride as a drug when used to prevent or mitigate disease (FDA 2000). As a matter of basic logic, adding fluoride to water for the sole purpose of preventing tooth decay (a non-waterborne disease) is a form of medical treatment. All other water treatment chemicals are added to improve the water's quality or safety, which fluoride does not do.

2) Fluoridation is unethical. Informed consent is standard practice for all medication, and one of the key reasons why most of Western Europe has ruled against fluoridation. With water fluoridation we are allowing governments to do to whole communities (forcing people to take a medicine irrespective of their consent) what individual doctors cannot do to individual patients.

Put another way: Does a voter have the right to require that their neighbor ingest a certain medication (even if it is against that neighbor's will)?

3) The dose cannot be controlled. Once fluoride is put in the water it is impossible to control the dose each individual receives because people drink different amounts of water. Being able to control the dose a patient receives is critical. Some people (e.g., manual laborers, athletes, diabetics, and people with kidney disease) drink substantially more water than others.

4) The fluoride goes to everyone regardless of age, health or vulnerability. According to Dr. Arvid Carlsson, the 2000 Nobel Laureate in Medicine and Physiology and one of the scientists who helped keep fluoridation out of Sweden:

"Water fluoridation goes against leading principles of pharmacotherapy, which is progressing from a stereotyped medication — of the type 1 tablet 3 times a day — to a much more individualized therapy as regards both dosage and selection of drugs. The addition of drugs to the drinking water means exactly the opposite of an individualized therapy" (Carlsson 1978).

5) People now receive fluoride from many other sources besides water. Fluoridated water is not the only way people are exposed to fluoride. Other sources of fluoride include food and beverages processed with fluoridated water (Kiritsy 1996; Heilman 1999), fluoridated dental products (Bentley 1999; Levy 1999), mechanically deboned meat (Fein 2001), tea (Levy 1999), and pesticide residues (e.g., from cryolite) on food (Stannard 1991; Burgstahler 1997). It is now widely acknowledged that exposure to non-water sources of fluoride has significantly increased since the water fluoridation program first began (NRC 2006).

6) Fluoride is not an essential nutrient. No disease, not even tooth decay, is caused by a "fluoride deficiency."(NRC 1993; Institute of Medicine 1997, NRC 2006). Not a single biological process has been shown to require fluoride. On the contrary there is extensive evidence that fluoride can interfere with many important biological processes. Fluoride interferes with numerous enzymes (Waldbott 1978). In combination with aluminum, fluoride interferes with G-proteins (Bigay 1985, 1987). Such interactions give aluminum-fluoride complexes the potential to interfere with signals from growth factors, hormones and neurotransmitters (Strunecka & Patocka 1999; Li 2003). More and more studies indicate that fluoride can interfere with biochemistry in fundamental ways (Barbier 2010).

7) The level in mothers' milk is very low. Considering reason #6 it is perhaps not surprising that the level of fluoride in mother's milk is remarkably low (0.004 ppm, NRC, 2006). This means that a bottle-fed baby consuming fluoridated water (0.6 – 1.2 ppm) can get up to 300 times more fluoride than a breast-fed baby. There are no benefits (see reasons #11-19), only risks (see reasons #21-36), for infants ingesting this heightened level of fluoride at such an early age (an age where susceptibility to environmental toxins is particularly high).

8) Fluoride accumulates in the body. Healthy adult kidneys excrete 50 to 60% of the fluoride ingested each day (Marier & Rose 1971). The remainder accumulates in the body, largely in calcifying tissues such as the bones and pineal gland (Luke 1997, 2001). Infants and children excrete less fluoride from their kidneys and take up to 80% of ingested fluoride into their bones (Ekstrand 1994). The fluoride concentration in bone steadily increases over a lifetime (NRC 2006).

9) No health agency in fluoridated countries is monitoring fluoride exposure or side effects. No regular measurements are being made of the levels of fluoride in urine, blood, bones, hair, or nails of either the general population or sensitive subparts of the population (e.g., individuals with kidney disease).

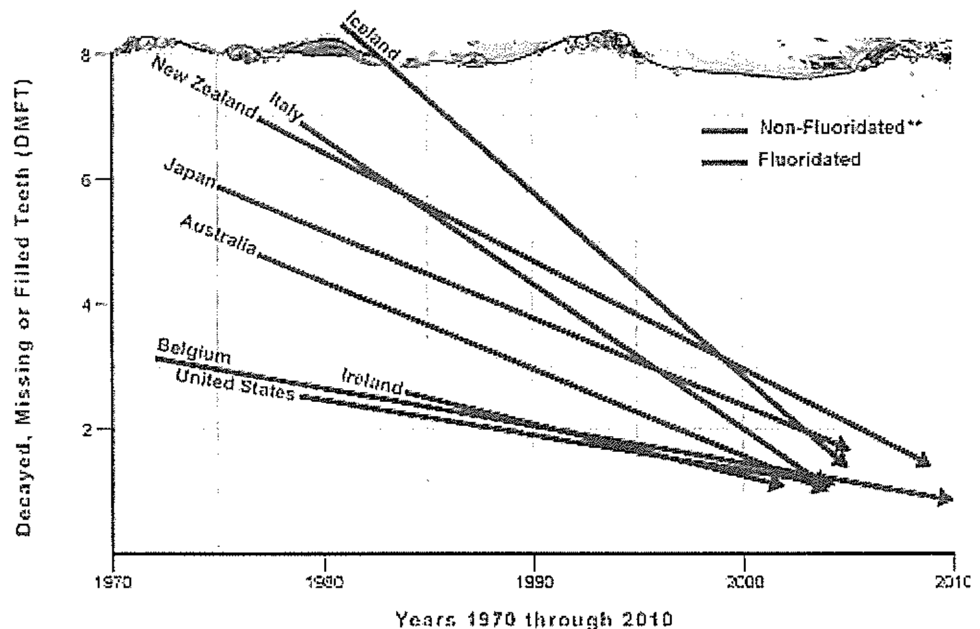
10) There has never been a single randomized controlled trial to demonstrate fluoridation's effectiveness or safety. Despite the fact that fluoride has been added to community water supplies for over 60 years, "there have been no randomized trials of water fluoridation" (Cheng 2007). Randomized trials are the standard method for determining the safety and effectiveness of any purportedly beneficial medical treatment. In 2000, the British Government's "York Review" could not give a single fluoridation trial a Grade A classification – despite 50 years of research (McDonagh 2000). The U.S. Food and Drug Administration (FDA) continues to classify fluoride as an "unapproved new drug."

