



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

to: askmedsafe

09/01/2015 08:53 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: 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

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

www.avast.com

SUBMISSION FORM

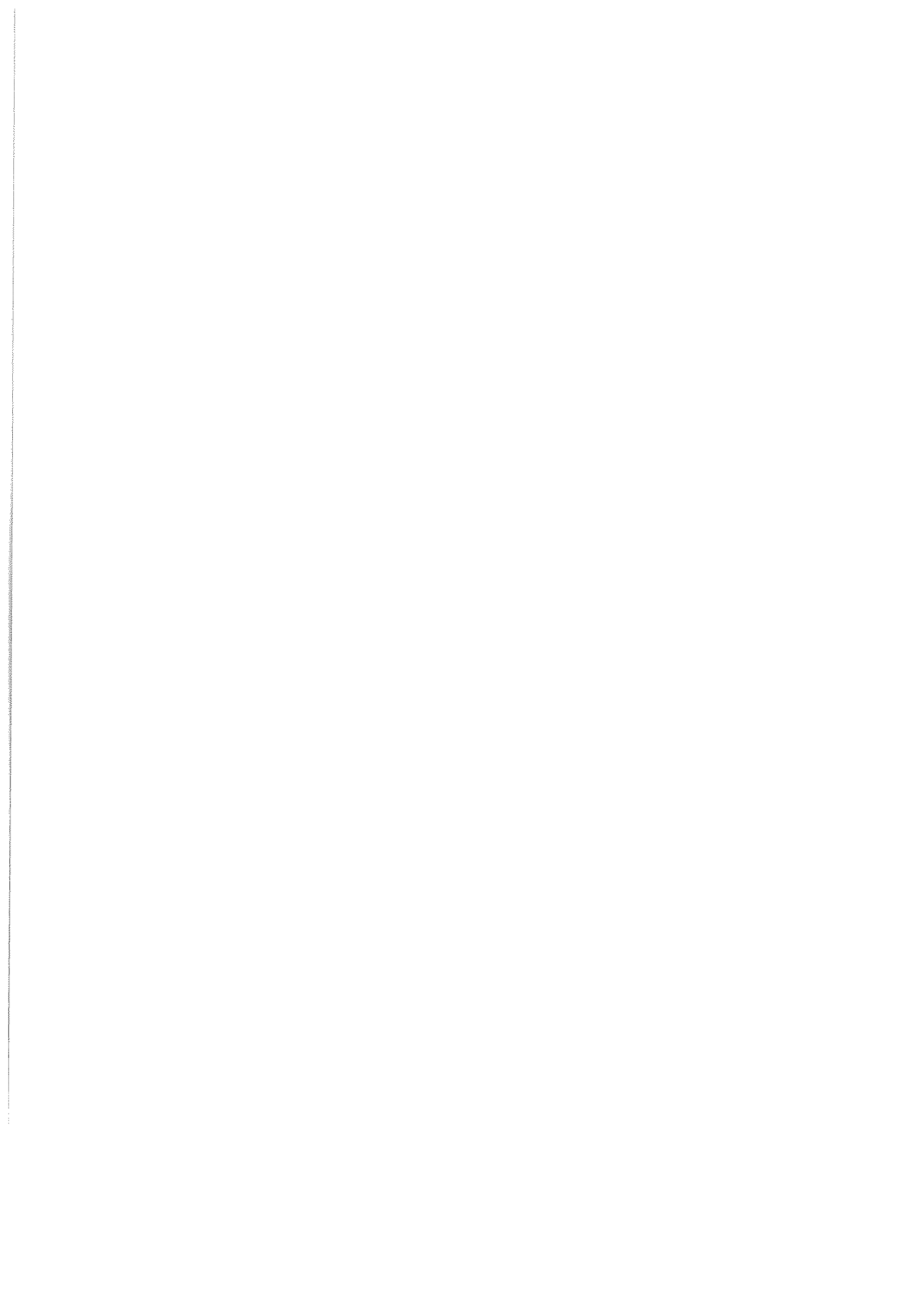
Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	Northland District Health Board
Please provide a brief description of the organisation if applicable:	
Address/email:	@northlanddhb.org.nz
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Health Professional
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	Yes, Northland District Health Board supports the proposed amendment to Regulations under the Medicines Act 1981.
Question 2 <i>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?</i>	Sodium fluoride, listed by the US Center for Disease Control (Centers for Disease Control and Prevention, 2014) as a type of fluoride additive should also be included with Hydrofluorosilicic acid (HFA) and Sodium Silico Fluoride (SSF) in the regulation.

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

Reference:

Centers for Disease Control and Prevention, 2014. [Online] Available at: <http://www.cdc.gov/fluoridation/factsheets/engineering/wfadditives.htm> [Accessed December 2014].





9 January 2015

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

askmedsafe@moh.govt.nz

Dear Sir/Madam

**Re: Submission on Amendment to the Medicines Regulations made under the Medicines Act 1981
(Re: Fluoride in Drinking Water): Consultation**

Thank you for the opportunity to provide a written submission on this consultation document.

Regional Public Health serves the greater Wellington region, through its three district health boards (DHBs): Capital and Coast, Hutt Valley and Wairarapa and as a service is part of the Hutt Valley District Health Board.

We work with our community to make it a healthier, safer place to live. We promote good health, prevent disease and improve the quality of life for our population, with a particular focus on children, Māori and working with primary care organisations. Our staff include a range of occupations such as: medical officers of health, public health advisors, health protection officers, public health nurses, and public health analysts.

We have provided comment on the questions presented for the proposed amendment, and are happy to provide further advice or clarification on any of the points raised in our written submission. The contact point for this submission is:

Barbara Stevenson
Health Protection Officer
Email: Barbara.Stevenson@huttvalleydhb.org.nz
Tel: (04) 570-9002

Kind regards

Dr Stephen Palmer
Medical Officer of Health

Peter Gush
Service Manager

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

Tooth decay remains the single most chronic disease amongst New Zealanders of all ages, with consequences of pain, infection, impaired chewing ability, tooth loss and absence from work and school. Tooth decay is an irreversible disease.

Regional Public Health considers dental decay to be an important public health issue, with poorer health outcomes reflective of differences within the community, with regards to ethnicity and socio-economic status.

In many parts of the world, community water fluoridation is used as a preventative measure. It is considered to be the most cost effective public health measure to reduce the burden of dental disease across the whole population.

The fluorine containing compounds used for fluoridation in New Zealand are sodium fluorosilicate or (SSF), and hydrofluorosilicic acid or (HFA). These compounds have all been shown to dissolve fully in water to release fluoride ions, which are identical to those found naturally in New Zealand water at levels (0.1-0.2 mg/L).

The World Health Organisation recognises an adequate lower level of intake and sets an upper limit on the levels of fluoride in drinking water (range 0.5-1.5 mg/L).

In New Zealand, the Ministry of Health (MOH) has similarly recommended that the fluoride content for drinking water range between (range 0.7-1.0 mg/L); and the maximum acceptable value for drinking water has been set at 1.5mg/L.

Regional Public Health supports the addition of fluoride substances into drinking water at the MOH prescribed acceptable levels (0.7-1.0 mg/L), and thus is supportive of the proposed amendment that fluoride substances that are used to treat drinking water are not medicines.

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

Regional Public Health supports the incorporation of the named fluoride substances sodium fluorosilicate (SSF), and hydrofluorosilicic acid (HFA), in the regulation. However, it is recommended that the regulations include a requirement for a quality standard, to control the purity of these substances which will be added to drinking 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):	Private citizen/ratepayer
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	Yes
Question 2 <i>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?</i>	

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.

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Amendment of Exemption of Fluoride Chemicals - submission

From: askmedsafe

Date: 09/01/2015 11:10 a.m.

History:

This message has been replied to.

Dear Sirs

Please find below my submission against the proposed amendment:

I 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:

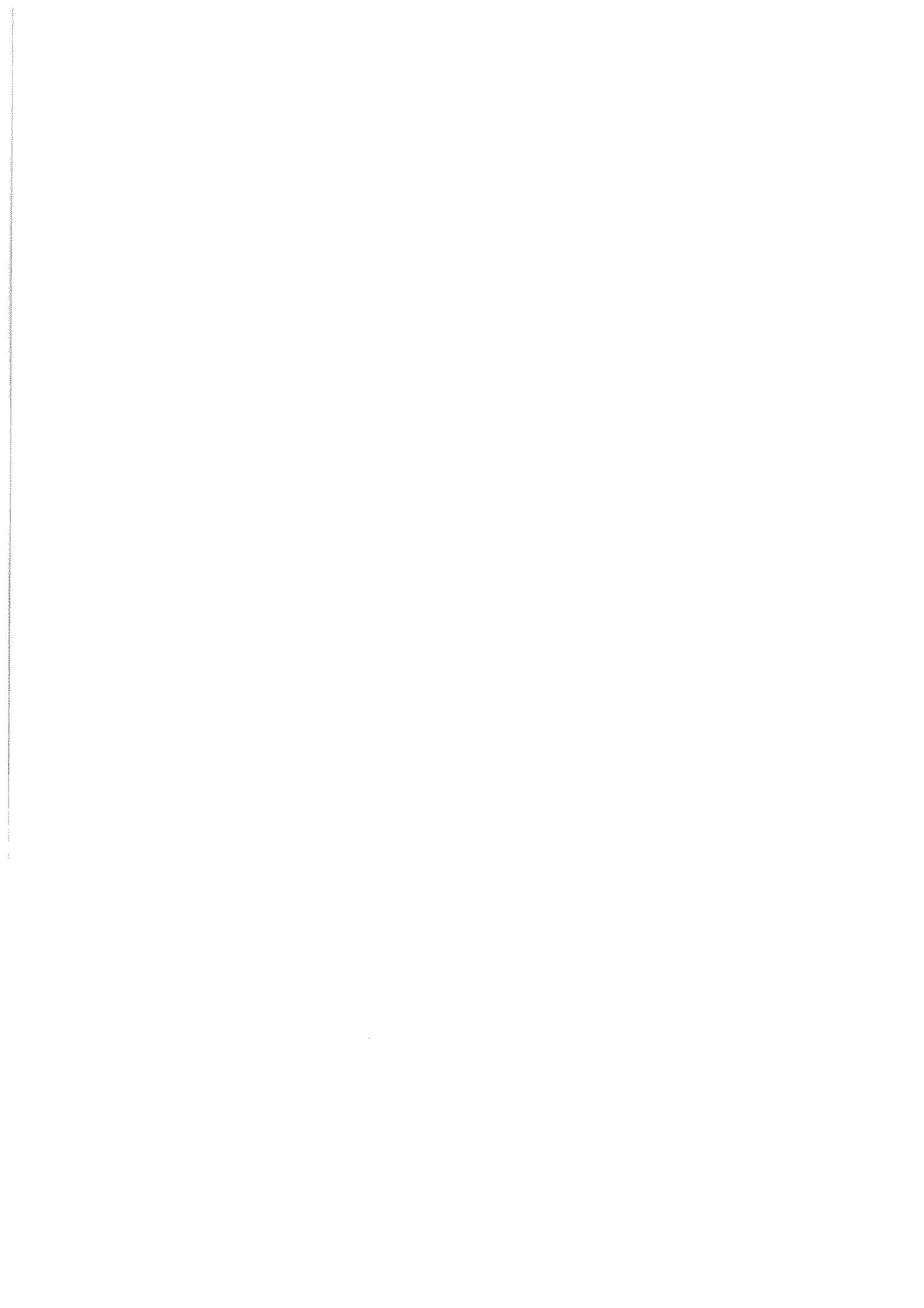
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals 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.

Regards





fluoride

to: askmedsafe
Sent by:

to: askmedsafe

09/01/2015 11:10 a.m.

History:

This message has been replied to.

I do not support the proposed amendment.

I have a special interest in nutrient testing. I have a brother with over 30 years as a dentist and sister with over 30 years working in the school dental system. She has worked in both fluoridated and non-fluoridated regions.

My reasons for not supporting the amendments is because *fluoride has powerful chemical effects on the human body - all creatures for that matter - and is therefore a medicine.*

Placing fluoride in water supplies is an extremely inefficient means of delivery.

Bear in mind that:

- Fluoride is the most reactive of the halogens which includes bromine, chlorine and iodine
- Fluorine, chlorine and bromine are now ubiquitous in our food, medicines, water and plastics.
- In my testing of people there is at least a 90% rate of deficiency in iodine which is essential for life including brain function, thyroid and disease resistance, including many cancers.
- Fluorine, chlorine and bromine interfere with their less reactive cousin: iodine. For example, crowding out the iodine receptors of the thyroid.
- We have a national epidemic of thyroid diseases that is increasing by the day. Iodine deficiency plus the widespread use of fluorine, chlorine and bromine are at the very heart of this.

I would point out that the actions of the halogen elements is basic Stage One Chemistry. The actions of these on the thyroid are also basic physiology and hardly rocket science.

Further points with regards to dental decay:

- Fluoride does harden teeth but only by surface contact for mature teeth. Delivery through water supplies is extremely inefficient and unhealthy as per my earlier points about thyroid diseases.

If we were really serious about dental health we would:

- Fund twice yearly visits to the dentist/dental therapist and build the school dental therapist system instead of progressively running it down as is currently the case.
- During these visits the patient can have fluoride painted onto the tooth surfaces and then the residue washed out and disposed of so that there is minimal systemic and environmental contamination.
- Deal with the real issues of dental decay which is poverty. This means a living wage that a family can live on in terms of being able to afford good housing, good food, visits to the dentist and a good education for their children. I recently visited Norway where the minimum wage is approximately the equivalent to NZ\$28. Needless to say, they generally have very good health, including dental, and their water is not fluoridated and most, if not all, is not even chlorinated.

The point is this: Fluoridating water supplies is missing the point, while being potentially harmful!

Consultant

Academic Qualifications:

DipPhEd, PGDipRehab, PGDipSportMed (Otago)

Are we any good at what we do?

More detail, including industry practitioner training:

Website

How to find my office

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

From: askmedsafe

Date: 09/01/2015 10:56 a.m.

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:

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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

I do not wish to speak to my submission.

Regards



Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 submission from

to: askmedsafe

09/01/2015 10:53 a.m.

History:

This message has been replied to.

Name:

If this submission is made on behalf of an organisation, please name that organisation here:
n/a

Please provide a brief description of the organisation if applicable:n/a

Address/email:

Your interest in this topic:

I have recently written a master thesis on irrationality and science denialism. The fluoridation debate has become a major focus of my attention due to it's current prominence in NZ.

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?

Yes. Sodium Fluoride should also be named. It can be used for water fluoridation, and it is not impossible that council will wish to resort to using it for fluoridation in favour of the more scary sounding chemicals. There is currently a push in "natural health" circles to not consume anything that you can not pronounce. Although irrational, this manta is very popular, and will likely lead some individuals to favour the use of sodium fluoride.


SUBMISSION FORM:

askmedsafe

09/01/2015 10:35 a.m.

History:

This message has been replied to.

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

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:

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I do / do not (delete whichever does not apply) 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

I would prefer that the Government continued to research as well as make the public aware of the effects that our processed foods especially the sugar content in the foods we eat.

We already have flouride toothpastes that the majority of New Zealanders use daily, if not twice daily.

I do not wish to speak to my submission.



fluoride IS a medicine

askmedsafe

09/01/2015 10:35 a.m.

History: This message has been replied to.

SUBMISSION FORM

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

Name: S

Email:

Address:

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

NO. I do not support the proposed amendment because:

1. A medicine is not defined by the dose used, but by the purpose for which it is administered - in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.

It is an absurd notion to try to support placing an established enzyme toxin into drinking water in the hope that it might prevent a cavity or two in a lifetime. In fact, many legitimate studies indicate that fluoridation might save barely half a tooth surface of the possible 128 surfaces. What is doubly absurd is to ask all thinking people to accept that adding fluoridating chemicals into drinking water to protect against dental caries does not constitute the administration of a medicine.

When a pharmacist creates a medicine he/she takes a chemical compound and dilutes it with water to arrive at a concentration (medicinal strength) that is beneficial to a particular patient. In doing so, they are creating a medicine of the compound.

Adding silicofluoride compounds to the drinking water supply at a typical dilution of 240,000:1 is no different than the earlier pharmaceutical act. A public health authority acts as the pharmacist in this case and authorizes others to mix the silicofluoride compound with drinking water in such a manner as to reach a concentration (medicinal strength) of somewhere between 0.7 mg/l and 1.0 mg/l, deemed by the authority to be protective against the disease of dental caries. Every lay person can see clearly that water fluoridation is the preparation and distribution of a medicine.

A medicine is not defined by the dose used, but by the purpose for which it is administered

If one looks up the word "medicine" in any major dictionary in the English language the definition is very simple and clear. A medicine is "a substance that is used to treat, prevent or mitigate a disease." In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

See,

Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, *The physiology and biochemistry of the mouth* (4th Ed) by G Neil Jenkins)

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ's Medicines' Act was a medicine, lowering the dose to a level of approximately 1 ppm used in water fluoridation could do two possible things: a) it could lower its effectiveness and b) it could reduce its toxic side effects, but it would not change the purpose for which these substances were added to the water supply. **At whatever dose used in**

tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.

For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

2. Fluoride is not a water treatment chemical to treat the water (like chlorine) but simply to use the water supply to deliver medical treatment.

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**
I do not wish to speak to my submission



Fluoride IS a medicine

askmedsafe

09/01/2015 10:30 a.m.

Sent by: \

Please respond to vic

History: This message has been replied to.

SUBMISSION FORM

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)

Name: V

Email: a

Address:

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

NO. I do not support the proposed amendment because:

1. A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.

In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. **A medicine is not defined by the dose used, but by the purpose for which it is administered**

If one looks up the word “medicine” in any major dictionary in the English language the definition is very simple and clear. A medicine is “a substance that is used to treat, prevent or mitigate a disease.” In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

See,

Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, *The physiology and biochemistry of the mouth* (4th Ed) by G Neil Jenkins)

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For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

2. Fluoride is not a water treatment chemical to treat the water (like chlorine) but simply to use the water supply to deliver medical treatment.

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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**

I do not wish to speak to my submission



Proposed Amendment to Regulations Under Medicines Act - Fluoride

askmedsafe

09/01/2015 10:29 a.m.

Please respond to email

History: This message has been replied to.

8th 2015

Dear Ministry of Health

I enclose my submission to the proposed amendment to the Medicines Act 1981 to exempt fluorides. I am a qualified teacher and now retired.

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

I do not support the proposed amendment. In 1983, Lord Jauncey (McColl v. Strathclyde) ruled that fluoridated water clearly falls under the Medicines Act, since its purpose is to prevent the disease of dental caries. Exempting fluoride from the New Zealand Medicines Act, will not change the fact that fluoridated water is a medicine.

"The truth does not cease to exist simply because it is ignored" - Aldous Huxley

The proposal is unethical since it will override the precautionary principle protecting New Zealand citizens from harm through the indiscriminate use of medicines and would violate the hypocratic oath to 'first do no harm'. It is impossible to control the dose through the water supply because it is not possible to monitor the amount of water that individuals ingest.

The World Health Organisation guidelines to assess the total fluoride intake of all individuals from all sources is not being observed in New Zealand and dental fluorosis, the outward sign of overexposure to fluoride, is now epidemic in children in fluoridated areas. No individual health monitoring is being conducted in fluoridated areas to assess the long term adverse health effects.

Senior EPA scientists, Dr William Hirzy and Dr Robert Carton conducted an intensive study into the harms from fluoride exposure and concluded that the only safe level of fluoride for babies is zero. The proposal to exempt fluoride would therefore put New Zealand babies at serious risk. It is more vital than ever to protect infants from exposure now that fluoride has been identified as a developmental neurotoxin by Harvard professors Dr Philippe Grandjean and Dr Philip Landrigan. This proves the effects are systemic and that fluoride is unquestionably a medicine.

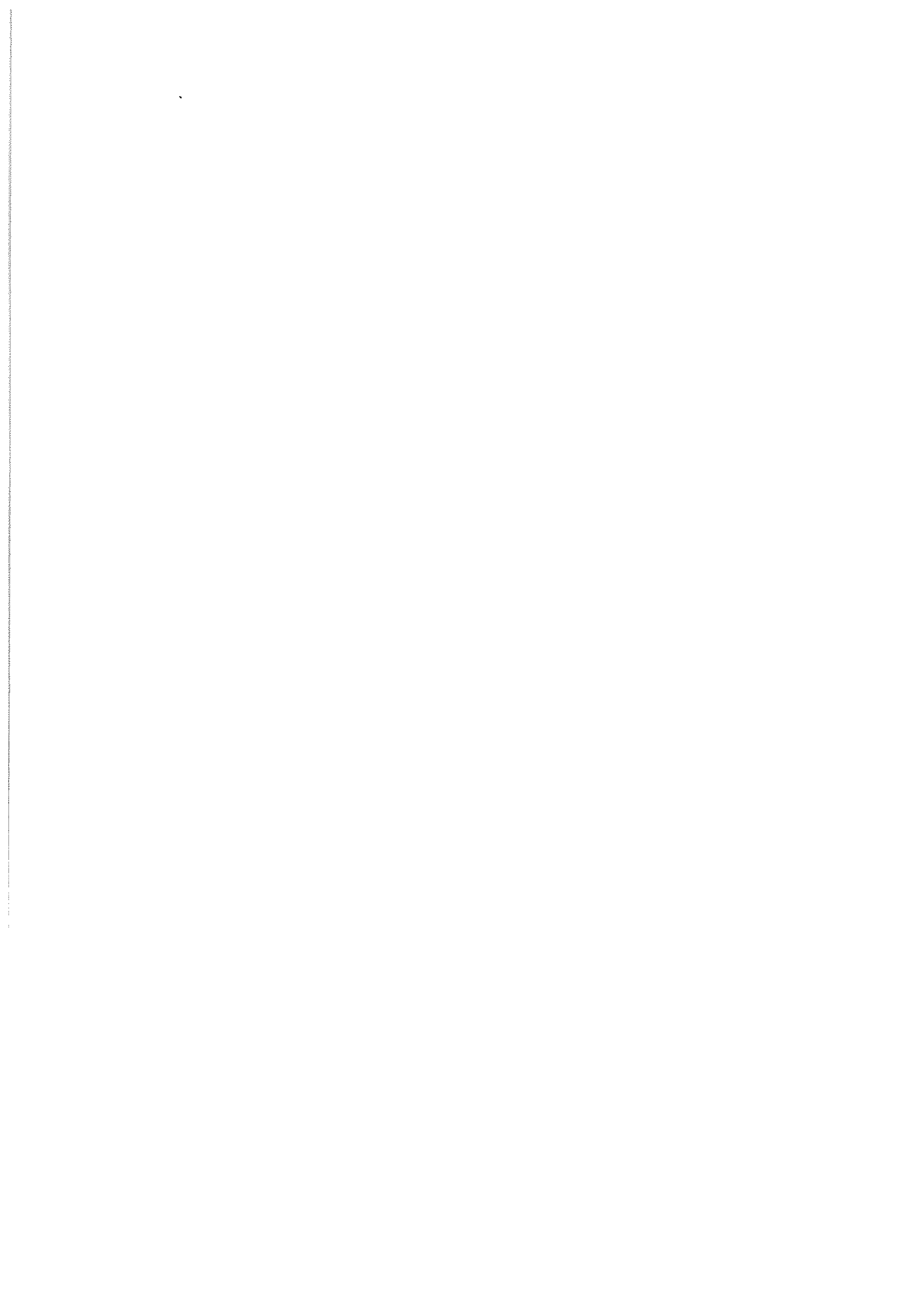
The New Zealand Ministry of Health risks international condemnation if this proposal is implemented, since fluoridation is now thoroughly discredited by the overwhelming weight of scientific research, including the Harvard research and over 40 scientific studies that support these findings.

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.

Yours sincerely



SUBMISSION FORM

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

Name:	Dr Robert Weir, Medical Officer of Health and Clinical Director (MidCentral Public Health Service) Dr Philip Marshall, Clinical Director (MidCentral DHB Child and Adolescent Oral Health Service)
If this submission is made on behalf of an organisation, please name that organisation here:	MidCentral Public Health Service and Child and Adolescent Oral Health Service
Please provide a brief description of the organisation if applicable:	
Address/email:	robert.weir@midcentraldhb.govt.nz
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Health professional
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	Yes
Question 2 <i>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?</i>	Not in the MidCentral DHB area

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Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer / Scientist / Science educator & communicator
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	Yes.
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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.



Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 submission from

to: askmedsafe

09/01/2015 10:53 a.m.

History: This message has been replied to.

Name:

If this submission is made on behalf of an organisation, please name that organisation here:
n/a

Please provide a brief description of the organisation if applicable:n/a

Address/email:

Your interest in this topic:

I have recently written a master thesis on irrationality and science denialism. The fluoridation debate has become a major focus of my attention due to it's current prominence in NZ.

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?

Yes. Sodium Fluoride should also be named. It can be used for water fluoridation, and it is not impossible that council will wish to resort to using it for fluoridation in favour of the more scary sounding chemicals. There is currently a push in "natural health" circles to not consume anything that you can not pronounce. Although irrational, this manta is very popular, and will likely lead some individuals to favour the use of sodium fluoride.



Fluoride

J : askmedsafe

09/01/2015 10:37 a.m.

History: This message has been replied to.

--

7-48





Fluoride

to: askmedsafe

09/01/2015 10:36 a.m.

History:

This message has been replied to.

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)

“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

Nar

Em: ..

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 believe that every New Zealander has a right to have their say. By making it compulsory that councils put Fluoride into our water supply then that is removing that right as a New Zealander to have our say.

I would prefer that the Government continued to research as well as make the public aware of the effects that our processed foods especially the sugar content in the foods we eat.

We already have flouride toothpastes that the majority of New Zealanders use daily, if not twice daily.

I do not wish to speak to my submission.



Fluoride Submission

askmedsafe

09/01/2015 10:10 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

Email

Address

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

NO. I do not support the proposed amendment because:

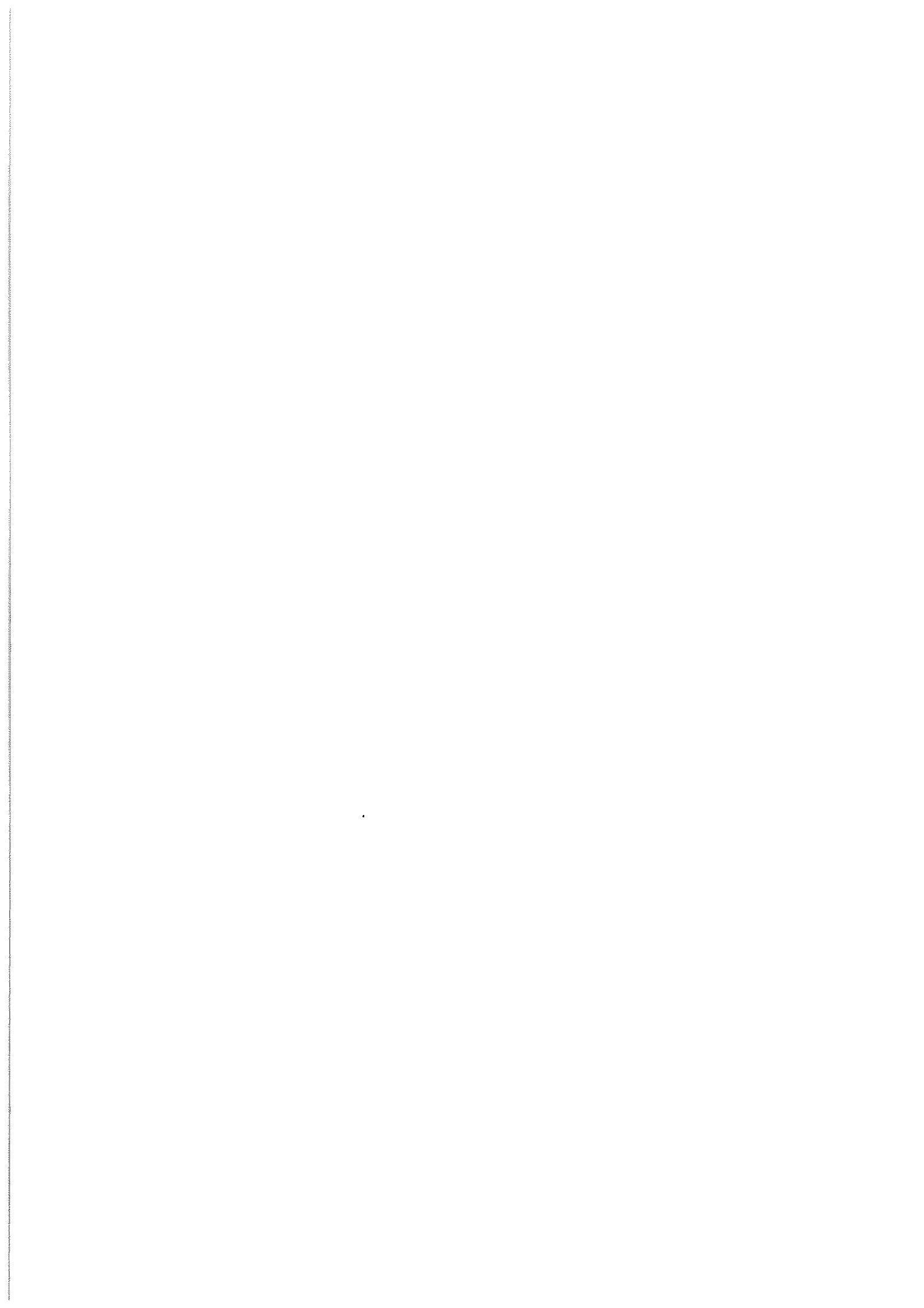
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals 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 (delete whichever does not apply) wish to speak to my submission.

Kind regards,



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):	Dental student
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	Yes I do
<p>Question 2</p> <p><i>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?</i></p>	<p>The practice of Water fluoridation should not be subject to the medicines act. HFA is commonly used, however, it's not what goes into the water that's relevant but what comes out of the tap.</p> <p>Fluoride ions at .7-1ppm do not represent a medicine as they do not render any known side effects.</p>

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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
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	Yes
<p>Question 2</p> <p><i>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?</i></p>	<p>The practice of Water fluoridation should not be subject to the medicines act. HFA is commonly used, however, it's not what goes into the water that's relevant but what comes out of the tap.</p> <p>Fluoride ions at .7-1ppm do not represent a medicine as they do not render any known side effects.</p>

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**Proposed Amendment to Regulations under the Medicines Act 1981**

to: askmedsafe

09/01/2015 10:21 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 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

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

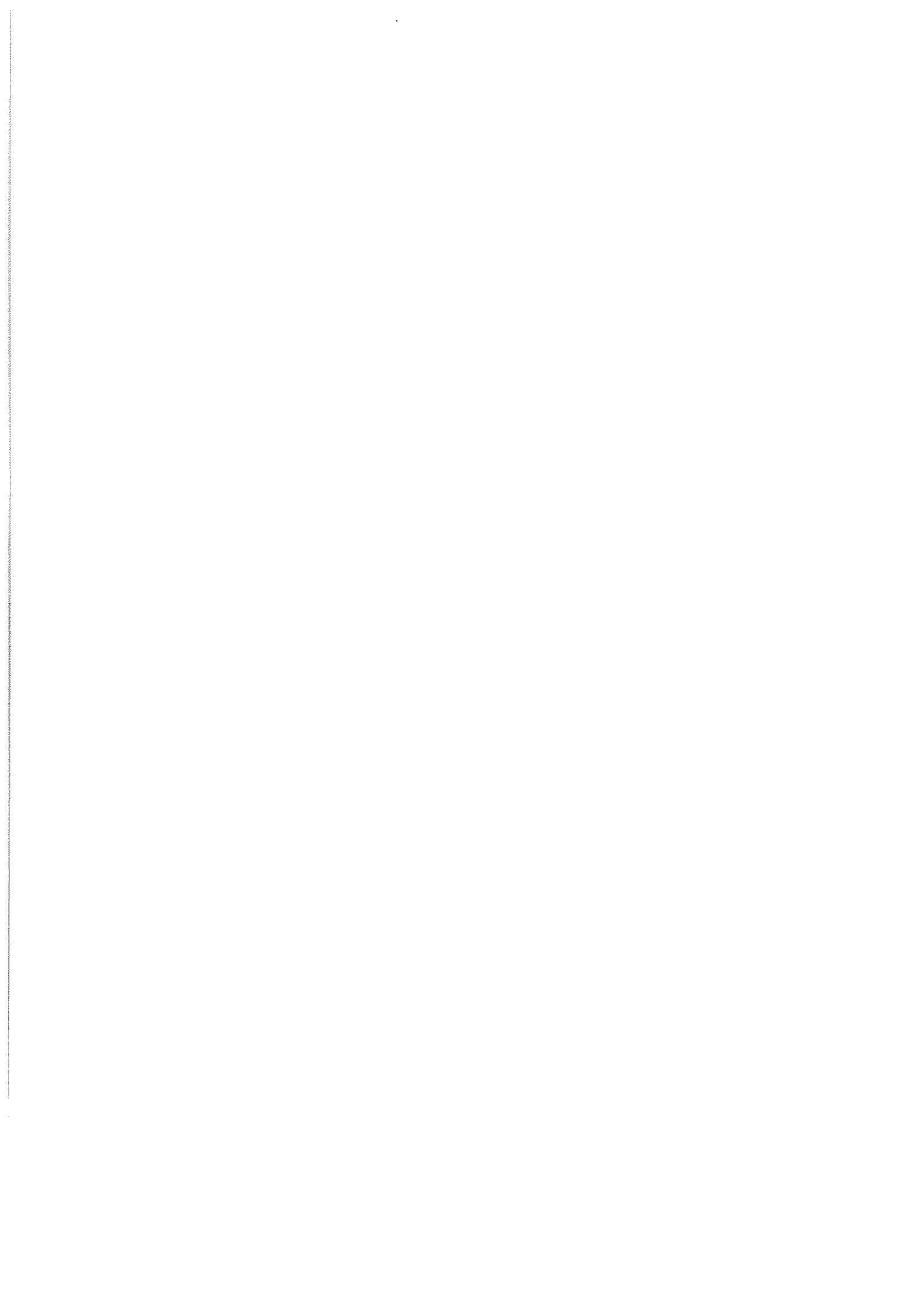
No. I do not support the proposed amendment because fluoride is not a water treatment like chlorine; it is used to treat dental caries, not to make the water supply safe to drink. Adding fluoride to the water in order to treat a medical problem makes it a medicine. People have the right to know that they are being medicated, and to refuse medication if they wish, regardless of what the medication is or how it is administered. The Medicines Act is designed to safeguard people from the indiscriminate use of medicines, and to protect these rights. The proposed amendment would remove this protection, and allow the forced medication of people against their will.

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 the water supply itself. Rather, they are used to treat people’s dental caries, making them medicines.

Thank you for your time,

--



1270



Fluoride

askmedsafe

09/01/2015 10:21 a.m.

History: This message has been replied to.

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)

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.

Name: J _____
Email: j _____
Address: J _____

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

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.

Faithfull



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):	Fluorine chemist, and
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	Yes.
Question 2 <i>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?</i>	Sodium fluoride, may also be used to treat community water supplies & should be specifically named in the legislation. The practice of water fluoridation should not be subject to the Medicines Act. Fluoride is of benefit at the concentrations used in CWF; and there are no harmful side effects at these concentrations. Fluoride ions do not constitute a medicine. Besides fluoride may be present at these or higher concentrations naturally.