Swallowing fluoride provides no (or very little) benefit

11) Benefit is topical not systemic. The Centers for Disease Control and Prevention (CDC, 1999, 2001) has now acknowledged that the mechanism of

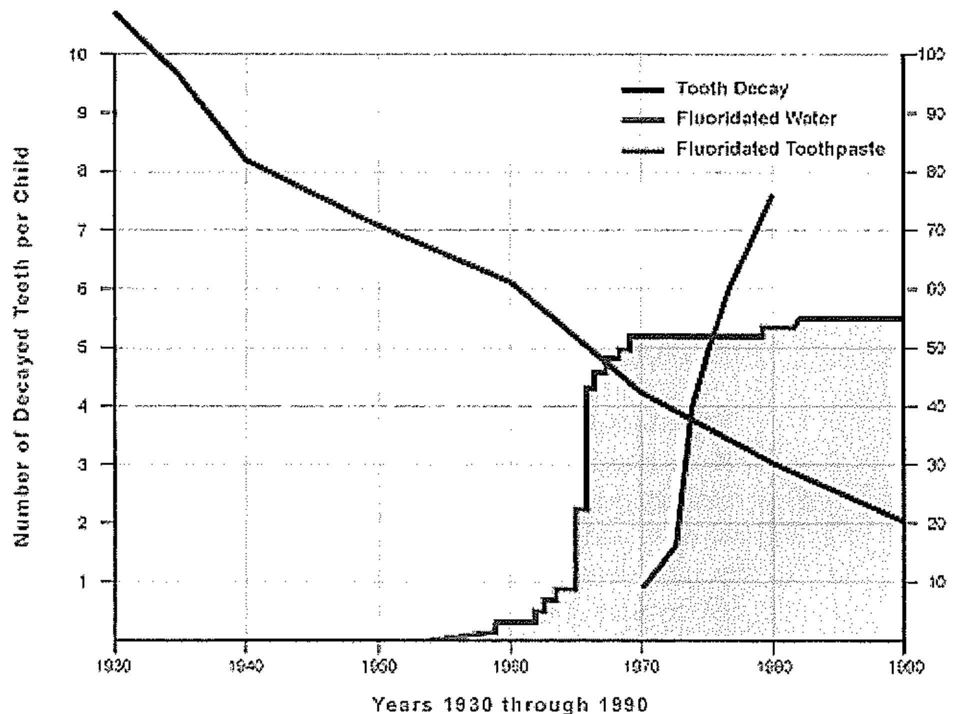
fluoride's benefits are mainly topical, not systemic. There is no need whatsoever, therefore, to swallow fluoride to protect teeth. Since the purported benefit of fluoride is topical, and the risks are systemic, it makes more sense to deliver the fluoride directly to the tooth in the form of toothpaste. Since swallowing fluoride is unnecessary, and potentially dangerous, there is no justification for forcing people (against their will) to ingest fluoride through their water supply.

12) Fluoridation is not necessary. Most western, industrialized countries have rejected water fluoridation, but have nevertheless experienced the same decline in childhood dental decay as fluoridated countries. (See data from World Health Organization presented graphically in Figure).



13) Fluoridation's role in the decline of tooth decay is in serious doubt. The largest survey ever conducted in the US (over 39,000 children from 84 communities) by the National Institute of Dental Research showed little difference in tooth decay among children in fluoridated and non-fluoridated communities (Hileman 1989). According to NIDR researchers, the study found an average difference of only 0.6 DMFS (Decayed, Missing, and Filled Surfaces) in the permanent teeth of children aged 5-17 residing their entire lives in either fluoridated or unfluoridated areas (Brunelle & Carlos, 1990). This difference is less than one tooth surface, and less than 1% of the 100+ tooth surfaces available in a child's mouth. Large surveys from

	three Australian states have found even less of a benefit, with decay reductions ranging from 0 to 0.3 of one permanent tooth surface (Spencer 1996; Armfield & Spencer 2004). None of these studies have allowed for the possible delayed eruption of the teeth that may be caused by exposure to fluoride, for which there is some evidence (Komarek 2005). A one-year delay in eruption of the permanent teeth would eliminate the very small benefit recorded in these modern studies. **14) NIH-funded study on individual fluoride ingestion and tooth decay found no significant correlation.** A multi-million dollar, U.S. National Institutes of Health (NIH)-funded study found no significant relationship between tooth decay and fluoride intake among children. (Warren 2009) This is the first time tooth decay has been investigated as a function of individual exposure (as opposed to mere residence in a fluoridated community). **15) Tooth decay is high in low-income communities that have been fluoridated for years.** Despite some claims to the contrary, water fluoridation cannot prevent the oral health crises that result from rampant poverty, inadequate nutrition, and lack of access to dental care. There have been numerous reports of severe dental crises in low-income neighborhoods of US cities that have been fluoridated for over 20 years (e.g., Boston, Cincinnati, New York City, and Pittsburgh). In addition, research has repeatedly found fluoridation to be ineffective at preventing the most serious oral health problem facing poor children, namely "baby bottle tooth decay," otherwise known as early childhood caries (Barnes 1992; Shiboski 2003). **16) Tooth decay does not go up when fluoridation is stopped.** Where fluoridation has been discontinued in communities from Canada, the former East Germany, Cuba and Finland, dental decay has not increased but has generally continued to decrease (Maupomé 2001; Kunzel & Fischer, 1997, 2000; Kunzel 2000; Seppa 2000). **17) Tooth decay was coming down before fluoridation started.** Modern research shows that decay rates were coming down before fluoridation was introduced in Australia and New Zealand and have continued to decline even after its benefits would have been maximized. (Colquhoun 1997; Diesendorf 1986). As the following figure indicates, many other factors are responsible for the decline of tooth decay that has been universally reported throughout the western world.



Colquhoun J. (1997). Why I changed my mind about fluoridation. *Perspectives in Biology and Medicine* 41(1):29-44.

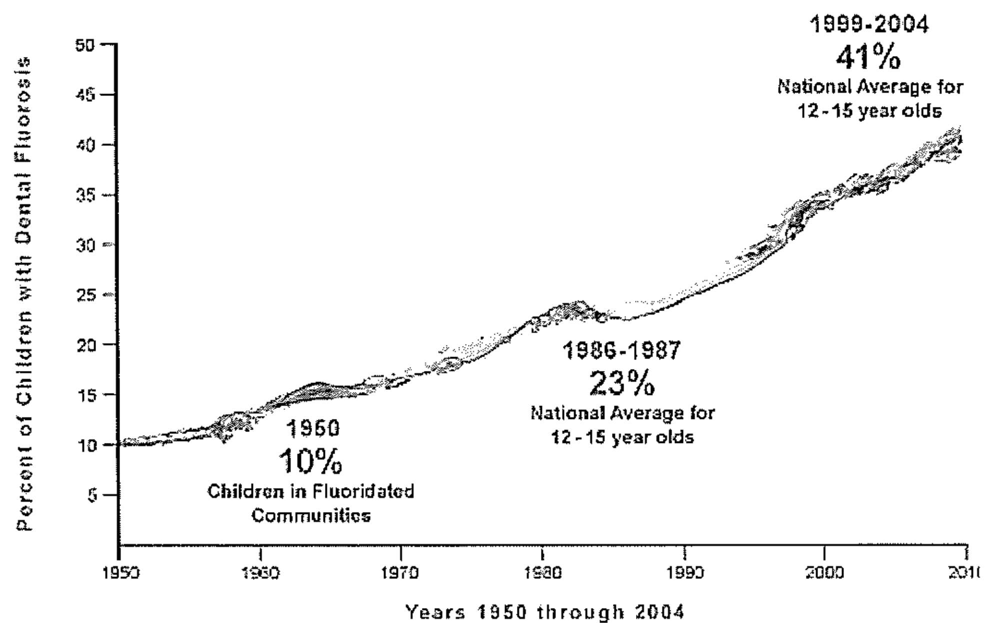
18) The studies that launched fluoridation were methodologically flawed. The early trials conducted between 1945 and 1955 in North America that helped to launch fluoridation, have been heavily criticized for their poor methodology and poor choice of control communities (De Stefano 1954; Sutton 1959, 1960, 1996; Ziegelbecker 1970). According to Dr. Hubert Arnold, a statistician from the University of California at Davis, the early fluoridation trials "are especially rich in fallacies, improper design, invalid use of statistical methods, omissions of contrary data, and just plain muddleheadedness and hebetude." Serious questions have also been raised about Trendley Dean's (the father of fluoridation) famous 21-city study from 1942 (Ziegelbecker 1981).

Children are being over-exposed to fluoride

19) Children are being over-exposed to fluoride. The fluoridation program has massively failed to achieve one of its key objectives, i.e., to lower dental decay rates while limiting the occurrence of dental fluorosis (a discoloring of tooth enamel caused by too much fluoride. The goal of the early promoters of fluoridation was to limit dental fluorosis (in its very mild form) to10% of children (NRC 1993, pp. 6-7). In 2010, however, the Centers for Disease Control and Prevention (CDC) reported that 41% of American adolescents had dental fluorosis, with 8.6% having mild fluorosis and 3.6% having either

moderate or severe dental fluorosis (Beltran-Aguilar 2010). As the 41% prevalence figure is a national average and includes children living in fluoridated and unfluoridated areas, the fluorosis rate in fluoridated communities will obviously be higher. The British Government's York Review estimated that up to 48% of children in fluoridated areas worldwide have dental fluorosis in all forms, with 12.5% having fluorosis of aesthetic concern (McDonagh, 2000).

Dental Fluorosis Rates in the United States:
1950 through 2004



Beltran ED, et al. (2010). Prevalence and Severity of Dental Fluorosis in the United States, 1999-2004. NCHS Data Brief No. 53. Figure 3.

National Research Council. (1993). Health Effects of Ingested Fluoride. National Academy Press. Washington DC. p. 4-5.

20) The highest doses of fluoride are going to bottle-fed babies. Because of their sole reliance on liquids for their food intake, infants consuming formula made with fluoridated water have the highest exposure to fluoride, by bodyweight, in the population. Because infant exposure to fluoridated water has been repeatedly found to be a major risk factor for developing dental fluorosis later in life (Marshall 2004; Hong 2006; Levy 2010), a number of dental researchers have recommended that parents of newborns not use fluoridated water when reconstituting formula (Ekstrand 1996; Pendrys 1998; Fomon 2000; Brothwell 2003; Marshall 2004). Even the American Dental Association (ADA), the most ardent institutional proponent of fluoridation, distributed a November 6, 2006 email alert to its members recommending that parents be advised that formula should be made with "low or no-fluoride water." Unfortunately, the ADA has done little to get this information into the hands of parents. As a result, many parents remain

unaware of the fluorosis risk from infant exposure to fluoridated water.

Evidence of harm to other tissues

21) Dental fluorosis may be an indicator of wider systemic damage. There have been many suggestions as to the possible biochemical mechanisms underlying the development of dental fluorosis (Matsuo 1998; Den Besten 1999; Sharma 2008; Duan 2011; Tye 2011) and they are complicated for a lay reader. While promoters of fluoridation are content to dismiss dental fluorosis (in its milder forms) as merely a cosmetic effect, it is rash to assume that fluoride is not impacting other developing tissues when it is visibly damaging the teeth by some biochemical mechanism (Groth 1973; Colquhoun 1997). Moreover, ingested fluoride can only cause dental fluorosis during the period before the permanent teeth have erupted (6-8 years), other tissues are potentially susceptible to damage throughout life. For example, in areas of naturally high levels of fluoride the first indicator of harm is dental fluorosis in children. In the same communities many older people develop skeletal fluorosis.