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**Fluoride**

F

:safe

09/01/2015 10:16 a.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 not give permission for my personal details to be released to persons under the Official Information Act 1982

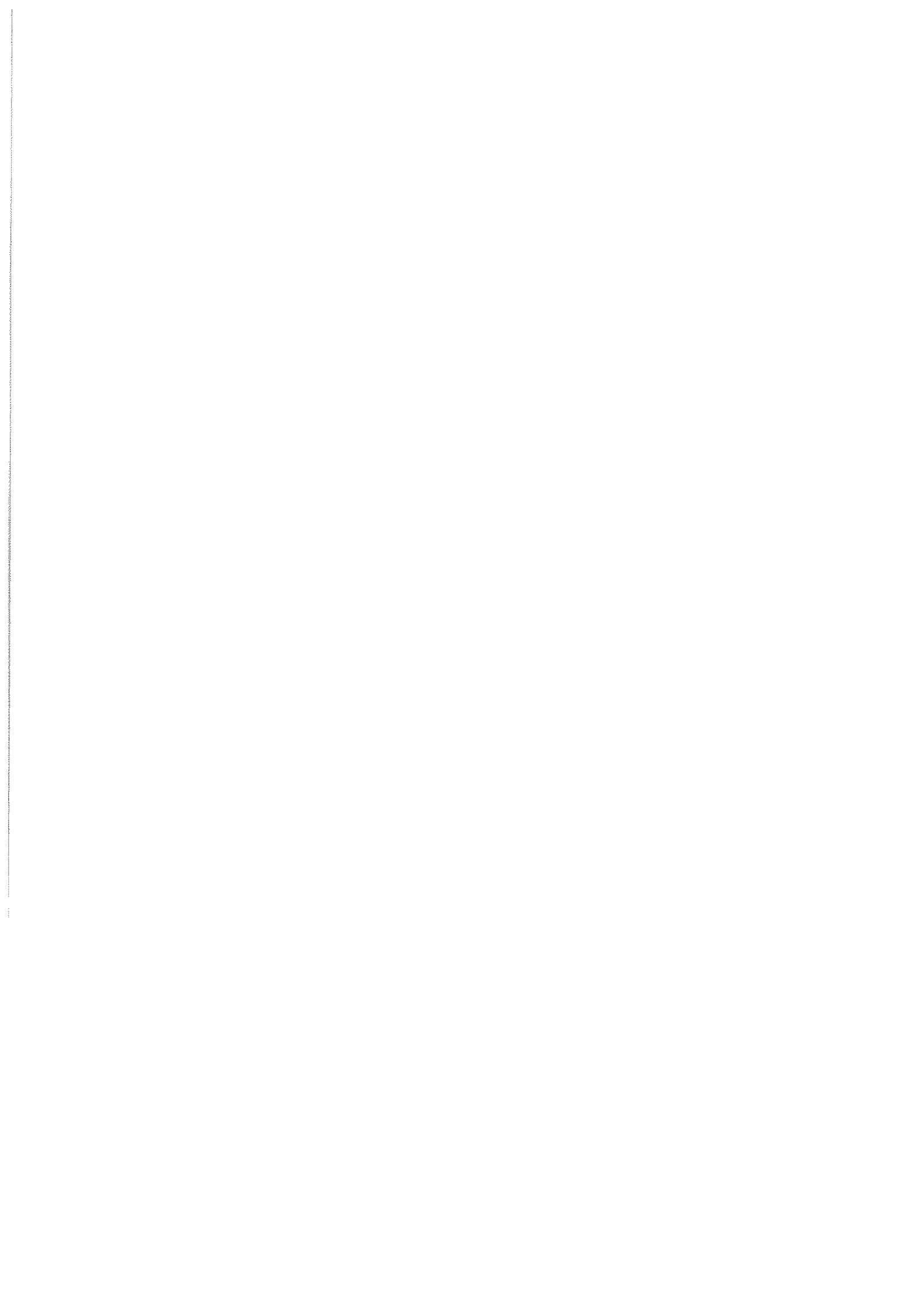
It is proposed that a new regulation be made under section 105(1)(i) that fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the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

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

No. I do not support the proposed amendment because fluoride is not a water treatment like chlorine; it is used to treat dental caries, not to make the water supply safe to drink. Adding fluoride to the water in order to treat a medical problem makes it a medicine. People have the right to know that they are being medicated, and to refuse medication if they wish, regardless of what the medication is or how it is administered. The Medicines Act is designed to safeguard people from the indiscriminate use of medicines, and to protect these rights. The proposed amendment would remove this protection, and allow the forced medication of people against their will.

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 the water supply itself. Rather, they are used to treat people, making them medicines.



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: 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

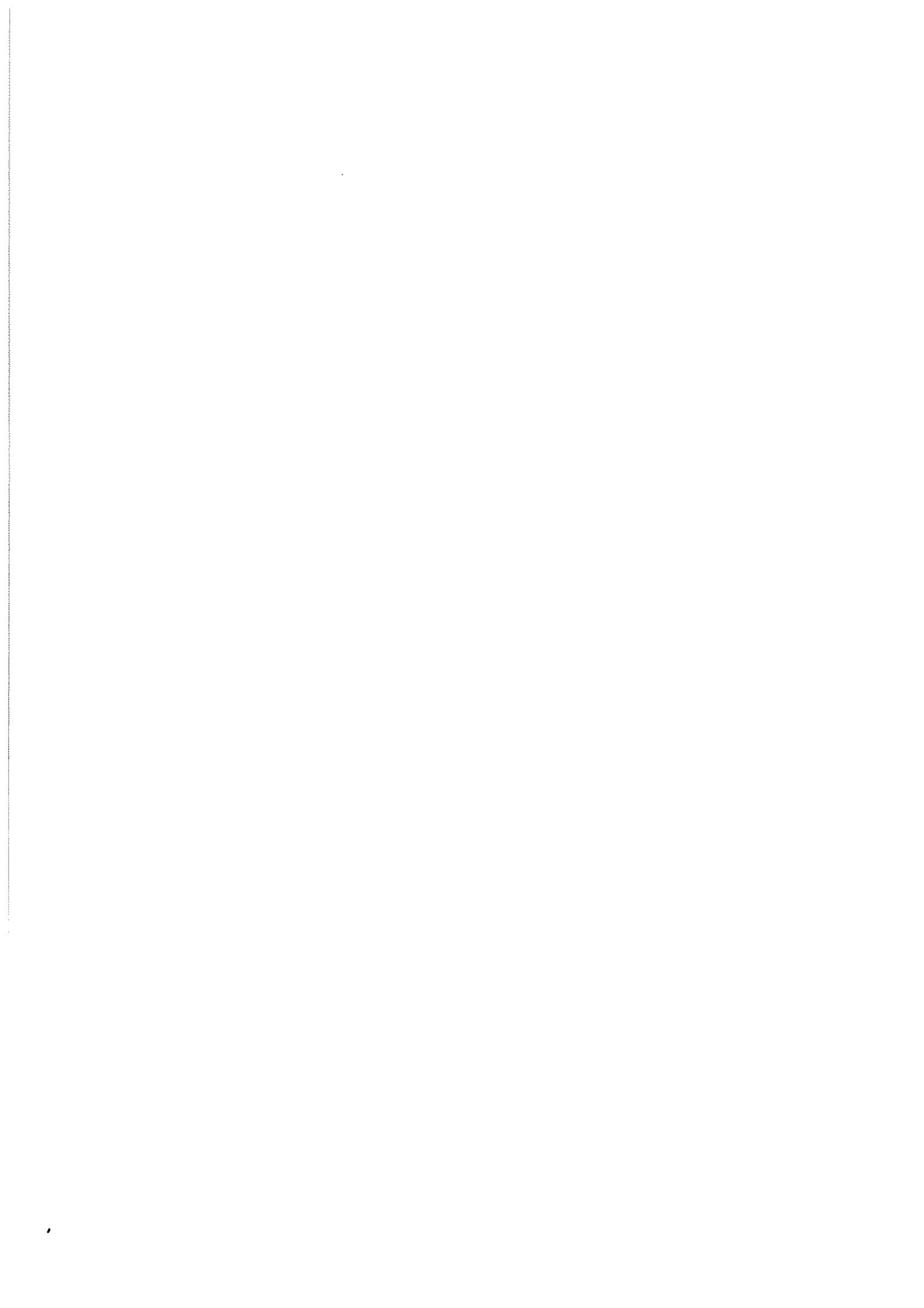
Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

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**

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)

iskmedsafe@moh.govt.nz

09/01/2015 09:27 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

Email

Address:

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

NO. I do not support the proposed amendment because:

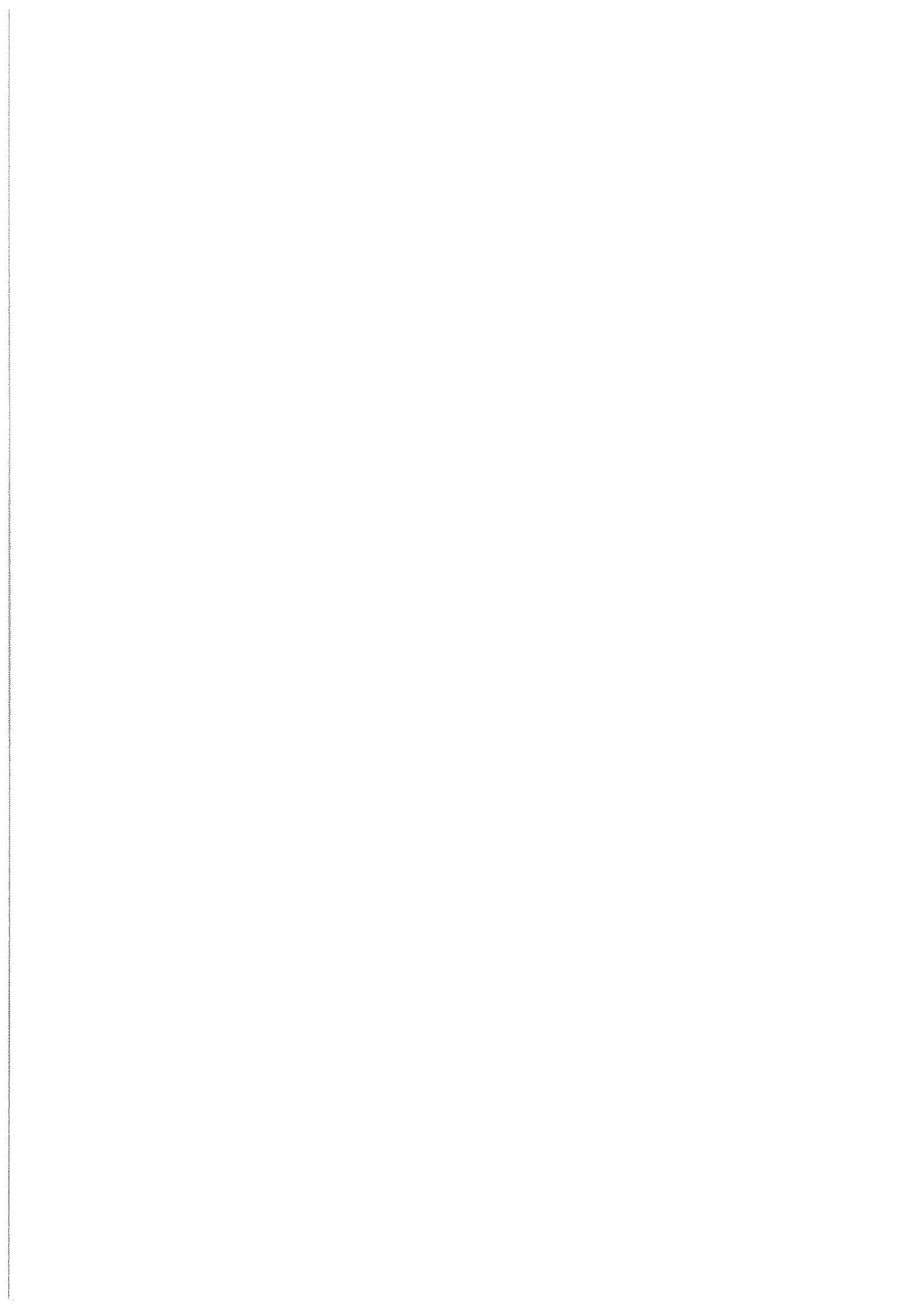
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals 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.

This email has been filtered by SMX. For more information visit smxemail.com



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):	Healthy individual and proponent of staying healthy naturally
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	<p>NO.</p> <p>This amendment frees the govt of it's responsibility to regulate hazardous/toxic substances in the community/country.</p>
<p>Question 2</p> <p><i>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?</i></p>	<p>NO, there are probably 50 to 100 chemical variations that could be called fluoride that could be used alternatively, if one or other chemical were specifically banned or restricted, just as the legal high saga has played out. All of those alternatives were more injurious than the natural product they were produced to circumvent the narcotic laws.</p>

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Further comment.

Fluoride in all of its forms has been removed by most metropolitan areas –worldwide- as the proof that that it works simply does not exist, no double blind studies have been successful in showing any benefits and of course the metadata analysis haven't been done or showed no correspondence.

A metadata analysis would definitely show a correspondence between fluoride use in watersupplies and oesteo conditions like decalcification, bone brittleness, age related injuries, joint replacements etc.

The argument that it is a natural product is absolute hogwash.

Even worse, in the 1920's it was noticed that the populations in areas where the ground-water supply had naturally occurring –calcium fluoride ions had great teeth and lower incidence of caries. This observation was carried over to insinuate sodium fluoride compounds must have the same beneficial effect and can be commercially produced directly or as a by-product of other industrial activity. These are added to the water supply in particulate form.

Simple observation of the process and precautions necessary to be undertaken by the operators at the water treatment plants **MUST** be proof that it should be halted altogether. It is a supremely toxic substance that would be treated as a war crime if it was used in Syria or Afghanistan. Yet here we accept it as lambs to slaughter. I propose that you our leaders take the unprecedented step and do the reverse of what you are proposing and ban all sodium fluoride compounds from NZ water supply.

Thank you

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

Firstly I wish to register my objection to the timing of this proposal and the deadline for submissions.

Given that millions of New Zealanders are involuntary consumers of water fluoridated with HFA & SSF and are unaware that HFA & SSF are in fact industrial waste products which also include unquantified amounts of other toxins including arsenic, mercury, and lead, you have a duty to ensure that they are aware of this proposal as well as the ramifications of it being accepted and are given sufficient opportunity to respond.

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

ANSWER TO QUESTION 1

I do not support the proposed amendment for the following reasons:

A:

There are two issues which are ongoing in the Courts relating to this proposal: the first involves the Bill Of Rights which protects us from forced medication.

The second involves our right to the protections of the Medicines Act in regard to the dispensing of toxic substances.

With both of these issues yet to be finalised in both the Appeals Court and the Supreme Court this proposal seeks to pre-empt both the due process of the Judiciary and Parliament with minimal publicity during the holiday season.

I submit that it is not appropriate for MOH officials to try to interfere with the protections that both the Bill of Rights Act and the Medicines Act provide. If the Judiciary who are charged with interpreting the law find that fluoridating our water with HFA & SSF breaches either Act the issue should then be dealt with by Parliament who are charged with creating and amending Laws.

B:

Given that Sodium Fluoride tablets which are subject to the Medicines Act, and are accordingly free of contaminants, controlled by pharmacy only distribution and come with an advisory based upon the science of toxicology that pregnant mothers and children under 3 years of age should avoid them completely, it defies all logic and ethical principle for the MOH to exempt industrial waste grade variants such as HFA & SSF when they are intended to be used for human consumption.

C:

Now that it is about to become known that the fluoride being added to water is not of a medicinal standard and can include unknown quantities of contaminants including arsenic, mercury, and lead it would pay to consider the fallout that is likely to arise from the general population, particularly from parents who use infant formula .

Based upon your own advice **the prescribed rate of medicinal grade fluoride intake for INFANTS is ZERO:**

The recommended baby formula intake for infants is 350 – 600 mls per day @ 1 month old to 600 - 800 mls per day @ 11 – 12 months old*.

The amount of fluoride ingested by infants on baby formula is accordingly **up to 2.2 times higher** than the maximum prescribed dose of medicinal grade fluoride for **3 – 5 year olds**, plus of course they are also at risk of consuming undisclosed amounts of other contaminants including arsenic, mercury, and lead. Can you imagine the uproar if these contaminants were found to be in the baby formula itself?

I submit that the ministry risks sustaining ongoing reputational harm by knowingly proceeding with this amendment.

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,

*(**Blue table at** http://www.babycareadvice.com/babycare/general_help/article.php?id=8)

**(<http://www.health.govt.nz/system/files/documents/publications/food-and-nutrition-guidelines-for-healthy-children-and-young-people-p5.pdf>)

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 / Scientist / Science educator & communicator
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	Yes.
Question 2 <i>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?</i>	CaF, calcium fluoride, may also be used to treat community water supplies & should be specifically named in the legislation. The practice of Water fluoridation should not be subject to the Medicines Act. Fluoride is a beneficial trace element at the concentrations used in CWF; at 0.7-1ppm fluoride ions have no harmful side effects and do not constitute a medicine.

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.

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

askmedsafe

09/01/2015 09:47 a.m.

History: This message has been replied to.

Dear Sir/Madam

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

"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."

Source: Medsafe website,
<http://www.medsafe.govt.nz/consultations/medicine-regulations-fluoride-in-drinking-water.asp>

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

Answer 1: No, I DO NOT support the proposed amendment.

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?

Answer 2: No.

Fluoride and its compounds are not used to "treat" community water supplies. The purpose of fluoride and its compounds in community water supplies is to treat people.

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

I do not wish to speak to my submission.

Sincerely,

R
l

F



Submission form - Medicines act 1981 - Fluoride (2014)

askmedsafe@moh.govt.nz

09/01/2015 10:00 a.m.

Please respond to

History: This message has been replied to.