22) Fluoride may damage the brain. According to the National Research Council (2006), "it is apparent that fluorides have the ability to interfere with the functions of the brain." In a review of the literature commissioned by the US Environmental Protection Agency (EPA), fluoride has been listed among about 100 chemicals for which there is "substantial evidence of developmental neurotoxicity." Animal experiments show that fluoride accumulates in the brain and alters mental behavior in a manner consistent with a neurotoxic agent (Mullenix 1995). In total, there have now been over 100 animal experiments showing that fluoride can damage the brain and impact learning and behavior. According to fluoridation proponents, these animal studies can be ignored because high doses were used. However, it is important to note that rats generally require five times more fluoride to reach the same plasma levels in humans (Sawan 2010). Further, one animal experiment found effects at remarkably low doses (Varner 1998). In this study, rats fed for one year with 1 ppm fluoride in their water (the same level used in fluoridation programs), using either sodium fluoride or aluminum fluoride, had morphological changes to their kidneys and brains, an increased uptake of aluminum in the brain, and the formation of beta-amyloid deposits which are associated with Alzheimer's disease. Other animal studies have found effects on the brain at water fluoride levels as low as 5 ppm (Liu 2010).

23) Fluoride may lower IQ. There have now been 33 studies from China, Iran, India and Mexico that have reported an association between fluoride exposure and reduced IQ. One of these studies (Lin 1991) indicates that even just moderate levels of fluoride exposure (e.g., 0.9 ppm in the water) can exacerbate the neurological defects of iodine deficiency. Other studies have found IQ reductions at 1.9 ppm (Xiang 2003a,b); 0.3-3.0 ppm (Ding 2011); 1.8-3.9 ppm (Xu 1994); 2.0 ppm (Yao 1996, 1997); 2.1-3.2 ppm (An 1992); 2.38 ppm (Poureslami 2011); 2.45 ppm (Eswar 2011); 2.5 ppm (Seraj 2006); 2.85 ppm (Hong 2001); 2.97 ppm (Wang 2001, Yang 1994); 3.15 ppm (Lu 2000); 4.12 ppm (Zhao 1996). In the Ding study, each 1 ppm increase of

	fluoride in urine was associated with a loss of 0.59 IQ points. None of these studies indicate an adequate margin of safety to protect all children drinking artificially fluoridated water from this affect. According to the National Research Council (2006), "the consistency of the results [in fluoride/IQ studies] appears significant enough to warrant additional research on the effects of fluoride on intelligence." The NRC's conclusion has recently been amplified by a team of Harvard scientists whose fluoride/IQ meta-review concludes that fluoride's impact on the developing brain should be a "high research priority." (Choi et al., 2012). Except for one small IQ study from New Zealand (Spittle 1998) no fluoridating country has yet investigated the matter. **24) Fluoride may cause non-IQ neurotoxic effects.** Reduced IQ is not the only neurotoxic effect that may result from fluoride exposure. At least three human studies have reported an association between fluoride exposure and impaired visual-spatial organization (Calderon 2000; Li 2004; Rocha-Amador 2009); while four other studies have found an association between prenatal fluoride exposure and fetal brain damage (Han 1989; Du 1992; Dong 1993; Yu 1996). **25) Fluoride affects the pineal gland.** Studies by Jennifer Luke (2001) show that fluoride accumulates in the human pineal gland to very high levels. In her Ph.D. thesis, Luke has also shown in animal studies that fluoride reduces melatonin production and leads to an earlier onset of puberty (Luke 1997). Consistent with Luke's findings, one of the earliest fluoridation trials in the U.S. (Schlesinger 1956) reported that on average young girls in the fluoridated community reached menstruation 5 months earlier than girls in the non-fluoridated community. Inexplicably, no fluoridating country has attempted to reproduce either Luke's or Schlesinger's findings or examine the issue any further. **26) Fluoride affects thyroid function.** According to the U.S. National Research Council (2006), "several lines of information indicate an effect of fluoride exposure on thyroid function." In the Ukraine, Bachinskii (1985) found a lowering of thyroid function, among otherwise healthy people, at 2.3 ppm fluoride in water. In the middle of the 20th century, fluoride was prescribed by a number of European doctors to reduce the activity of the thyroid gland for those suffering from hyperthyroidism (overactive thyroid) (Stecher 1960; Waldbott 1978). According to a clinical study by Galletti and Joyet (1958), the thyroid function of hyperthyroid patients was effectively reduced at just 2.3 to 4.5 mg/day of fluoride ion. To put this finding in perspective, the Department of Health and Human Services (DHHS, 1991) has estimated that total fluoride exposure in fluoridated communities ranges from 1.6 to 6.6 mg/day. This is a remarkable fact, particularly considering the rampant and increasing problem of hypothyroidism (underactive thyroid) in the United States and other fluoridated countries. Symptoms of hypothyroidism include depression, fatigue, weight gain, muscle and joint pains, increased cholesterol levels, and heart disease. In 2010, the second most prescribed drug of the year was Synthroid (sodium levothyroxine)