SUBMISSION FORM

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)

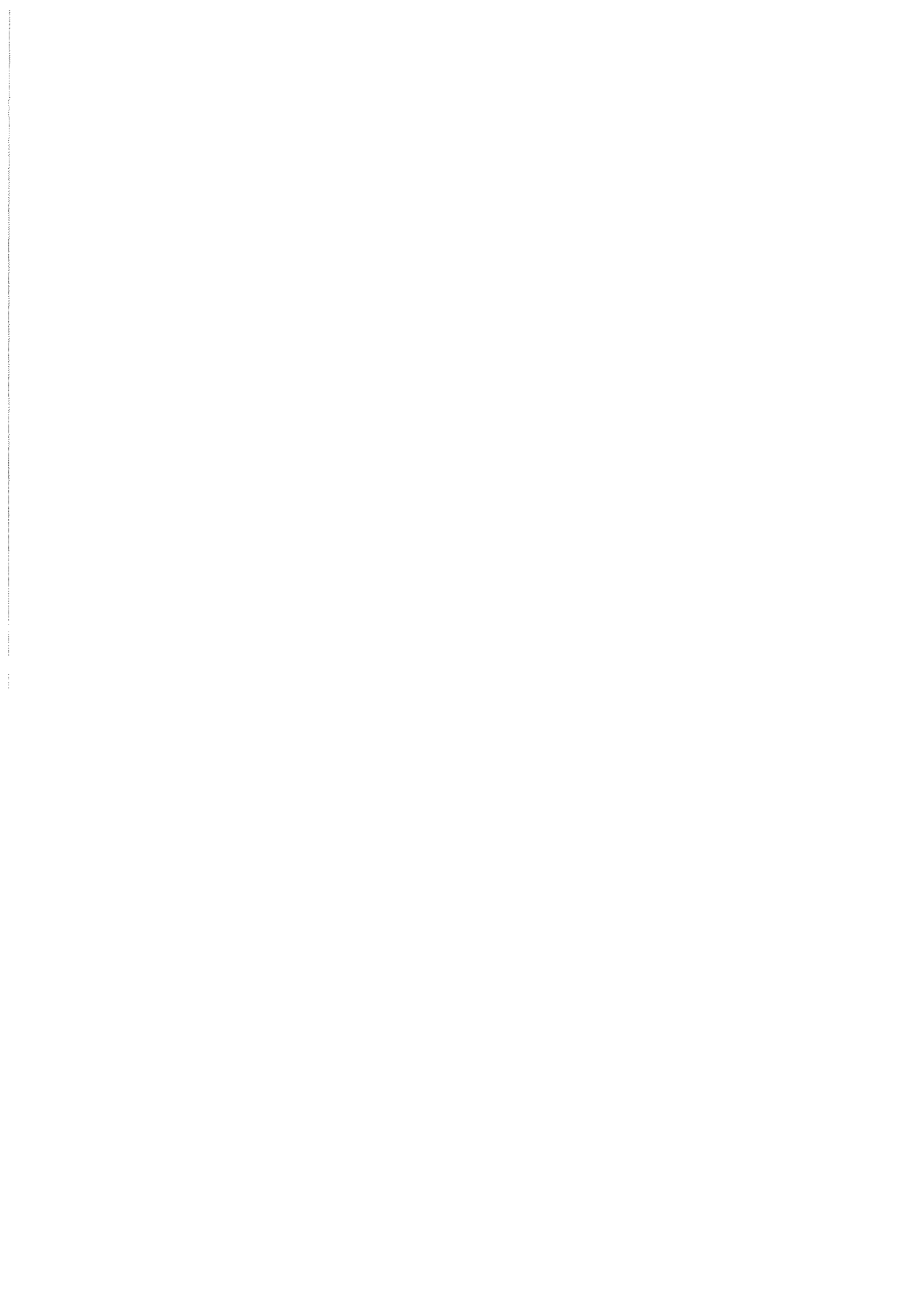
"It is proposed that a new regulation be made under section 105(1)(i) that:

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 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.



SUBMISSION FORM

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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:	1 F F
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	<p>No.</p> <p>Hydrofluorosilicic Acid and Sodium Silico Fluoride have never been tested for safety. Various other contaminants are added alongside these to the water supply including Arsenic which is a known carcinogen with no minimum safety level. It is also proven that fluoride causes fluorosis of the teeth which can be a negative health effect depending on severity it can actually damage teeth.</p> <p>Individual dosage cannot be controlled through the water supply which means certain members of the public will be receiving doses of fluoride exceeding maximum recommended levels, these include bottle fed babies, athletes, labourers, kidney patients, diabetics.</p> <p>Fluoride is added to water to treat a dental disease not to treat the water, therefore it has to be regarded as a medicine and it must be regulated as such.</p> <p>It is my right to refuse a medical treatment</p>

	no matter how it is administered or who it is administered by. Neurological disorders and cancers are on the rise, there has been little progress discovering the cause of these diseases. It would be a serious mistake to exempt fluoride from being classified as a medicine which has been recognised as a neurotoxin by Harvard medical School and could cause harm in the developing fetal brain either by itself or in combination with other toxins in the environment.
<p>Question 2</p> <p><i>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?</i></p>	

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Fluoride IS a medicine

askmedsafe

09/01/2015 10:03 a.m.

History: This message has been replied to.

SUBMISSION FORM

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

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. A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.

As President and co-founder of Clean Water California, I am steadfastly opposed to the practice of water fluoridation, which I believe to be inequitable and irresponsible. In the United States. the Food and Drug Administration (FDA) has classified fluoride as an unapproved drug. A drug is a medicine. One must have a prescription from a doctor to buy fluoride tablets in the States. In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. **A medicine is not defined by the dose used, but by the purpose for which it is administered.**

If one looks up the word “medicine” in any major dictionary in the English language the definition is very simple and clear. A medicine is “a substance that is used to treat, prevent or mitigate a disease.” In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

See,

Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, *The physiology and biochemistry of the mouth* (4th Ed) by G Neil Jenkins)

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ's Medicines' Act was a medicine, lowering the dose to a level of approximately 1 ppm used in water fluoridation could do two possible things: a) it could lower its effectiveness and b) it could reduce its toxic side effects, but it would not change the purpose for which these substances were added to the water supply. **At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.**

For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

2. Fluoride is not a water treatment chemical to treat the water (like chlorine) but simply to use the water supply to deliver medical treatment.
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**, which is precisely why fluoride is **a medicine**.

I do not wish to speak to my submission

Regards,

President, Clean Water California

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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

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Name:

Email:

Address:

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All of the above.

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

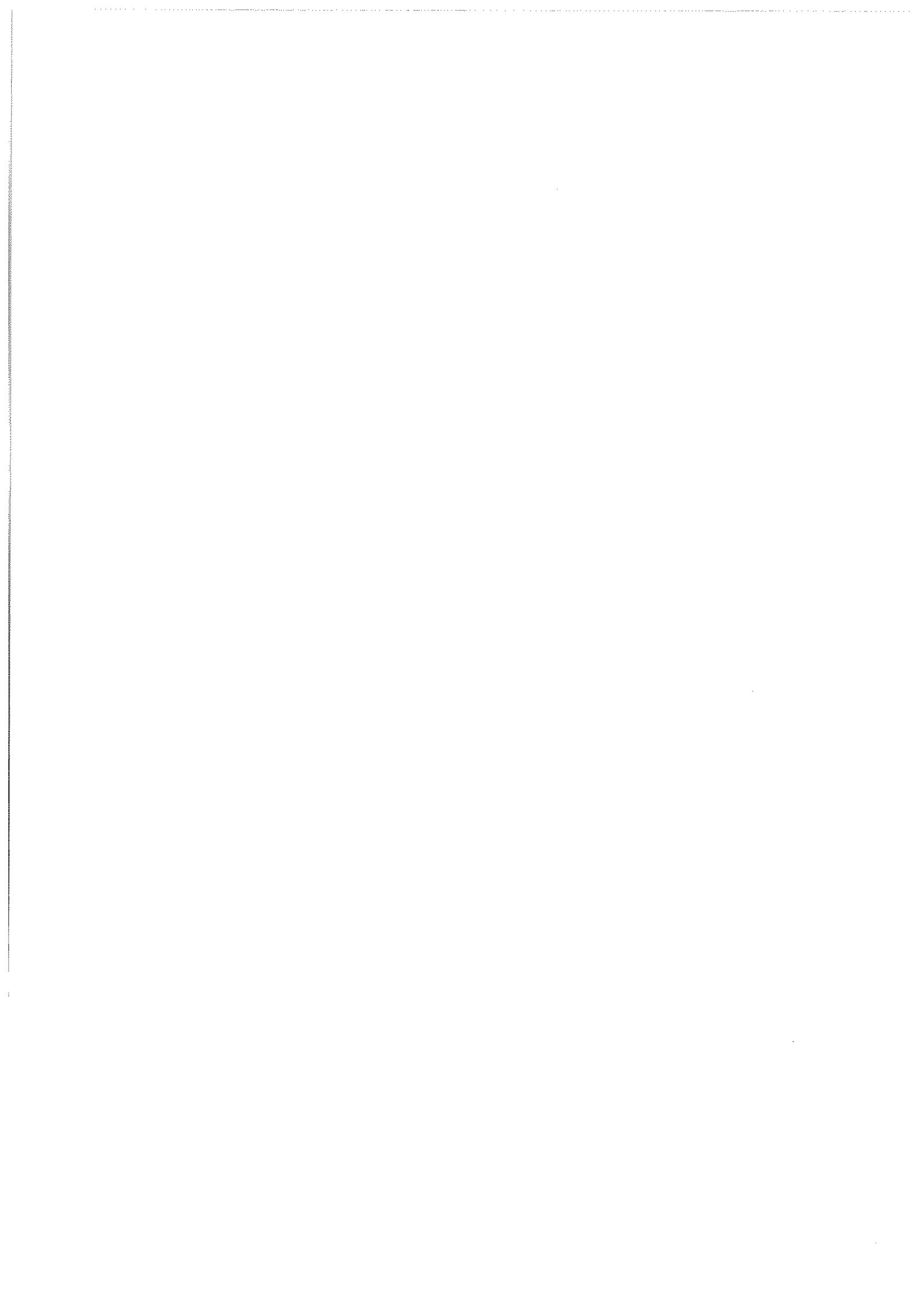
PO Box 5013

Wellington 6145

Email to: askmedsafe@moh.govt.nz

* do on-line: → tried. Could not.

This is not a user friendly way to go about Consultation.



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:	NA
Please provide a brief description of the organisation if applicable:	NA
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	<p>Yes</p> <p>I support the proposed amendment to provide that fluoride-containing substances are not medicines for the purposes of the Act when they are used for the purpose of fluoridating community water supplies, including because:</p> <ul style="list-style-type: none"> • water fluoridation is conceptually similar to other common public health approaches such as chlorinating water or pasteurising milk, and the Medicines Act is not the best place for considering such matters • it is helpful to have this matter made certain through regulations

Question 2 <i>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?</i>	No
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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:	Fluoridate Our Water, Hamilton
Please provide a brief description of the organisation if applicable:	A group of scientists and others formed to promote the continuation of fluoridation in community water supplies.
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumers
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	Yes
Question 2 <i>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?</i>	None known to us.

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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.

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“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**

That this whole situation has to be brought to question is nothing short of ludicrous if it was not so ultimately lethal in its application. The same old story from dentists quoting tooth decay prevention being aided by fluoride is so outdated and untrue. I question once more where they get their 'evidence' from and I suspect the same ole from training school and well supervised data along with chemical companies and the like. (This is no fabrication and anyone reading this knows fine well the agenda of pharmaceutical and chemical companies).

There are many world respected Scientists (Professors in that field) and many Doctors and Dentists who disagree with adding fluoride and the reasons are readily available – what it boils down to is:- What is your agenda and those whom you represent?

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

Post to:

Regulations under the Medicines Act 1981 Consultation

Medsafe

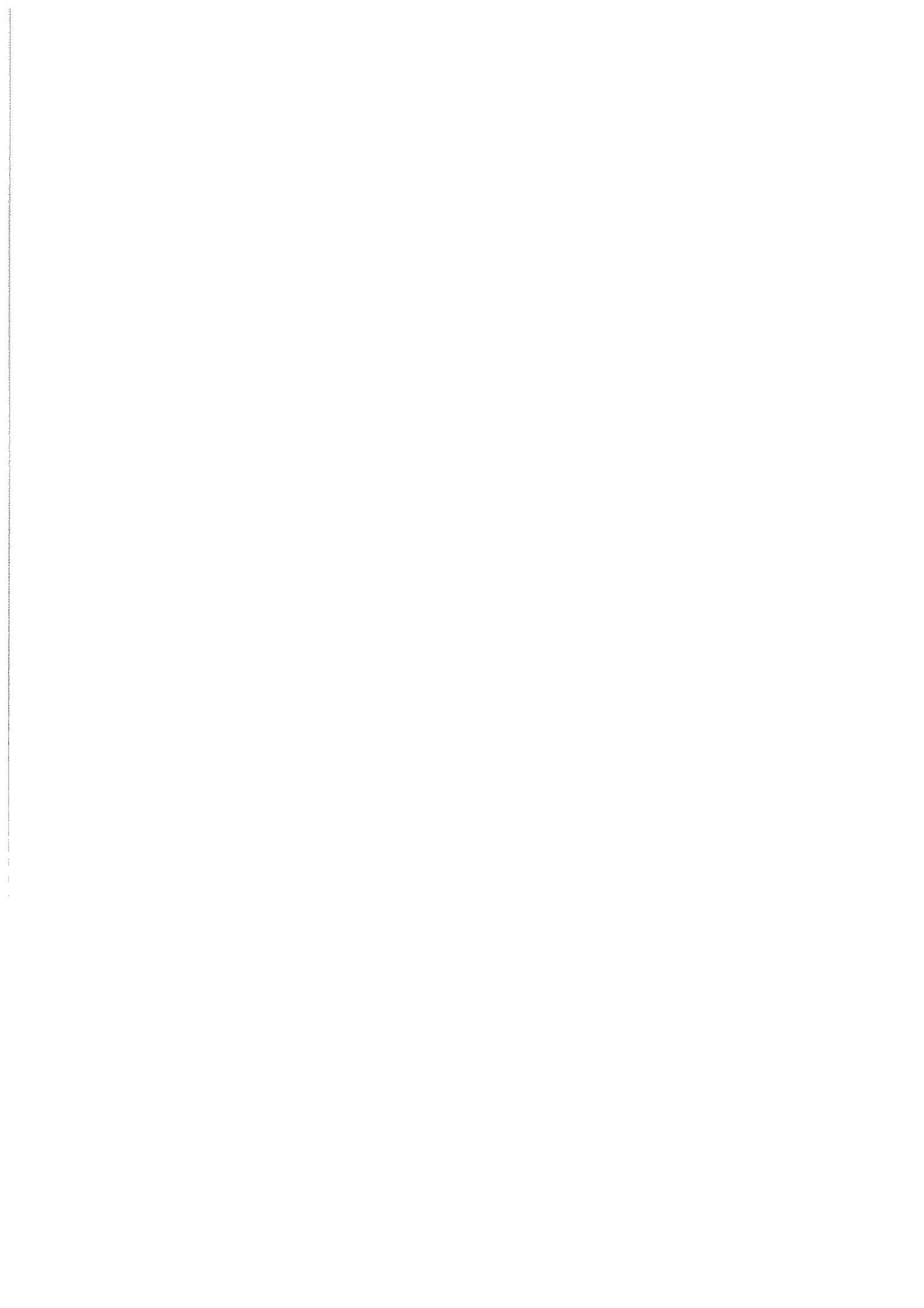
Clinical Leadership Protection & Regulation

Ministry of Health

PO Box 5013

Wellington 6145

I have been a health professional in business over 15 years.



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

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Name

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Address:

Date: 7/1/2015

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Our public health officials claim water fluoridation is an effective way to prevent tooth decay, particularly the high rates of tooth decay now found in low-income children. There are problems with this idea:

1) There are observations and research showing that dental health is greatly influenced by lifestyle, with diet being the main influencing factor. People need nutritious food as a priority over medication.

See:

Price Weston, "Nutrition and Physical Degeneration", Benediction Classics, 2010

Nagel Ramiel, "Cure Tooth Decay", Golden Child Publishing, 2010

I am not willing to accept medicating with fluoride for dental health (that has not been shown to be reliable anyway), when lifestyle changes have been shown to have such a strong influence in this area and on wellbeing in general.

2) There are oral health crises in low-income areas that have been fluoridated for decades. Fluoridation has not prevented low-income neighbourhoods from suffering a crisis of tooth decay

3) Published studies have repeatedly found that fluoridation does not prevent the type of tooth decay – baby bottle tooth decay (BBTD) – that is one hallmark of the current local oral health crisis. Photos used to emphasize the urgent need for fluoridation are almost always photos of BBTD. Only education can prevent BBTD. Fluoridation will have no effect.

4) The poor are most harmed by fluoride, suffering higher rates of dental fluorosis, as well as the other health effects of fluoride, especially diabetes and asthma. Poor diet results in more tooth decay *and* more harm from fluoride.....

5) some people are reactive to fluoride and can't clear it from their systems – putting it into drinking water will exacerbate health problems including infertility and hypothyroidism due to the F1 competing with Iodine as well as the more obvious fluorosis issue.

6) There is much more detailed research that can be cited, that I expect you have received from other submitters, showing that the ingestion and absorption of fluoride, from water supplies is at best a highly contentious health issue, and arguably a threat to health.

page 2

As there is no proof of no harm done, and lots of proof that harm is done, there is no way that you can make fluoride a water-treatment. It is NOT SAFE, it is NOT EFFECTIVE – please see *John Colquhoun's* (Auckland's Chief Dental officer) article:

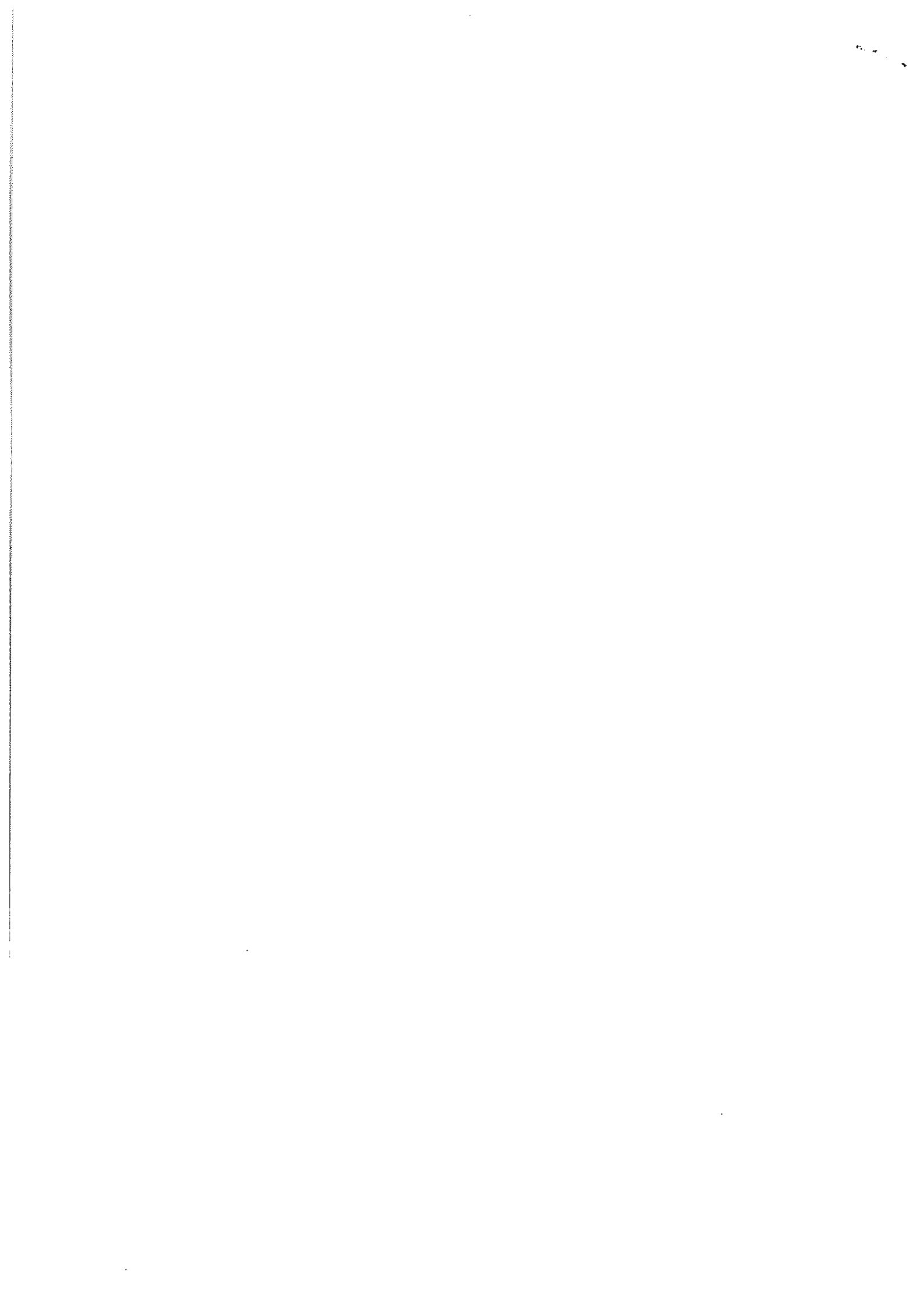
Why I Changed My Mind About Water Fluoridation

John Colquhoun, D.D.S., Ph.D.