	which is a hormone replacement drug used to treat an underactive thyroid. **27) Fluoride causes arthritic symptoms**. Some of the early symptoms of skeletal fluorosis (a fluoride-induced bone and joint disease that impacts millions of people in India, China, and Africa), mimic the symptoms of arthritis (Singh 1963; Franke 1975; Teotia 1976; Carnow 1981; Czerwinski 1988; DHHS 1991). According to a review on fluoridation published in Chemical & Engineering News, "Because some of the clinical symptoms mimic arthritis, the first two clinical phases of skeletal fluorosis could be easily misdiagnosed" (Hileman 1988). Few, if any, studies have been done to determine the extent of this misdiagnosis, and whether the high prevalence of arthritis in America (1 in 3 Americans have some form of arthritis – CDC, 2002) and other fluoridated countries is related to growing fluoride exposure, which is highly plausible. Even when individuals in the U.S. suffer advanced forms of skeletal fluorosis (from drinking large amounts of tea), it has taken years of misdiagnoses before doctors finally correctly diagnosed the condition as fluorosis. **28) Fluoride damages bone**. An early fluoridation trial (Newburgh-Kingston 1945-55) found a significant two-fold increase in cortical bone defects among children in the fluoridated community (Schlesinger 1956). The cortical bone is the outside layer of the bone and is important to protect against fracture. While this result was not considered important at the time with respect to bone fractures, it did prompt questions about a possible link to osteosarcoma (Caffey, 1955; NAS, 1977). In 2001, Alarcon-Herrera and co-workers reported a linear correlation between the severity of dental fluorosis and the frequency of bone fractures in both children and adults in a high fluoride area in Mexico. **29) Fluoride may increase hip fractures in the elderly.** When high doses of fluoride (average 26 mg per day) were used in trials to treat patients with osteoporosis in an effort to harden their bones and reduce fracture rates, it actually led to a higher number of fractures, particularly hip fractures (Inkovaara 1975; Gerster 1983; Dambacher 1986; O'Duffy 1986; Hedlund 1989; Bayley 1990; Gutteridge 1990. 2002; Orcel 1990; Riggs 1990 and Schnitzler 1990). Hip fracture is a very serious issue for the elderly, often leading to a loss of independence or a shortened life. There have been over a dozen studies published since 1990 that have investigated a possible relationship between hip fractures and long term consumption of artificially fluoridated water or water with high natural levels. The results have been mixed – some have found an association and others have not. Some have even claimed a protective effect. One very important study in China, which examined hip fractures in six Chinese villages, found what appears to be a dose-related increase in hip fracture as the concentration of fluoride rose from 1 ppm to 8 ppm (Li 2001) offering little comfort to those who drink a lot of fluoridated water. Moreover, in the only human epidemiological study to assess bone strength as a function of bone fluoride concentration, researchers from the University of Toronto found that (as with animal studies) the strength of bone declined with increasing fluoride content (Chachra 2010). Finally, a recent study from Iowa (Levy 2009), published data suggesting that

	low-level fluoride exposure may have a detrimental effect on cortical bone density in girls (an effect that has been repeatedly documented in clinical trials and which has been posited as an important mechanism by which fluoride may increase bone fracture rates). **30) People with impaired kidney function are particularly vulnerable to bone damage.** Because of their inability to effectively excrete fluoride, people with kidney disease are prone to accumulating high levels of fluoride in their bone and blood. As a result of this high fluoride body burden, kidney patients have an elevated risk for developing skeletal fluorosis. In one of the few U.S. studies investigating the matter, crippling skeletal fluorosis was documented among patients with severe kidney disease drinking water with just 1.7 ppm fluoride (Johnson 1979). Since severe skeletal fluorosis in kidney patients has been detected in small case studies, it is likely that larger, systematic studies would detect skeletal fluorosis at even lower fluoride levels. **31) Fluoride may cause bone cancer (osteosarcoma).** A U.S. government-funded animal study found a dose-dependent increase in bone cancer (osteosarcoma) in fluoride-treated, male rats (NTP 1990). Following the results of this study, the National Cancer Institute (NCI) reviewed national cancer data in the U.S. and found a significantly higher rate of osteosarcoma (a bone cancer) in young men in fluoridated versus unfluoridated areas (Hoover et al 1991a). While the NCI concluded (based on an analysis lacking statistical power) that fluoridation was not the cause (Hoover et al 1991b), no explanation was provided to explain the higher rates in the fluoridated areas. A smaller study from New Jersey (Cohn 1992) found osteosarcoma rates to be up to 6 times higher in young men living in fluoridated versus unfluoridated areas. Other epidemiological studies of varying size and quality have failed to find this relationship (a summary of these can be found in Bassin, 2001 and Connett & Neurath, 2005). There are three reasons why a fluoride-osteosarcoma connection is plausible: First, fluoride accumulates to a high level in bone. Second, fluoride stimulates bone growth. And, third, fluoride can interfere with the genetic apparatus of bone cells in several ways; it has been shown to be mutagenic, cause chromosome damage, and interfere with the enzymes involved with DNA repair in both cell and tissue studies (Tsutsui 1984; Caspary 1987; Kishi 1993; Mihashi 1996; Zhang 2009). In addition to cell and tissue studies, a correlation between fluoride exposure and chromosome damage in humans has also been reported (Sheth 1994; Wu 1995; Meng 1997; Joseph 2000). **32) Proponents have failed to refute the Bassin-Osteosarcoma study.** In 2001, Elise Bassin, a dentist, successfully defended her doctoral thesis at Harvard in which she found that young boys had a five-to-seven fold increased risk of getting osteosarcoma by the age of 20 if they drank fluoridated water during their mid-childhood growth spurt (age 6 to 8). The study was published in 2006 (Bassin 2006) but has been largely discounted by fluoridating countries because her thesis adviser Professor Chester Douglass (a promoter of fluoridation and a consultant for Colgate) promised a larger study that he claimed would discount her thesis (Douglass and

Joshipura, 2006). Now, after 5 years of waiting the Douglass study has finally been published (Kim 2011) but in no way does this study discount Bassin's findings. The study, which used far fewer controls than Bassin's analysis, did not even attempt to assess the age-specific window of risk that Bassin identified. Indeed, by the authors' own admission, the study had no capacity to assess the risk of osteosarcoma among children and adolescents (the precise population of concern). For a critique of the Douglass study, click here.