*Published in: Perspectives in Biology and Medicine Volume 41, page29-44.
1997*

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



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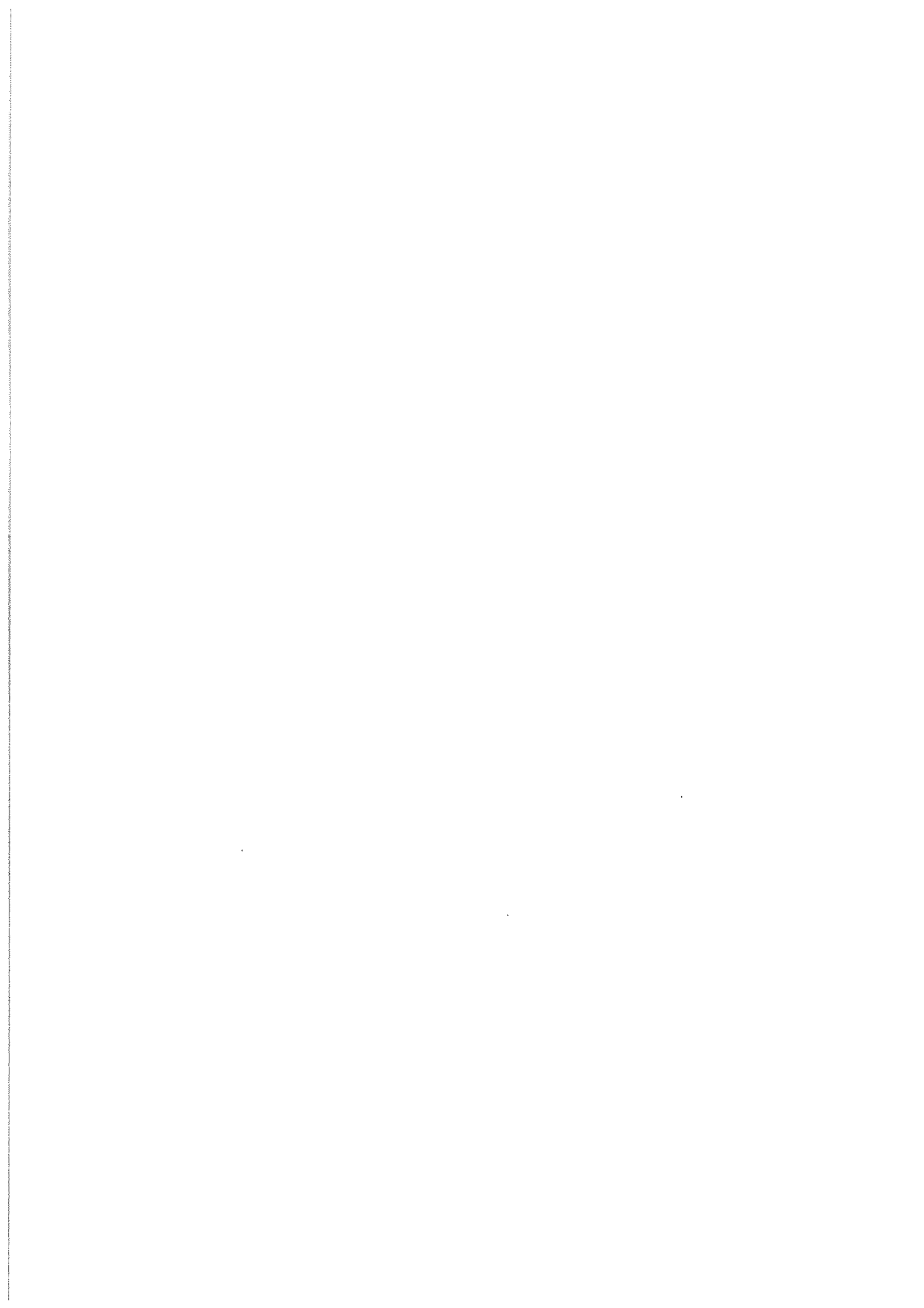
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The Royal Australasian
College of Physicians

New Zealand

9 January 2015

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

Via email: askmedsafe@moh.govt.nz

Dear Sir/Madam

Consultation on Proposed Amendment to Regulations under the Medicines Act 1981

The Royal Australasian College of Physicians (the RACP) thanks you for the opportunity to make a submission to the Ministry of Health regarding the following proposed amendment to the Medicines Act 1981:

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.

The RACP acknowledges that the statement will go some way in providing clarity to the public in a definitive manner.

The RACP advocates strongly for all health policy to be developed from a base of scientific evidence¹. It notes the oral health benefits of Community Water Fluoridation (CWF) have been extensively researched through cohort studies and a diverse range of analyses since the mid-twentieth century. It is a cost-effective method to mitigate incidences of dental caries and contribute to improved oral health, particularly for lower socio-economic populations and children, and there is a growing evidence base proving its efficacy for communities in New Zealand and around the world^{2 3 4}.

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

The RACP endorses the proposed amendment to the Medicines Act and supports the statement on fluoride substances being used in the process of community water fluoridation and that it does not constitute a medicine for the purposes of the Act.

The New Zealand context: Evidence and prevention

The RACP also notes that most drinking water supplied in New Zealand contains low levels of naturally-present fluoride (around ~0.1-0.2 mg/L), and the addition of fluoride substances including hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) increases these levels to between 0.7

¹ Gluckman P. (2013) The role of evidence in policy formation and implementation: A report from the Prime Minister's Chief Science Advisor. Auckland:

² Esfandiari S, Jamla, N & Feine, J. Community-specific, preventative oral health policies: Preventative measures on dental caries. *J. Investig. Clin. Dent.* 2010 Aug; 1(1) DOI: 10.1111/j.2041-1626.2010.00006.x.

³ Griffin SO, Jones K & Tomar SL. An economic evaluation of community water fluoridation. *J. Pub. Health Dent.* 2001 Spring; 61(2), 78-86. DOI: 10.1111/j.1752-7325.2001.tb03370.x

⁴ Wright J, Bates MN, Cutress T, & Lee, M. The cost-effectiveness of fluoridating water supplies in New Zealand. *Aust. and NZ J. Pub. Health.* 2001; 25(2) 170-178. DOI: 10.1111/j.1753-6405.2001.tb01841.x

and 1.0 mg/L⁵. At these levels, fluoride present naturally or added to community water supplies is not associated with an increased risk of developing dental fluorosis^{6 7}.

The RACP supports policy and strategy to reduce health inequities in the population. Dental caries are highly preventable, and although the incidence has reduced in the last 30 years due to increases in the supply of fluoridated water and the use of fluoridated toothpaste, significant disparities exist for 36% of children who brush their teeth less than twice daily, lower socio-economic populations, rural communities, and Māori and Pacific peoples^{8 9 10}.

National Community Water Fluoridation policy

The RACP strongly supports the Ministry's endorsement of CWF as an effective preventative oral health intervention, given the proven and positive outcomes for at-risk populations as detailed in the evidence base. Community water fluoridation is a safe and cost-effective way to prevent dental caries and longer-term oral conditions in populations of greater than 1000 people, with a population of 25,000 people generating net savings of \$4.12 million in dental costs, or averting approximately 37,100 permanently decayed tooth surfaces¹¹.

The RACP recommends that all communities of greater than 1000 people in New Zealand have access to fluoridated water¹². The RACP advocates for a national CWF policy that is mandated and controlled by the Ministry of Health as an investment for effective oral health outcomes.

About the RACP:

The RACP trains, educates and advocates on behalf of more than 14,500 physicians – often referred to as medical specialists – and 6,500 trainees, across Australia and New Zealand. It represents more than 32 medical specialities including paediatrics and child health, cardiology, respiratory medicine, neurology, oncology and public health medicine, occupational and environmental medicine, palliative medicine, rehabilitation medicine, geriatric medicine and addiction medicine. Beyond the drive for medical excellence, the RACP is committed to developing health and social policies which bring vital improvements to the wellbeing of patients.

Thank you again for the opportunity to comment on the proposed amendment. If you have any questions regarding the RACP's submission, please contact Harriet Wild, Policy and Advocacy Officer on (04) 460 8157 or via email at harriet.wild@racp.org.nz.

Yours sincerely



A/Prof Mark Lane MBChB FRACP
RACP New Zealand President
The Royal Australasian College of Physicians

⁵ Gluckman P & Skegg D. (2014) Health effects of water fluoridation: A review of the scientific evidence. Auckland & Wellington: Office of the Prime Minister's Chief Science Advisor and the Royal Society of New Zealand, 4.

⁶ Ministry of Health (2010) Our oral health: Key findings of the 2009 New Zealand oral health survey. Wellington: Ministry of Health.

⁷ Gluckman P & Skegg D., 39-43.

⁸ Ministry of Health (2010), 159.

⁹ Gluckman P & Skegg D., 53-54.

¹⁰ Royal Australasian College of Physicians (2012) Oral health in children and young people position statement. Sydney: Royal Australasian College of Physicians, 11. PDF available <http://racp.edu.au/page/paed-policy>

¹¹ Wright J, Bates MN, Cutress T & Lee M, 174.

¹² Royal Australasian College of Physicians, 6.



Regulations under the Medicines Act 1981 Consultation

Medsafe

Clinical Leadership Protection & Regulation

Ministry of Health

PO Box 5013

Wellington 6145

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)

"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 (delete whichever does not apply) wish to speak to my submission.

☐ : ☐



Fluoride IS a medicine - Oppose the Medicines Act 1982 amendment - Fluoride (2014)

to: askmedsafe

09/01/2015 11:27 a.m.

SUBMISSION FORM

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)

Name: -

Email: ξ

Address:

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

NO. I do not support the proposed amendment because:

1. A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.

I have studied the practice of fluoridation as an attorney and a professional engineer for the last ten years. The only purpose of adding fluoridation chemicals to public water supplies is to aid in the prevention and treatment of tooth decay disease. However, over the last 15 years, a consensus has developed that fluoride benefits are topical not systemic. That means that any benefit from fluoride occurs while the fluoridated water is in the mouth. Fluoride is not an essential nutrient. There is no benefit derived from ingesting fluoride. There are harms. Current research shows that, in fluoridated areas, bottle-fed babies as a group are being subject to mental health harm resulting in lowered IQ. All of the statistically significant studies in the York Report show increased levels of hip fracture for the elderly (65+) when in fluoridated areas. There are other harms as well. If fluoridating chemicals are being added to water for a benefit, then there must be an effort to consider both benefits and harms in order to determine if there is actually a net benefit. The latest scientific research shows that the benefit in treating and preventing tooth decay disease in a sample of 34,000 school children from 5 to 17 averaged 0.6 surfaces per child. <http://www.slweb.org/NIDR-DMFS.html> (Table 6 therein.) The

authors could not claim this benefit was statistically significant. But would any reasonable person trade this possible benefit for a loss in IQ points, the likelihood of dental fluorosis, and an increased risk of hip fracture when they get older. Teaching children in school how to brush their teeth will likely cost less than fluoridation and reap more benefits. Fluoridation is being used to distribute a medicine and, as such, it should be subject to ongoing scientific study as to whether there actually is a net benefit. I believe there are enough harms caused by fluoridation chemicals already discovered to end the practice of water fluoridation. Fluoridation chemicals are medicines, but an honest assessment should conclude that they are no longer a good medicine and actions should be taken to end the practice of fluoridation.

In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. **A medicine is not defined by the dose used, but by the purpose for which it is administered**

If one looks up the word “medicine” or its equivalent “drug” in any major dictionary in the English language the definition is very simple and clear. A medicine is “a substance that is used to treat, prevent or mitigate a disease.” In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

See,

Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, *The physiology and biochemistry of the mouth* (4th Ed) by G Neil Jenkins)

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ’s Medicines’ Act as a medicine, lowering the dose to a level of approximately 1 ppm used in water fluoridation could do two possible things: a) it could lower its effectiveness and b) it could reduce its toxic side effects, but it would not change the purpose for which these substances were

added to the water supply. **At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.**

For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

2. Fluoride is not a water treatment chemical to treat the water (like chlorine) but simply to use the water supply to deliver medical treatment.
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

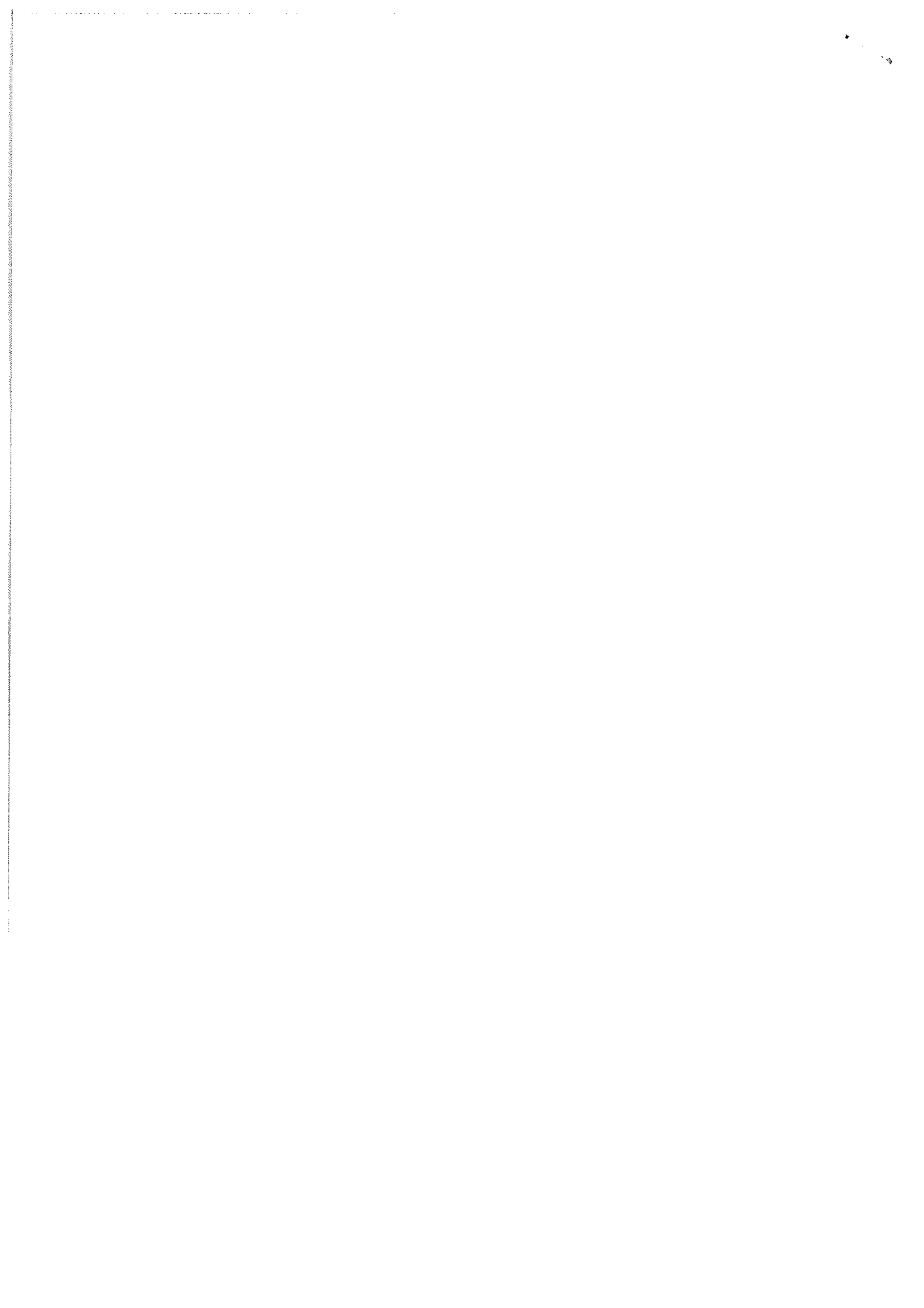
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2025-11-11



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

SUBMISSION FORM

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
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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



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

kmedsafe@moh.govt.nz

09/01/2015 11:29 a.m.

Cc: Undisclosed Recipient

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?*

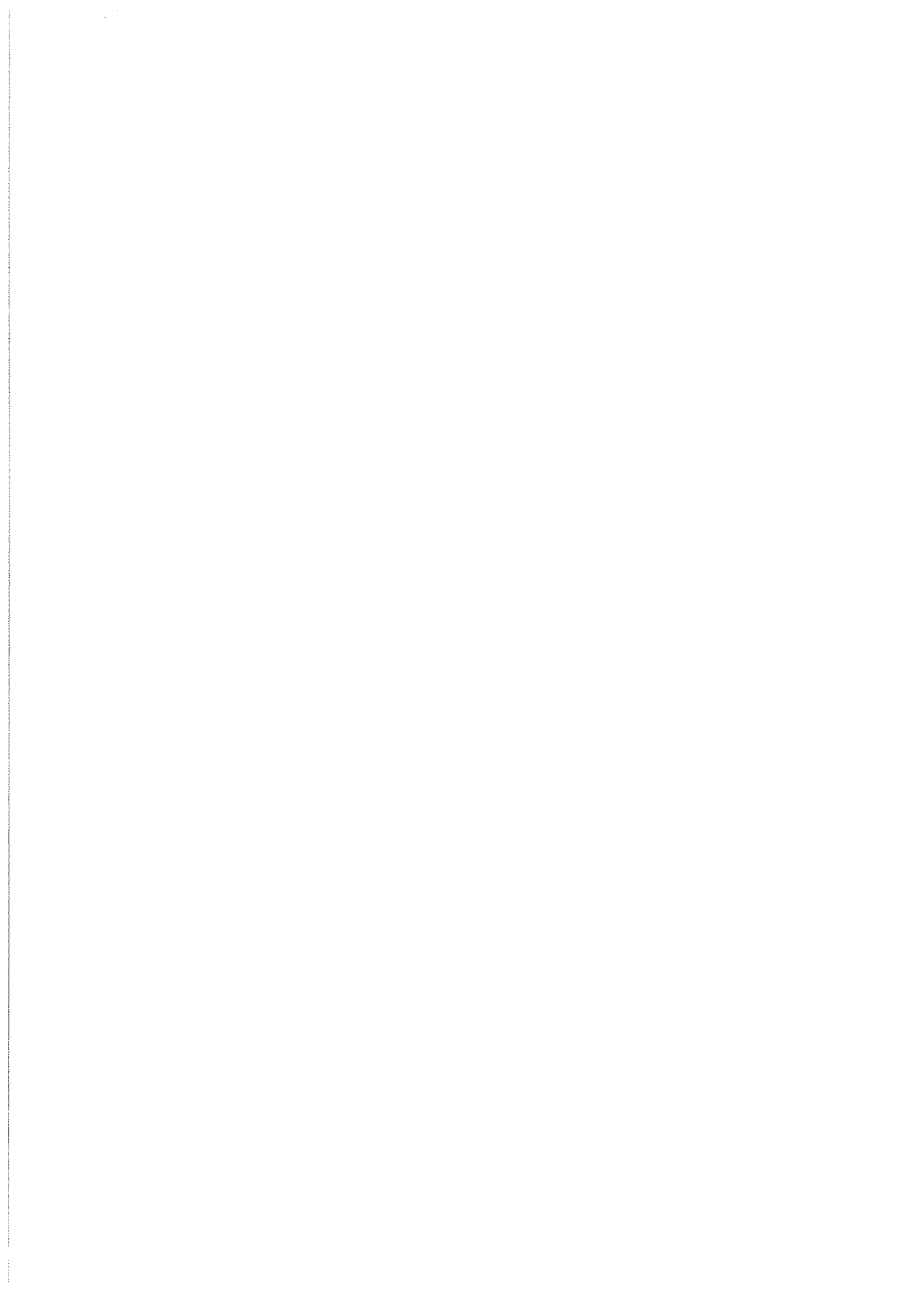
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NO. Fluoride and its compounds are **not** used to ‘treat’ community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to 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:	<p>-----</p> <p>-----</p>
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	<p>I do not support the proposed amendment.</p> <p>Fluoridation of drinking water is not a water treatment. Addition of fluoride to drinking water is intended for the treatment of poor oral health, therefore its use is medicinal.</p> <p>The Medicines Act offers protection from indiscriminate use of medicines. Addition of Fluoride to water for the treatment of a subset of the population with poor oral hygiene is effectively mass medication without consent.</p> <p>Mass treatment of entire populations is not consistent with individual human rights conveyed by the NZ Bill of Rights Act 1990.</p>

	<p>An Act</p> <p>(a) to affirm, protect, and promote human rights and fundamental freedoms in New Zealand; and</p> <p>(b) to affirm New Zealand's commitment to the International Covenant on Civil and Political Rights</p> <p>Additionally, the US National Institute of Health class fluoride as a medicine (http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682727.html).</p>
<p>Question 2</p> <p><i>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?</i></p>	<p>Not known.</p>

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 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:	N/A
Please provide a brief description of the organisation if applicable:	N/A
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	consumer
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	<p>No.</p> <p>Sodium Fluoride Drops is a prescription medicine. One bottle contains 25 mg of fluoride in 50 mL of water, which means it is water fluoridated at 500 mg/L (ppm).</p> <p>If 0.5 mL of this medicine (containing 0.25 mg of fluoride) is mixed into 0.25 liters of water, you create water fluoridated at 1.0 ppm – the equivalent of fluoridated tap water.</p> <p>It makes absolutely no sense to say a dose of prescription medicine is no longer considered a medicine, just because you swallow it with a glass of water.</p>

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.

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fluoride

J

to:

askmedsafe

09/01/2015 11:45 a.m.

Hide Details

From: J

... .l.com>

To: askmedsafe@moh.govt.nz,

1 Attachment



fluoride-submission-form-1

Attached is the submission form with my comments on why I do not support the proposed amendment:

Sodium Fluoride Drops is a prescription medicine. One bottle contains 25 mg of fluoride in 50 mL of water, which means it is water fluoridated at 500 mg/L (ppm).

If 0.5 mL of this medicine (containing 0.25 mg of fluoride) is mixed into 0.25 liters of water, you create water fluoridated at 1.0 ppm – the equivalent of fluoridated tap water.

It makes absolutely no sense to say a dose of prescription medicine is no longer considered a medicine, just because you swallow it with a glass of water.

Thank

you



SUBMISSION FORM

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)

Name:

Email:

Address:Dallas, Tx

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

NO. I do not support the proposed amendment because:

1. A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.

- In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. **A medicine is not defined by the dose used, but by the purpose for which it is administered**

If one looks up the word “medicine” in any major dictionary in the English language the definition is very simple and clear. A medicine is “a substance that is used to treat, prevent or mitigate a disease.” In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

See,

Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, *The physiology and biochemistry of the mouth* (4th Ed) by G Neil Jenkins)

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ’s Medicines’ Act was a medicine, lowering the dose to a level of approximately 1 ppm used in water fluoridation could do two possible things: a) it could lower its effectiveness and b) it could

reduce its toxic side effects, but it would not change the purpose for which these substances were added to the water supply. **At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.**

For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

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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**

I do not wish to speak to 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:	Dr MB Ch B, Dip Obs, RNZCGP, FACNEM
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:	Nutritional and Environmental Medical practice (GP) specialising in paediatrics with an interest in neurodevelopment and toxicity .
Address/email:	_____
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Medical Dr Board member and Education faculty Australasian College Of Nutritional and Environmental Medicine

I do not support the proposed amendment.

Water fluoridation has the potential to cause harm, therefore we need to ensure regulation and oversight . If there is no regulation, interested bodies not ensure the doses are therapeutic as opposed to toxic for all individuals.

We can establish that fluoride is a drug - as it meets all definitions of a drug as per the FDA's statement: from <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>

Drug

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

The primary concerns with fluoride's impact on human health can be summarized as follows:

- **Current safety standards only protect against the most obvious forms of harm:** Current safety standards for fluoride are based on the premise that severe dental fluorosis and crippling skeletal fluorosis are the first adverse effects that fluoride can have on the body. These effects represent the crudest, most obvious harm caused by fluoride. In the words of American University chemistry professor, Dr. William Hirzy, it would be a "biological miracle" if fluoride did not cause other harm prior to producing these end-stage forms of toxicity. Research already shows, in fact, that fluoride can cause arthritic symptoms and bone fracture well before the onset of crippling fluorosis, and can affect many other tissues besides bone and teeth, including the brain and thyroid gland.
- **The current "safe" daily dose for fluoride fails to withstand scrutiny:** The Institute of Medicine (IOM) states that anyone over 8 years of age — irrespective of their health condition — can safely ingest 10 milligrams of fluoride each day for their entire life without developing symptomatic bone damage. Ten milligrams, however, is the same dose that the IOM concedes can cause clinical signs of skeletal fluorosis within just 10 to 20 years of exposure. People with clinical signs of fluorosis can suffer significant symptoms, including chronic joint pain and overt osteoarthritis. The IOM's safety standard instills little confidence in the medical understanding that currently underlies fluoride policies in the U.S.
- **Some people are particularly susceptible to fluoride toxicity:** It is well known that individual susceptibility to fluoride varies greatly across the population, and yet, the National Research Council has recently found that breathtakingly large gaps still exist in the safety literature on the effects these populations may be experiencing as a result of current fluoride exposures. The bewildering degree of uncertainties identified by the NRC stands in stark contrast to the IOM's conclusion that 10 mg/day is so definitively safe that no "uncertainty factor" needs to be applied to protect vulnerable members of the population.
- **The margin between the toxic and therapeutic dose is very narrow:** The NRC concluded that the allegedly "safe" upper limit of fluoride in water (4 mg/l) is toxic to human health. While the NRC did not determine the safe level, their conclusion means that the safe level is less than 4 times the level added to water (0.7-1.2 mg/l) in community fluoridation programs. This is far too slim a margin to protect vulnerable members of the population, including those who consume high amounts of water.

There is evidence of potential harm .

Please see studies and websites listed below and attached with this email.

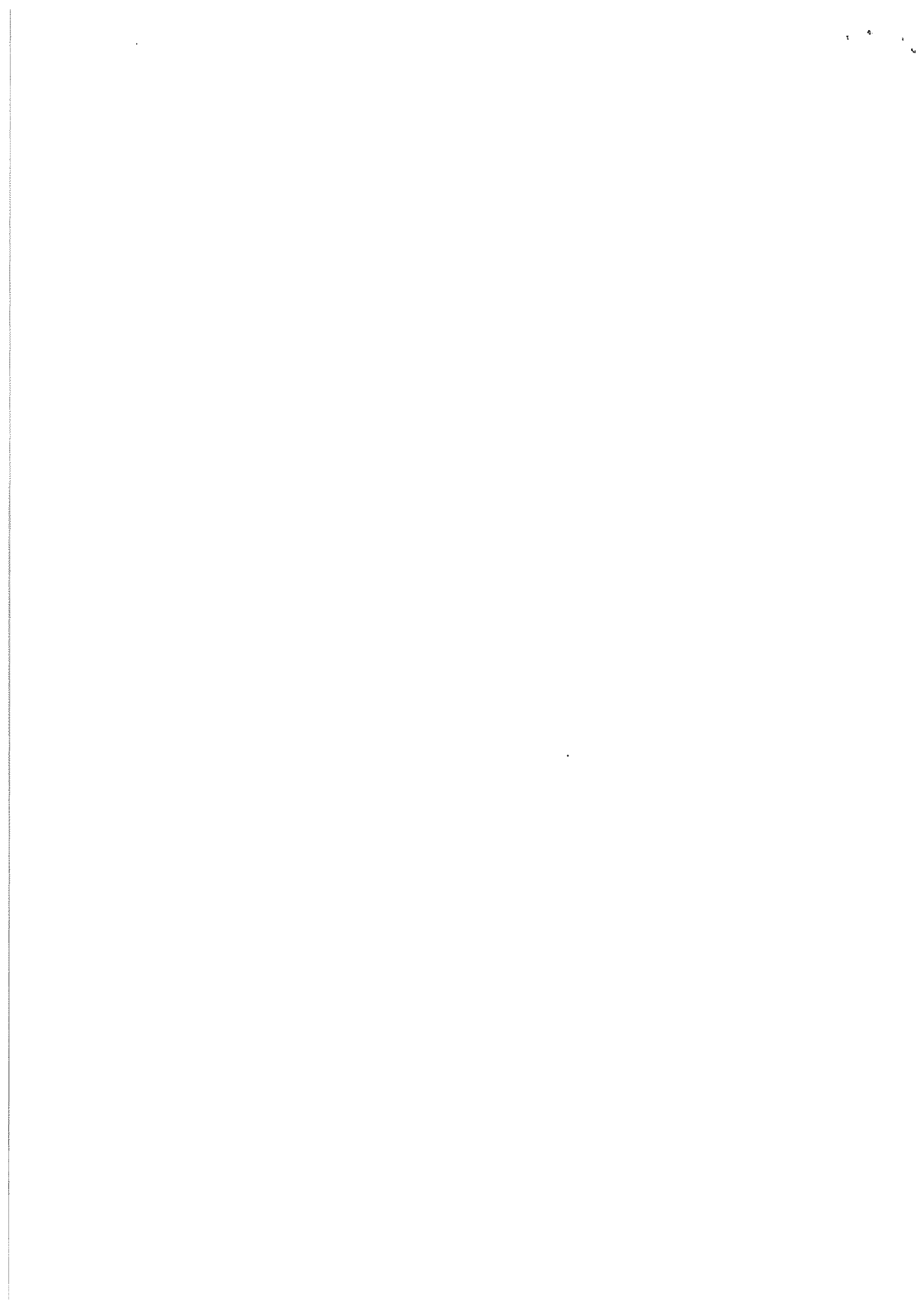
- neurodevelopmental concerns and meta analysis: <http://www.ncbi.nlm.nih.gov/pubmed/22820538>
- dysregulation of neurotransmitters linked to fluoride in autism <http://www.ncbi.nlm.nih.gov/pubmed/19149568>
- <http://fluoridealert.org/issues/health/>

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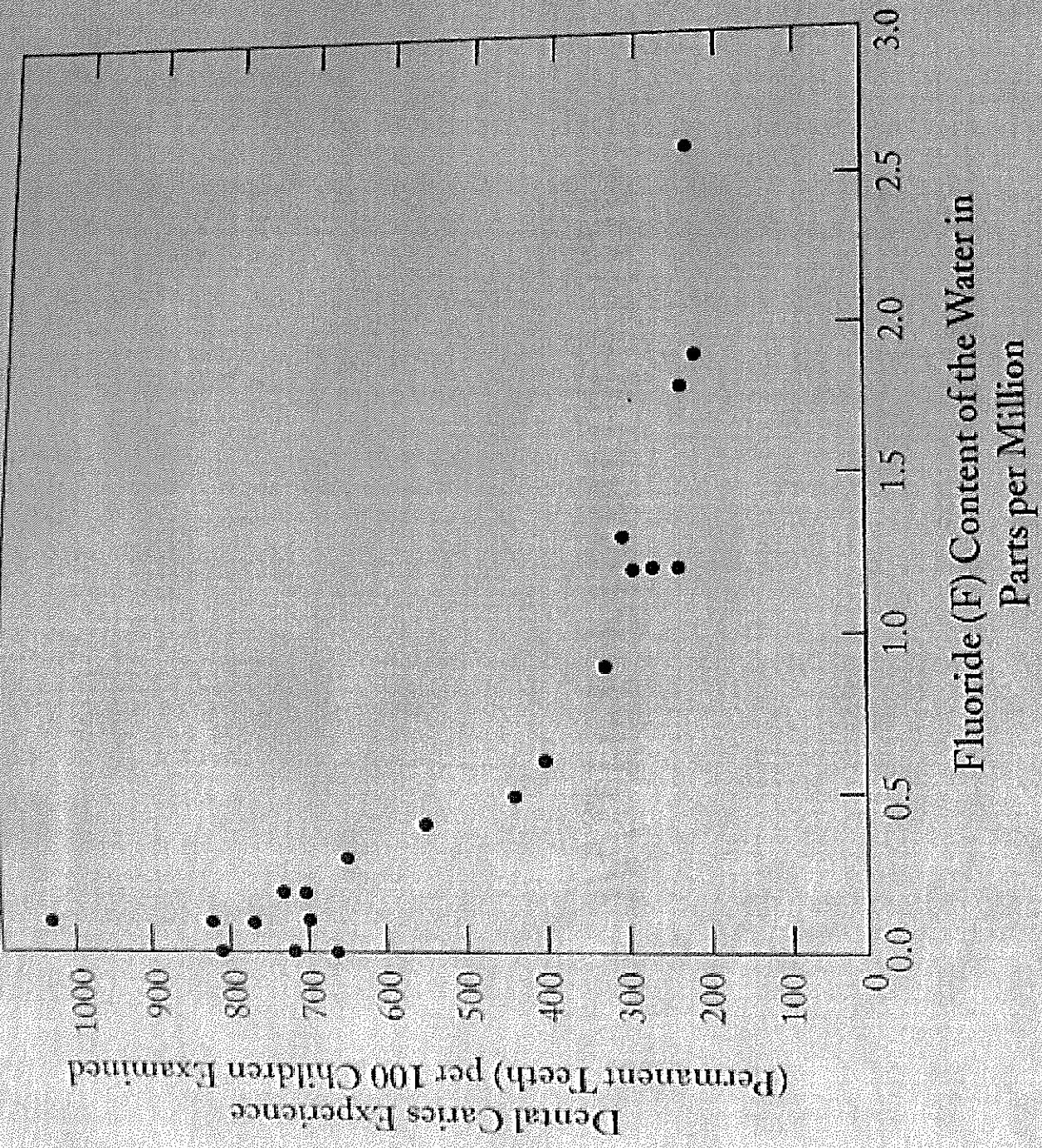
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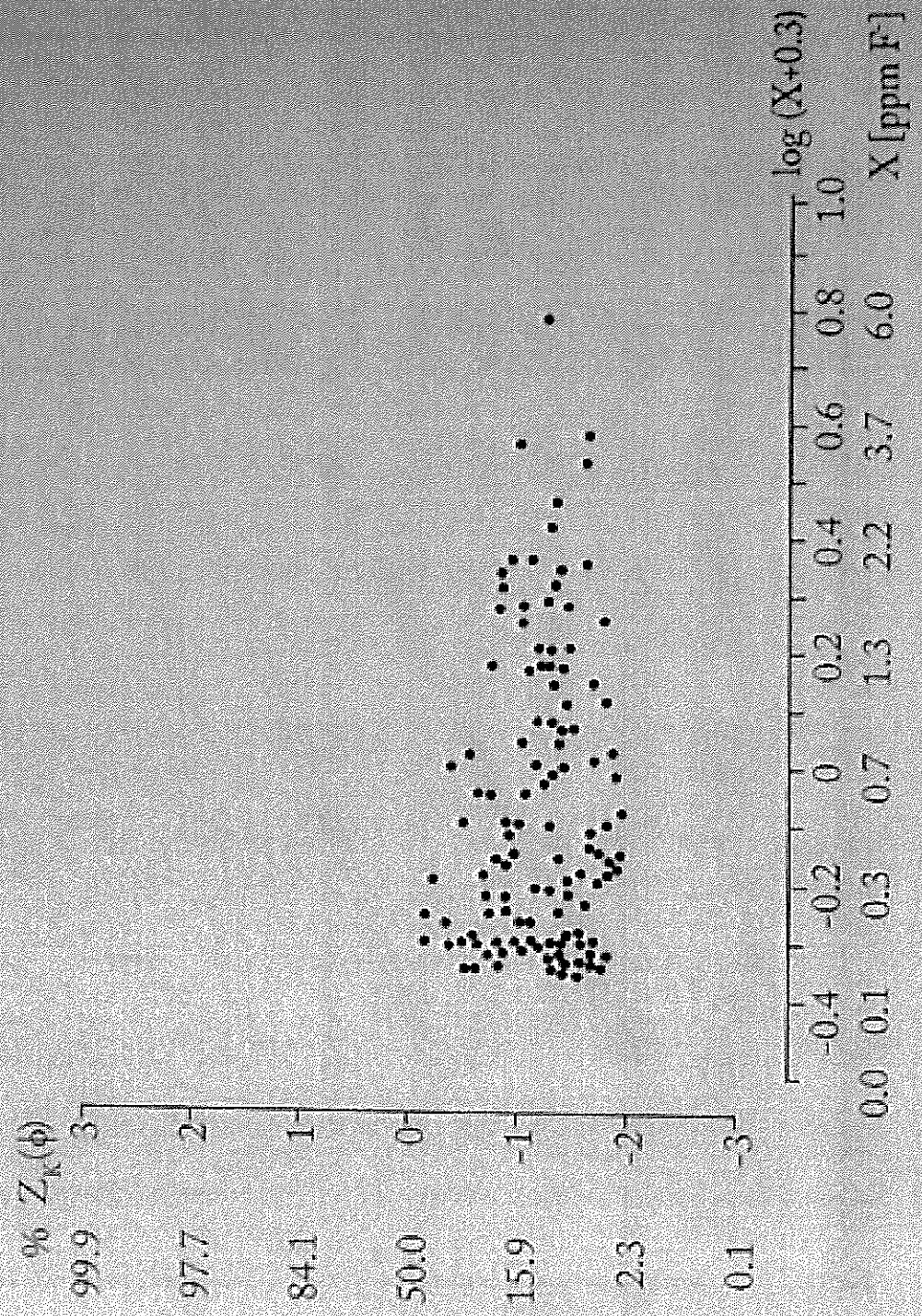
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Water Fluoridation