33) Fluoride may cause reproductive problems. Fluoride administered to animals at high doses wreaks havoc on the male reproductive system – it damages sperm and increases the rate of infertility in a number of different species (Kour 1980; Chinoy 1989; Chinoy 1991; Susheela 1991; Chinoy 1994; Kumar 1994; Narayana 1994a,b; Zhao 1995; Elbetieha 2000; Ghosh 2002; Zakrzewska 2002). In addition, an epidemiological study from the US found increased rates of infertility among couples living in areas with 3 ppm or more fluoride in the water (Freni 1994), two studies have found increased fertility among men living in high-fluoride areas of China and India (Liu 1988; Neelam 1987); four studies have found reduced level of circulating testosterone in males living in high fluoride areas (Hao 2010; Chen P 1997; Susheela 1996; Barot 1998), and a study of fluoride-exposed workers reported a "subclinical reproductive effect" (Ortiz-Perez 2003). While animal studies by FDA researchers have failed to find evidence of reproductive toxicity in fluoride-exposed rats (Sprando 1996, 1997, 1998), the National Research Council (2006) has recommended that, "the relationship between fluoride and fertility requires additional study."

34) Some individuals are highly sensitive to low levels of fluoride as shown by case studies and double blind studies. In one study, which lasted 13 years, Feltman and Kosel (1961) showed that about 1% of patients given 1 mg of fluoride each day developed negative reactions. Many individuals have reported suffering from symptoms such as fatigue, headaches, rashes and stomach and gastro intestinal tract problems, which disappear when they avoid fluoride in their water and diet. (Shea 1967; Waldbott 1978; Moolenburgh 1987) Frequently the symptoms reappear when they are unwittingly exposed to fluoride again (Spittle, 2008). No fluoridating government has conducted scientific studies to take this issue beyond these anecdotal reports. Without the willingness of governments to investigate these reports scientifically, should we as a society be forcing these people to ingest fluoride?

35) Other subsets of population are more vulnerable to fluoride's toxicity. In addition to people suffering from impaired kidney function discussed in reason #30 other subsets of the population are more vulnerable to fluoride's toxic effects. According to the Agency for Toxic Substances and Disease Registry (ATSDR 1993) these include: infants, the elderly, and those with diabetes mellitus. Also vulnerable are those who suffer from malnutrition (e.g., calcium, magnesium, vitamin C, vitamin D and iodine deficiencies and protein-poor diets) and those who have diabetes insipidus. See: Greenberg 1974; Klein 1975; Massler & Schour 1952; Marier & Rose

	1977; Lin 1991; Chen 1997; Seow 1994; Teotia 1998.
	No Margin of Safety **36) There is no margin of safety for several health effects**. No one can deny that high natural levels of fluoride damage health. Millions of people in India and China have had their health compromised by fluoride. The real question is whether there is an adequate margin of safety between the doses shown to cause harm in published studies and the total dose people receive consuming uncontrolled amounts of fluoridated water and non-water sources of fluoride. This margin of safety has to take into account the wide range of individual sensitivity expected in a large population (a safety factor of 10 is usually applied to the lowest level causing harm). Another safety factor is also needed to take into account the wide range of doses to which people are exposed. There is clearly no margin of safety for dental fluorosis (CDC, 2010) and based on the following studies nowhere near an adequate margin of safety for lowered IQ (Xiang 2003a,b; Ding 2011; Choi 2012); lowered thyroid function (Galletti & Joyet 1958; Bachinskii 1985; Lin 1991); bone fractures in children (Alarcon-Herrera 2001) or hip fractures in the elderly (Kurttio 1999; Li 2001). All of these harmful effects are discussed in the NRC (2006) review. **Environmental Justice** **37) Low-income families penalized by fluoridation.** Those most likely to suffer from poor nutrition, and thus more likely to be more vulnerable to fluoride's toxic effects, are the poor, who unfortunately, are the very people being targeted by new fluoridation programs. While at heightened risk, poor families are least able to afford avoiding fluoride once it is added to the water supply. No financial support is being offered to these families to help them get alternative water supplies or to help pay the costs of treating unsightly cases of dental fluorosis. **38) Black and Hispanic children are more vulnerable to fluoride's toxicity.** According to the CDC's national survey of dental fluorosis, black and Mexican-American children have significantly higher rates of dental fluorosis than white children (Beltran-Aguilar 2005, Table 23). The recognition that minority children appear to be more vulnerable to toxic effects of fluoride, combined with the fact that low-income families are less able to avoid drinking fluoridated water, has prompted prominent leaders in the environmental-justice movement to oppose mandatory fluoridation in Georgia. In a statement issued in May 2011, Andrew Young, a colleague of Martin Luther King, Jr., and former Mayor of Atlanta and former US Ambassador to the United Nations, stated: "I am most deeply concerned for poor families who have babies: if they cannot afford unfluoridated water for their babies' milk formula, do their babies not count? Of course they do. This is an issue of fairness, civil rights, and compassion. We must find better ways to prevent cavities, such as helping those most at risk for cavities obtain access to the services of a

dentist…My father was a dentist. I formerly was a strong believer in the benefits of water fluoridation for preventing cavities. But many things that we began to do 50 or more years ago we now no longer do, because we have learned further information that changes our practices and policies. So it is with fluoridation."

39) Minorities are not being warned about their vulnerabilities to fluoride. The CDC is not warning black and Mexican-American children that they have higher rates of dental fluorosis than Caucasian children (see #38). This extra vulnerability may extend to other toxic effects of fluoride. Black Americans have higher rates of lactose intolerance, kidney problems and diabetes, all of which may exacerbate fluoride's toxicity.

40) Tooth decay reflects low-income not low-fluoride intake. Since dental decay is most concentrated in poor communities, we should be spending our efforts trying to increase the access to dental care for low-income families. The highest rates of tooth decay today can be found in low-income areas that have been fluoridated for many years. The real "Oral Health Crisis" that exists today in the United States, is not a lack of fluoride but poverty and lack of dental insurance. The Surgeon General has estimated that 80% of dentists in the US do not treat children on Medicaid.

The largely untested chemicals used in fluoridation programs

41) The chemicals used to fluoridate water are not pharmaceutical grade. Instead, they largely come from the wet scrubbing systems of the phosphate fertilizer industry. These chemicals (90% of which are sodium fluorosilicate and fluorosilicic acid), are classified hazardous wastes contaminated with various impurities. Recent testing by the National Sanitation Foundation suggest that the levels of arsenic in these silicon fluorides are relatively high (up to 1.6 ppb after dilution into public water) and of potential concern (NSF 2000 and Wang 2000). Arsenic is a known human carcinogen for which there is no safe level. This one contaminant alone could be increasing cancer rates – and unnecessarily so.