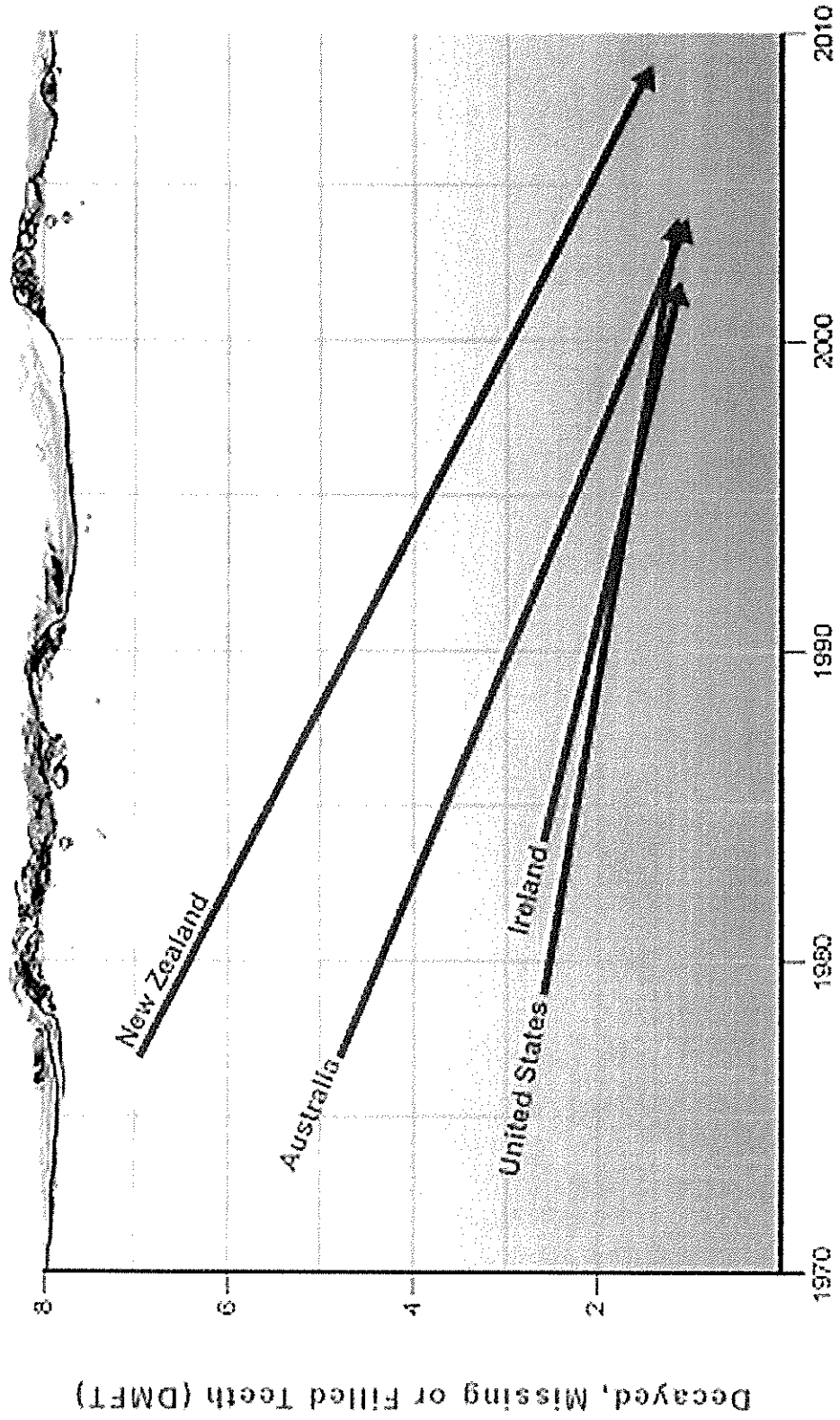


Dental Caries
Prevalence
(% DMFT per child)



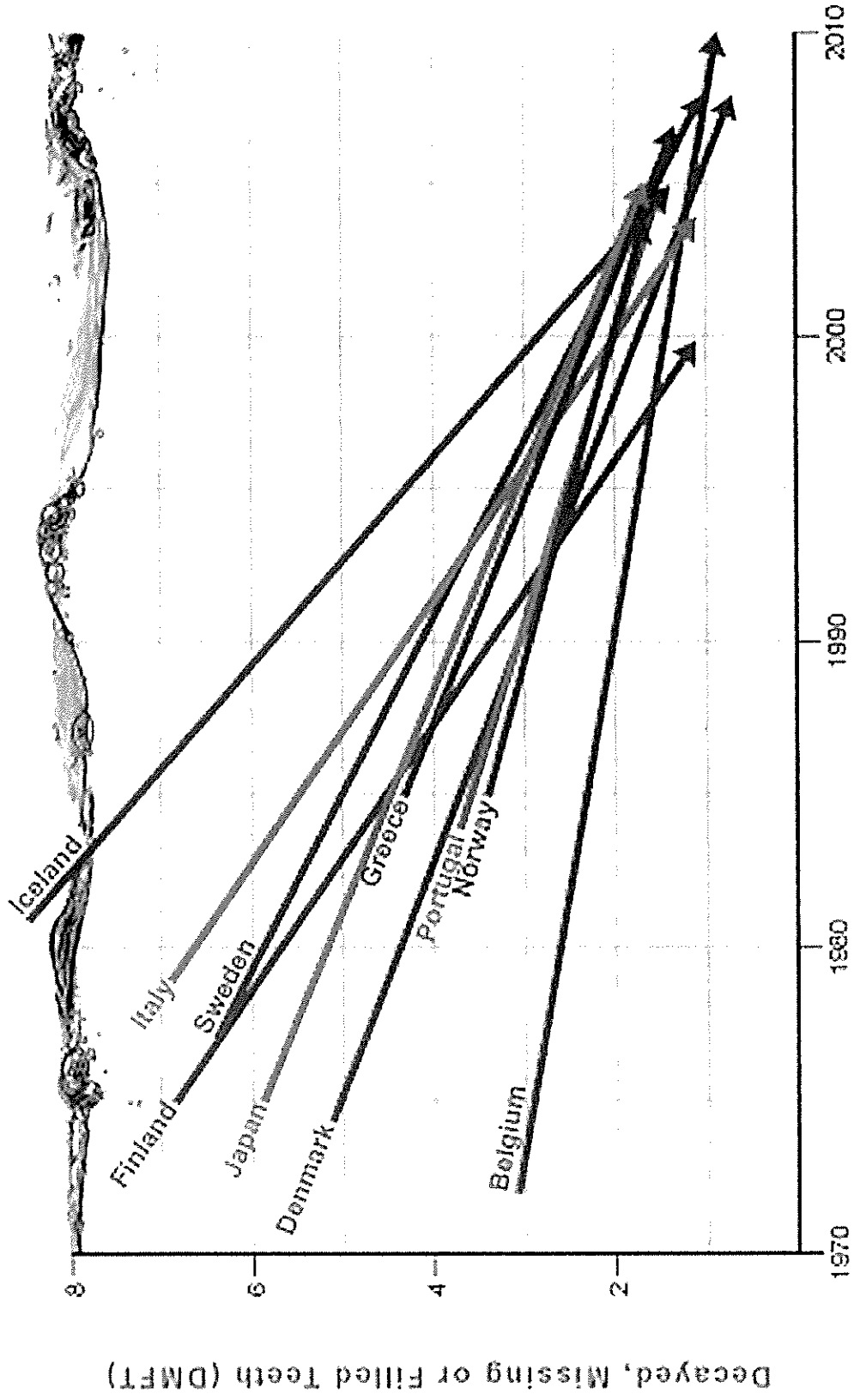
Natural Fluoride Content in Drinking Water

Tooth decay in countries that fluoridate most of the water



WHO data on DMFT in 12 year olds*

Tooth decay in countries with NO water or salt fluoridation





HEALTH EFFECTS

Fluoride is a highly toxic substance that can cause a range of adverse health effects. Certain members of the public are at particularly high risk of harm.

▶▶ SELECT A TOPIC IN HEALTH EFFECTS:

FLUORIDE & HEALTH

TABLE of CONTENTS

Arthritis	Gastrointestinal Effects
Bone Fracture	Hypersensitivity
Brain Effects	Kidney Disease
Cancer	Male Fertility
Cardiovascular Disease	Pineal Gland
Diabetes	Skeletal Fluorosis
Endocrine Disruption	Thyroid Disease
	Acute Toxicity



Neurobehavioural effects of developmental toxicity

Philippe Grandjean, Philip J Landrigan

Lancet Neurol 2014; 13: 330–38

Published Online

February 15, 2014

[http://dx.doi.org/10.1016/S1474-4422\(13\)70278-3](http://dx.doi.org/10.1016/S1474-4422(13)70278-3)

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Neurodevelopmental disabilities, including autism, attention-deficit hyperactivity disorder, dyslexia, and other cognitive impairments, affect millions of children worldwide, and some diagnoses seem to be increasing in frequency. Industrial chemicals that injure the developing brain are among the known causes for this rise in prevalence. In 2006, we did a systematic review and identified five industrial chemicals as developmental neurotoxicants: lead, methylmercury, polychlorinated biphenyls, arsenic, and toluene. Since 2006, epidemiological studies have documented six additional developmental neurotoxicants—manganese, fluoride, chlorpyrifos, dichlorodiphenyltrichloroethane, tetrachloroethylene, and the polybrominated diphenyl ethers. We postulate that even more neurotoxicants remain undiscovered. To control the pandemic of developmental neurotoxicity, we propose a global prevention strategy. Untested chemicals should not be presumed to be safe to brain development, and chemicals in existing use and all new chemicals must therefore be tested for developmental neurotoxicity. To coordinate these efforts and to accelerate translation of science into prevention, we propose the urgent formation of a new international clearinghouse.

Introduction

Disorders of neurobehavioural development affect 10–15% of all births,¹ and prevalence rates of autism spectrum disorder and attention-deficit hyperactivity disorder seem to be increasing worldwide.² Subclinical decrements in brain function are even more common than these neurobehavioural developmental disorders. All these disabilities can have severe consequences³—they diminish quality of life, reduce academic achievement, and disturb behaviour, with profound consequences for the welfare and productivity of entire societies.⁴

The root causes of the present global pandemic of neurodevelopmental disorders are only partly understood. Although genetic factors have a role,⁵ they cannot explain recent increases in reported prevalence, and none of the genes discovered so far seem to be responsible for more than a small proportion of cases.⁵ Overall, genetic factors seem to account for no more than perhaps 30–40% of all cases of neurodevelopmental disorders. Thus, non-genetic, environmental exposures are involved in causation, in some cases probably by interacting with genetically inherited predispositions.

Strong evidence exists that industrial chemicals widely disseminated in the environment are important contributors to what we have called the global, silent pandemic of neurodevelopmental toxicity.^{6,7} The developing human brain is uniquely vulnerable to toxic chemical exposures, and major windows of developmental vulnerability occur in utero and during infancy and early childhood.⁸ During these sensitive life stages, chemicals can cause permanent brain injury at low levels of exposure that would have little or no adverse effect in an adult.

In 2006, we did a systematic review of the published clinical and epidemiological studies into the neurotoxicity of industrial chemicals, with a focus on developmental neurotoxicity.⁶ We identified five industrial chemicals that could be reliably classified as developmental neurotoxicants: lead, methylmercury, arsenic, polychlorinated biphenyls, and toluene. We also noted 201 chemicals that had been reported to cause injury

to the nervous system in adults, mostly in connection with occupational exposures, poisoning incidents, or suicide attempts. Additionally, more than 1000 chemicals have been reported to be neurotoxic in animals in laboratory studies.

We noted that recognition of the risks of industrial chemicals to brain development has historically needed decades of research and scrutiny, as shown in the cases of lead and methylmercury.^{9,10} In most cases, discovery began with clinical diagnosis of poisoning in workers and episodes of high-dose exposure. More sophisticated epidemiological studies typically began only much later. Results from such studies documented developmental neurotoxicity at much lower exposure levels than had previously been thought to be safe. Thus, recognition of widespread subclinical toxicity often did not occur until decades after the initial evidence of neurotoxicity. A recurring theme was that early warnings of subclinical neurotoxicity were often ignored or even dismissed.¹¹ David P Rall, former Director of the US National Institute of Environmental Health Sciences, once noted that “if thalidomide had caused a ten-point loss of intelligence quotient (IQ) instead of obvious birth defects of the limbs, it would probably still be on the market”.¹² Many industrial chemicals marketed at present probably cause IQ deficits of far fewer than ten points and have therefore eluded detection so far, but their combined effects could have enormous consequences.

In our 2006 review,⁶ we expressed concern that additional developmental neurotoxicants might lurk undiscovered among the 201 chemicals then known to be neurotoxic to adult human beings and among the many thousands of pesticides, solvents, and other industrial chemicals in widespread use that had never been tested for neurodevelopmental toxicity. Since our previous review, new data have emerged about the vulnerability of the developing brain and the neurotoxicity of industrial chemicals. Particularly important new evidence derives from prospective epidemiological birth cohort studies.

In this Review, we consider recent information about the developmental neurotoxicity of industrial chemicals

to update our previous report.⁶ Additionally, we propose strategies to counter this pandemic and to prevent the spread of neurological disease and disability in children worldwide.

Unique vulnerability of the developing brain

The fetus is not well protected against industrial chemicals. The placenta does not block the passage of many environmental toxicants from the maternal to the fetal circulation,¹³ and more than 200 foreign chemicals have been detected in umbilical cord blood.¹⁴ Additionally, many environmental chemicals are transferred to the infant through human breastmilk.¹³ During fetal life and early infancy, the blood–brain barrier provides only partial protection against the entry of chemicals into the CNS.¹⁵

Moreover, the developing human brain is exceptionally sensitive to injury caused by toxic chemicals,⁶ and several developmental processes have been shown to be highly vulnerable to chemical toxicity. For example, in-vitro studies suggest that neural stem cells are very sensitive to neurotoxic substances such as methylmercury.¹⁶ Some pesticides inhibit cholinesterase function in the developing brain,¹⁷ thereby affecting the crucial regulatory role of acetylcholine before synapse formation.¹⁸ Early-life epigenetic changes are also known to affect subsequent gene expression in the brain.¹⁹ In summary, industrial chemicals known or suspected to be neurotoxic to adults are also likely to present risks to the developing brain.

Figure 1 shows the unique vulnerability of the brain during early life and indicates how developmental exposures to toxic chemicals are particularly likely to lead to functional deficits and disease later in life.

New findings about known hazards

Recent research on well-documented neurotoxicants has generated important new insights into the neurodevelopmental consequences of early exposures to these industrial chemicals.