42) The silicon fluorides have not been tested comprehensively. The chemical usually tested in animal studies is pharmaceutical grade sodium fluoride, not industrial grade fluorosilicic acid. Proponents claim that once the silicon fluorides have been diluted at the public water works they are completely dissociated to free fluoride ions and hydrated silica and thus there is no need to examine the toxicology of these compounds. However, while a study from the University of Michigan (Finney et al., 2006) showed complete dissociation at neutral pH, in acidic conditions (pH 3) there was a stable complex containing five fluoride ions. Thus the possibility arises that such a complex may be regenerated in the stomach where the pH lies between 1 and 2.

43) The silicon fluorides may increase lead uptake into children's blood. Studies by Masters and Coplan (1999, 2000, 2007), and to a lesser

extent Macek (2006), show an association between the use of fluorosilicic acid (and its sodium salt) to fluoridate water and an increased uptake of lead into children's blood. Because of lead's acknowledged ability to damage the developing brain, this is a very serious finding. Nevertheless, it is being largely ignored by fluoridating countries. This association received some strong biochemical support from an animal study by Sawan et al. (2010) who found that exposure of rats to a combination of fluorosilicic acid and lead in their drinking water increased the uptake of lead into blood some threefold over exposure to lead alone.

44) Fluoride may leach lead from pipes, brass fittings and soldered joints. In tightly controlled laboratory experiments, Maas et al (2007) have shown that fluoridating agents in combination with chlorinating agents such as chloroamine increase the leaching of lead from brass fittings used in plumbing. While proponents may argue about the neurotoxic effects of low levels of fluoride there is no argument that lead at very low levels lowers IQ in children.

Continued promotion of fluoridation is unscientific

45) Key health studies have not been done. In the January 2008 issue of Scientific American, Professor John Doull, the chairman of the important 2006 National Research Council review, Fluoride in Drinking Water: A Review of EPA's Standards, is quoted as saying:

What the committee found is that we've gone with the status quo regarding fluoride for many years—for too long really—and now we need to take a fresh look . . . In the scientific community people tend to think this is settled. I mean, when the U.S. surgeon general comes out and says this is one of the top 10 greatest achievements of the 20th century, that's a hard hurdle to get over. But when we looked at the studies that have been done, we found that many of these questions are unsettled and we have much less information than we should, considering how long this [fluoridation] has been going on.

The absence of studies is being used by promoters as meaning the absence of harm. This is an irresponsible position.

46) Endorsements do not represent scientific evidence. Many of those promoting fluoridation rely heavily on a list of endorsements. However, the U.S. PHS first endorsed fluoridation in 1950, before one single trial had been completed and before any significant health studies had been published (see chapters 9 and 10 in *The Case Against Fluoride* for the significance of this PHS endorsement for the future promotion of fluoridation). Many other endorsements swiftly followed with little evidence of any scientific rational for doing so. The continued use of these endorsements has more to do with political science than medical science.

47) Review panels hand-picked to deliver a pro-fluoridation result. Every so often, particularly when their fluoridation program is under threat, governments of fluoridating countries hand-pick panels to deliver reports that

provide the necessary re-endorsement of the practice. In their recent book Fluoride Wars (2009), which is otherwise slanted toward fluoridation, Alan Freeze and Jay Lehr concede this point when they write:

There is one anti-fluoridationist charge that does have some truth to it. Anti-fluoride forces have always claimed that the many government-sponsored review panels set up over the years to assess the costs and benefits of fluoridation were stacked in favor of fluoridation. A review of the membership of the various panels confirms this charge. The expert committees that put together reports by the American Association for the Advancement of Science in 1941, 1944 and 1954; the National Academy of Sciences in 1951, 1971, 1977 and 1993; the World Health Organization in 1958 and 1970; and the U.S. Public Health Service in 1991 are rife with the names of well-known medical and dental researchers who actively campaigned on behalf of fluoridation or whose research was held in high regard in the pro-fluoridation movement. Membership was interlocking and incestuous.

The most recent examples of these self-fulfilling prophecies have come from the Irish Fluoridation Forum (2002); the National Health and Medical Research Council (NHMRC, 2007) and Health Canada (2008, 2010). The latter used a panel of six experts to review the health literature. Four of the six were pro-fluoridation dentists and the other two had no demonstrated expertise on fluoride. A notable exception to this trend was the appointment by the U.S. National Research Council of the first balanced panel of experts ever selected to look at fluoride's toxicity in the U.S. This panel of twelve reviewed the US EPA's safe drinking water standards for fluoride. After three and half years the panel concluded in a 507- page report that the safe drinking water standard was not protective of health and a new maximum contaminant level goal (MCLG) should be determined (NRC, 2006). If normal toxicological procedures and appropriate margins of safety were applied to their findings this report should spell an end to water fluoridation. Unfortunately in January of 2011 the US EPA Office of Water made it clear that they would not determine a value for the MCLG that would jeopardize the water fluoridation program (EPA press release, Jan 7, 2011. Once again politics was allowed to trump science.

More and more independent scientists oppose fluoridation

48) Many scientists oppose fluoridation. Proponents of fluoridation have maintained for many years— despite the fact that the earliest opponents of fluoridation were biochemists—that the only people opposed to fluoridation are not bona fide scientists. Today, as more and more scientists, doctors, dentists and other professionals, read the primary literature for themselves, rather than relying on self-serving statements from the ADA and the CDC, they are realizing that they and the general public have not been diligently informed by their professional bodies on this subject. As of January 2012, over 4,000 professionals have signed a statement calling for an end to water fluoridation worldwide. This statement and a list of signatories can be found

on the website of the Fluoride Action Network. A glimpse of the caliber of those opposing fluoridation can be gleaned by watching the 28-minute video "Professional Perspectives on Water fluoridation" which can be viewed online at the same FAN site.

Proponents' dubious tactics

49) Proponents usually refuse to defend fluoridation in open debate. While pro-fluoridation officials continue to promote fluoridation with undiminished fervor, they usually refuse to defend the practice in open public debate – even when challenged to do so by organizations such as the Association for Science in the Public Interest, the American College of Toxicology, or the U.S. EPA (Bryson 2004). According to Dr. Michael Easley, a prominent lobbyist for fluoridation in the US, "Debates give the illusion that a scientific controversy exists when no credible people support the fluorophobics' view" (Easley, 1999). In light of proponents' refusal to debate this issue, Dr. Edward Groth, a Senior Scientist at Consumers Union, observed that, "the political profluoridation stance has evolved into a dogmatic, authoritarian, essentially antiscientific posture, one that discourages open debate of scientific issues" (Martin 1991).

50) Proponents use very dubious tactics to promote fluoridation. Many scientists, doctors and dentists who have spoken out publicly on this issue have been subjected to censorship and intimidation (Martin 1991). Dr. Phyllis Mullenix was fired from her position as Chair of Toxicology at Forsythe Dental Center for publishing her findings on fluoride and the brain (Mullenix 1995); and Dr. William Marcus was fired from the EPA for questioning the government's handling of the NTP's fluoride-cancer study (Bryson 2004). Many dentists and even doctors tell opponents in private that they are opposed to this practice but dare not speak out in public because of peer pressure and the fear of recriminations. Tactics like this would not be necessary if those promoting fluoridation were on secure scientific and ethical grounds.

Conclusion

When it comes to controversies surrounding toxic chemicals, vested interests traditionally do their very best to discount animal studies and quibble with epidemiological findings. In the past, political pressures have led government agencies to drag their feet on regulating asbestos, benzene, DDT, PCBs, tetraethyl lead, tobacco and dioxins. With fluoridation we have had a sixty-year delay. Unfortunately, because government officials and dental leaders have put so much of their credibility on the line defending fluoridation, and because of the huge liabilities waiting in the wings if they admit that fluoridation has caused an increase in hip fracture, arthritis, bone cancer, brain disorders or thyroid problems, it will be very difficult for them to speak honestly and openly about the issue. But they must, not only to protect millions of people from unnecessary harm, but to protect the notion that, at its core, public health policy must be based on sound science, not political expediency. They have a tool with which to do this: it's called the

Precautionary Principle. Simply put, this says: if in doubt leave it out. This is what most European countries have done and their children's teeth have not suffered, while their public's trust has been strengthened.

Just how much doubt is needed on just one of the health concerns identified above, to override a benefit, which when quantified in the largest survey ever conducted in the US, amounts to less than one tooth surface (out of 128) in a child's mouth?

While fluoridation may not be the greatest environmental health threat, it is one of the easiest to end. It is as easy as turning off a spigot in the public water works. But to turn off that spigot takes political will and to get that we need masses more people informed and organized. Please get these 50 reasons to all your friends and encourage them to get fluoride out of their community and to help ban this practice worldwide.

Postscript

Further arguments against fluoridation, can be viewed at http://www.fluoridealert.org and in the book The Case Against Fluoridation (Chelsea Green, 2010). Arguments for fluoridation can be found at http://www.ada.org

Publication history of the 50 Reasons

The 50 Reasons were first compiled by Paul Connett and presented in person to the Irish Fluoridation Forum in October 2000. The document was refined in 2004 and published in *Medical Veritas*. In the introduction to the 2004 version it was explained that after over four years the Irish authorities had not been able to muster a response to the 50 Reasons, despite agreeing to do so in 2000. Eventually, an anonymous, incomplete and superficial response was posted on the Irish Department of Health and Children's website (see this response and addendum at:http://www.dohc.ie/other_health_issues/dental_research/. Paul Connett's comprehensive response to this response can be accessed at http://www.fluoridealert.org/50reasons.ireland.pdf. We learned on August 7, 2011 that this governmental response was prepared by an external contractor at a cost to the Irish taxpayers' of over 30,000 Euros.

Since 2004, there have been many major scientific developments including the publication of the U.S. National Research Council report (NRC, 2006); the publication of Bassin's study on Osteosarcoma (Bassin 2006), and many more studies of fluoride's interaction with the brain, that necessitated a major update of the 50 Reasons in August 2011. This update was made with the generous assistance of James Beck, MD, PhD, Michael Connett, JD, Hardy Limeback, DDS, PhD, David McRae and Spedding Micklem, D.Phil. Additional developments in 2012, including FAN's translation of over 20 Chinese studies on fluoride toxicity and publication of the Harvard team's meta-review of fluoride and IQ (Choi 2012), warranted a further update in August 2012, with the extremely helpful assistance of my son,

Xiang Q, et al. (2003a). Effect of fluoride in drinking water on children's intelligence. *Fluoride.* 36: 84-94.

Xiang Q. (2003b). Blood lead of children in Wamiao-Xinhuai intelligence study. *Fluoride.* 36: 138.

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Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	Sodium fluoride

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

x **I do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Fw: Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

askmedsafe 05/01/2015 08:23 p.m.

History: This message has been replied to.

From·
Sent: .....uay, January 05, 2015 8:20 PM
To: askmedsafe@moh.govt.nz1
Subject: Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Nam(

Email: '

...
Addre

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

Post to:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)
to: askmedsafe 05/01/2015 08:47 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
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Name:

Email:

Address:

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International research has shown that flouride in drinking water is toxic to humans and has

detrimental effects to brain function, nervous system, bones and teeth.

Why does the Ministry of Health continue to promote poisoning the population when enlightened countries ceased the practise decades ago?

Fwd: Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

r to: askmedsafe 05/01/2015 08:49 p.m.

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
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Name:

Email:

Address:

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Why does the Ministry of Health continue to promote poisoning the population when enlightened countries ceased the practise decades ago?

fluoride

to: askmedsafe 05/01/2015 08:59 p.m.

History: This message has been replied to.

SUBMISSION FORM
Name:
Adress/email:

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

Question 1. *Do you support the proposed amendment? If not why not?*
NO. I do not support the proposed amendment because:

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2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
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I do not wish to speak to my submission.