Joint analyses that gathered data for lead-associated IQ deficits from seven international studies^{20,21} support the conclusion that no safe level of exposure to lead exists.²² Cognitive deficits in adults who had previously shown lead-associated developmental delays at school age suggest that the effects of lead neurotoxicity are probably permanent.²³ Brain imaging of young adults who had raised lead concentrations in their blood during childhood showed exposure-related decreases in brain volume.²⁴ Lead exposure in early childhood is associated with reduced school performance²⁵ and with delinquent behaviour later in life.^{26,27}

Developmental neurotoxicity due to methylmercury occurs at much lower exposures than the concentrations that affect adult brain function.²⁸ Deficits at 7 years of age that were linked to low-level prenatal exposures to methylmercury were still detectable at the age of 14 years.²⁹ Some common genetic polymorphisms seem to increase the vulnerability of the developing brain to

methylmercury toxicity.³⁰ Functional MRI scans of people exposed prenatally to excess amounts of methylmercury showed abnormally expanded activation of brain regions in response to sensory stimulation and motor tasks (figure 2).³¹ Because some adverse effects might be counterbalanced by essential fatty acids from seafood, statistical adjustment for maternal diet during pregnancy results in stronger methylmercury effects.^{32,33}

Prenatal and early postnatal exposures to inorganic arsenic from drinking water are associated with cognitive deficits that are apparent at school age.^{34,35} Infants who survived the Morinaga milk arsenic poisoning incident had highly raised risks of neurological disease during adult life.³⁶

The developmental neurotoxicity of polychlorinated biphenyls has been consolidated and strengthened by recent findings.³⁷ Although little new information has been published about the developmental neurotoxicity of toluene, much has been learned about the developmental neurotoxicity of another common solvent, ethanol, through research on fetal alcohol exposure. Maternal consumption of alcohol during pregnancy, even in very small quantities, has been linked to a range of neurobehavioural adverse effects in offspring, including reduced IQ, impaired executive function and social judgment, delinquent behaviour, seizures, other neurological signs, and sensory problems.³⁸

Newly recognised developmental neurotoxicants

Prospective epidemiological birth cohort studies make it possible to measure maternal or fetal exposures in real time during pregnancy as these exposures actually occur, thus generating unbiased information about the degree and timing of prenatal exposures. Children in these prospective studies are followed longitudinally and assessed with age-appropriate tests to show delayed or deranged neurobehavioural development. These powerful epidemiological methods have enabled the discovery of additional developmental neurotoxicants.

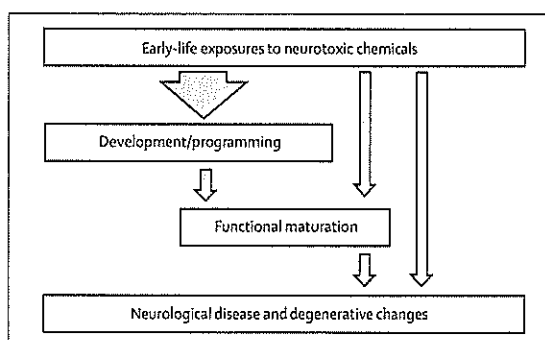


Figure 1: Effect of neurotoxicants during early brain development
Exposures in early life to neurotoxic chemicals can cause a wide range of adverse effects on brain development and maturation that can manifest as functional impairments or disease at any point in the human lifespan, from early infancy to very old age.

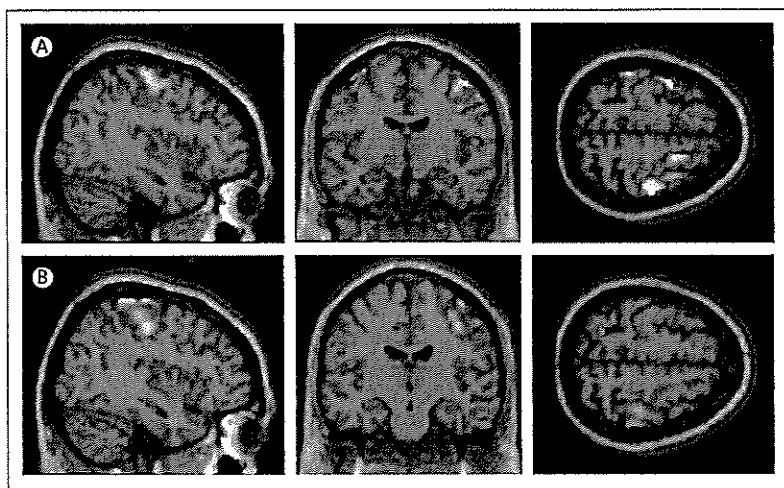


Figure 2: Functional MRI scans show abnormal activation in the brain. Average activation during finger tapping with the left hand in three adolescents with increased prenatal methylmercury exposure (A) and three control adolescents (B). The control participants activate the premotor and motor cortices on the right, whereas participants exposed to methylmercury activate these areas bilaterally.³¹

Cross-sectional data from Bangladesh show that exposure to manganese from drinking water is associated with reduced mathematics achievement scores in school children.³⁹ A study in Quebec, Canada, showed a strong correlation between manganese concentrations in hair and hyperactivity.⁴⁰ School-aged children living near manganese mining and processing facilities have shown associations between airborne manganese concentrations and diminished intellectual function⁴¹ and with impaired motor skills and reduced olfactory function.⁴² These results are supported by experimental findings in mice.⁴³

A meta-analysis of 27 cross-sectional studies of children exposed to fluoride in drinking water, mainly from China, suggests an average IQ decrement of about seven points in children exposed to raised fluoride concentrations.⁴⁴ Confounding from other substances seemed unlikely in most of these studies. Further characterisation of the dose–response association would be desirable.

The occupational health literature⁴⁵ suggests that solvents can act as neurotoxicants, but the identification of individual responsible compounds is hampered by the complexity of exposures. In a French cohort study of 3000 children, investigators linked maternal occupational solvent exposure during pregnancy to deficits in behavioural assessment at 2 years of age.⁴⁶ The data showed dose-related increased risks for hyperactivity and aggressive behaviour. One in every five mothers in this cohort reported solvent exposures in common jobs, such as nurse or other hospital employee, chemist, cleaner, hairdresser, and beautician. In Massachusetts, USA, follow-up of a well-defined population with prenatal and early childhood exposure to the solvent tetrachloroethylene (also called perchlorethylene) in drinking water showed a tendency towards deficient neurological function and increased risk of psychiatric diagnoses.⁴⁷

Acute pesticide poisoning occurs frequently in children worldwide, and subclinical pesticide toxicity is also widespread. Clinical data suggest that acute pesticide poisoning during childhood might lead to lasting neurobehavioural deficits.^{48,49} Highly toxic and bio-accumulative pesticides are now banned in high-income nations, but are still used in many low-income and middle-income countries. In particular, the organochlorine compounds dichlorodiphenyltrichloroethane (DDT), its metabolite dichlorodiphenyldichloroethylene (DDE), and chlordecone (Kepone), tend to be highly persistent and remain widespread in the environment and in people's bodies in high-use regions. Recent studies have shown inverse correlations between serum concentrations of DDT or DDE (which indicate accumulated exposures), and neurodevelopmental performance.^{50,51}

Organophosphate pesticides are eliminated from the human body much more rapidly than are organochlorines, and exposure assessment is therefore inherently less precise. Nonetheless, three prospective epidemiological birth cohort studies provide new evidence that prenatal exposure to organophosphate pesticides can cause developmental neurotoxicity. In these studies, prenatal organophosphate exposure was assessed by measurement of maternal urinary excretion of pesticide metabolites during pregnancy. Dose-related correlations were recorded between maternal exposures to chlorpyrifos or other organophosphates and small head circumference at birth—which is an indication of slowed brain growth in utero—and with neurobehavioural deficits that have persisted to at least 7 years of age.^{52–54} In a subgroup study, MRI of the brain showed that prenatal chlorpyrifos exposure was associated with structural abnormalities that included thinning of the cerebral cortex.⁵⁵

Herbicides and fungicides might also have neurotoxic potential.⁵⁶ Propoxur,⁵⁷ a carbamate pesticide, and permethrine,⁵⁸ a member of the pyrethroid class of pesticides, have recently been linked to neurodevelopmental deficits in children.

The group of compounds known as polybrominated diphenyl ethers (PBDEs) are widely used as flame retardants and are structurally very similar to the polychlorinated biphenyls. Experimental evidence now suggests that the PBDEs might also be neurotoxic.⁵⁹ Epidemiological studies in Europe and the USA have shown neurodevelopmental deficits in children with increased prenatal exposures to these compounds.^{60–62} Thus, the PBDEs should be regarded as hazards to human neurobehavioural development, although attribution of relative toxic potentials to individual PBDE congeners is not yet possible.

Other suspected developmental neurotoxicants

A serious difficulty that complicates many epidemiological studies of neurodevelopmental toxicity in children is the problem of mixed exposures. Most populations are exposed to more than one neurotoxicant at a time, and yet

most studies have only a finite amount of power and precision in exposure assessment to discern the possible effects of even single neurotoxicants. A further problem in many epidemiological studies of non-persistent toxicants is that imprecise assessment of exposure tends to obscure associations that might actually be present.⁶³ Guidance from experimental neurotoxicity studies is therefore crucial. In the assessment of potential developmental neurotoxicants, we have used a strength of evidence approach similar to that used by the International Agency for Research on Cancer for assessing epidemiological and experimental studies.

Phthalates and bisphenol A are added to many different types of plastics, cosmetics, and other consumer products. Since they are eliminated rapidly in urine, exposure assessment is complicated, and such imprecision might lead to underestimation of the true risk of neurotoxicity. The best-documented effects of early-life exposure to phthalates are the consequence of disruption of endocrine signalling.⁶⁴ Thus, prenatal exposures to phthalates have been linked to both neurodevelopmental deficits and to behavioural abnormalities characterised by shortened attention span and impaired social interactions.⁶⁵ The neurobehavioural toxicity of these compounds seems to affect mainly boys and could therefore relate to endocrine disruption in the developing brain.⁶⁶ In regard to bisphenol A, a prospective study showed that point estimates of exposure during gestation were linked to abnormalities in behaviour and executive function in children at 3 years of age.⁶⁷

Exposure to air pollution can cause neurodevelopmental delays and disorders of behavioural functions.^{68,69} Of the individual components of air pollution, carbon monoxide is a well-documented neurotoxicant, and indoor exposure to this substance has now been linked to deficient neurobehavioural performance in children.⁷⁰ Less clear is the reported contribution of nitrogen oxides to neurodevelopmental deficits,⁷¹ since these compounds often co-occur with carbon monoxide as part of complex emissions. Tobacco smoke is a complex mixture of hundreds of chemical compounds and is now a well-documented cause of developmental neurotoxicity.⁷² Infants exposed prenatally to polycyclic aromatic hydrocarbons from traffic exhausts at 5 years of age showed greater cognitive impairment and lower IQ than those exposed to lower levels of these compounds.⁶⁸

Perfluorinated compounds, such as perfluorooctanoic acid and perfluorooctane sulphonate, are highly persistent in the environment and in the human body, and seem to be neurotoxic.⁷³ Emerging epidemiological evidence suggests that these compounds might indeed impede neurobehavioural development.⁷⁴

Developmental neurotoxicity and clinical neurology

Exposures in early life to developmental neurotoxicants are now being linked to specific clinical syndromes in

children. For example, an increased risk of attention-deficit hyperactivity disorder has been linked to prenatal exposures to manganese, organophosphates,⁷⁵ and phthalates.⁷⁶ Phthalates have also been linked to behaviours that resemble components of autism spectrum disorder.⁷⁷ Prenatal exposure to automotive air pollution in California, USA, has been linked to an increased risk for autism spectrum disorder.⁷⁸

The persistent decrements in intelligence documented in children, adolescents, and young adults exposed in early life to neurotoxicants could presage the development of neurodegenerative disease later in life. Thus, accumulated exposure to lead is associated with cognitive decline in the elderly.⁷⁹ Manganese exposure may lead to parkinsonism, and experimental studies have reported Parkinson's disease as a result of developmental exposures to the insecticide rotenone, the herbicides paraquat and maneb, and the solvent trichloroethylene.⁸⁰ Any environmental exposure that increases the risk of neurodegenerative disorders in later life (figure 1) requires urgent investigation as the world's population continues to age.⁸¹

The expanding complement of neurotoxicants

In our 2006 review,⁶ we expressed concern that additional developmental neurotoxicants might lie undiscovered in the 201 chemicals that were then known to be neurotoxic to human adults, in the roughly 1000 chemicals known to be neurotoxic in animal species, and in the many thousands of industrial chemicals and pesticides that have never been tested for neurotoxicity. Exposure to neurotoxic chemicals is not rare, since almost half of the 201 known human neurotoxicants are regarded as high production volume chemicals.

Our updated literature review shows that since 2006 the list of recognised human neurotoxicants has expanded by 12 chemicals, from 202 (including ethanol) to 214 (table 1 and appendix)—that is, by about two substances per year. Many of these chemicals are widely used and disseminated extensively in the global environment. Of the newly identified neurodevelopmental toxicants, pesticides constitute the largest group, as was already the case in

See Online for appendix

	Number known in 2006	Number known in 2013	Identified since 2006
Metals and inorganic compounds	25	26	Hydrogen phosphide ⁸²
Organic solvents	39*	40	Ethyl chloride ⁸³
Pesticides	92	101	Acetamiprid, ⁸⁴ amitraz, ⁸⁵ avermectin, ⁸⁶ emamectin, ⁸⁷ fipronil (Termidor), ⁸⁸ glyphosate, ⁸⁹ hexaconazole, ⁹⁰ imidacloprid, ⁹¹ tetramethylenedisulfotetramine ⁹²
Other organic compounds	46	47	1,3-butadiene ⁹³
Total	202*	214	12 new substances

*Including ethanol.

Table 1: Industrial chemicals known to be toxic to the human nervous system in 2006 and 2013, according to chemical group

	Known in 2006	Newly identified
Metals and inorganic compounds	Arsenic and arsenic compounds, lead, and methylmercury	Fluoride and manganese
Organic solvents	(Ethanol) toluene	Tetrachloroethylene
Pesticides	None	Chlorpyrifos and DDT/DDE
Other organic compounds	Polychlorinated biphenyls	Brominated diphenyl ethers
Total	6*	6

DDT=dichlorodiphenyltrichloroethane. DDE=dichlorodiphenyldichloroethylene. *Including ethanol.

Table 2: Industrial chemicals known to cause developmental neurotoxicity in human beings in 2006 and 2013, according to chemical group

	Number of IQ points lost
Major medical and neurodevelopmental disorders	
Preterm birth	34 031 025
Autism spectrum disorders	7 109 899
Paediatric bipolar disorder	8 164 080
Attention-deficit hyperactivity disorder	16 799 400
Postnatal traumatic brain injury	5 827 300
Environmental chemical exposures	
Lead	22 947 450
Methylmercury	1 590 000*
Organophosphate pesticides	16 899 488
Other neurotoxicants	Unknown

IQ=intelligence quotient. Data from from Bellinger.⁵⁴ *From Grandjean and colleagues.²³

Table 3: Total losses of IQ points in US children 0–5 years of age associated with major risk factors, including developmental exposure to industrial chemicals that cause neurotoxicity

2006. In the same 7-year period, the number of known developmental neurotoxicants has doubled from six to 12 (table 2). Although the pace of scientific discovery of new neurodevelopmental hazards is more rapid today than in the past, it is still slower than the identification of adult neurotoxicants.

The gap that exists between the number of substances known to be toxic to the adult brain and the smaller number known to be toxic to the much more vulnerable developing brain is unlikely to close in the near future. This discrepancy is attributable to the fact that toxicity to the adult brain is usually discovered as a result of acute poisoning incidents, typically with a clear and immediate association between causative exposure and adverse effects, as occurs for workplace exposures or suicide attempts. By contrast, the recognition of developmental neurotoxicity relies on two sets of evidence collected at two different points in time: exposure data (often obtained from the mother during pregnancy), and data for the child's postnatal neurobehavioural development (often obtained 5–10 years later). Because brain functions develop sequentially, the full effects of early neurotoxic damage might not become apparent until school age or beyond. The most reliable evidence of developmental neurotoxicity is obtained through prospective studies that include

real-time recording of information about exposure in early life followed by serial clinical assessments of the child. Such research is inherently slow and is hampered by the difficulty of reliable assessment of exposures to individual toxicants in complex mixtures.

Consequences of developmental neurotoxicity

Developmental neurotoxicity causes brain damage that is too often untreatable and frequently permanent. The consequence of such brain damage is impaired CNS function that lasts a lifetime and might result in reduced intelligence, as expressed in terms of lost IQ points, or disruption in behaviour. A recent study compared the estimated total IQ losses from major paediatric causes and showed that the magnitude of losses attributable to lead, pesticides, and other neurotoxicants was in the same range as, or even greater than, the losses associated with medical events such as preterm birth, traumatic brain injury, brain tumours, and congenital heart disease (table 3).²⁴

Loss of cognitive skills reduces children's academic and economic attainments and has substantial long-term economic effects on societies.⁴ Thus, each loss of one IQ point has been estimated to decrease average lifetime earnings capacity by about €12 000 or US\$18 000 in 2008 currencies.²⁶ The most recent estimates from the USA indicate that the annual costs of childhood lead poisoning are about US\$50 billion and that the annual costs of methylmercury toxicity are roughly US\$5 billion.²⁷ In the European Union, methylmercury exposure is estimated to cause a loss of about 600 000 IQ points every year, corresponding to an annual economic loss of close to €10 billion. In France alone, lead exposure is associated with IQ losses that correspond to annual costs that might exceed €20 billion.²⁸ Since IQ losses represent only one aspect of developmental neurotoxicity, the total costs are surely even higher.

Evidence from worldwide sources indicates that average national IQ scores are associated with gross domestic product (GDP)—a correlation that might be causal in both directions.²⁹ Thus, poverty can cause low IQ, but the opposite is also true. In view of the widespread exposures to lead, pesticides, and other neurotoxicants in developing countries, where chemical controls might be ineffective compared with those in more developed countries,^{100,101} developmental exposures to industrial chemicals could contribute substantially to the recorded correlation between IQ and GDP. If this theory is true, developing countries could take decades to emerge from poverty. Consequently, pollution abatement might then be delayed, and a vicious circle can result.

The antisocial behaviour, criminal behaviour, violence, and substance abuse that seem to result from early-life exposures to some neurotoxic chemicals result in increased needs for special educational services, institutionalisation, and even incarceration. In the USA, the murder rate fell sharply 20 years after the removal of lead from petrol,¹⁰² a finding consistent with the idea that

exposure to lead in early life is a powerful determinant of behaviour decades later. Although poorly quantified, such behavioural and social consequences of neurodevelopmental toxicity are potentially very costly.⁷⁶

Prevention of developmental neurotoxicity caused by industrial chemicals is highly cost effective. A study that quantified the gains resulting from the phase-out of lead additives from petrol reported that in the USA alone, the introduction of lead-free petrol has generated an economic benefit of \$200 billion in each annual birth cohort since 1980,⁸⁰ an aggregate benefit in the past 30 years of over \$3 trillion. This success has since been repeated in more than 150 countries, resulting in vast additional savings. Every US\$1 spent to reduce lead hazards is estimated to produce a benefit of US\$17–220, which represents a cost-benefit ratio that is even better than that for vaccines.⁴ Furthermore, the costs associated with the late-life consequences of developmental neurotoxicity are enormous, and the benefits from prevention of degenerative brain disorders could be very substantial.

New methods to identify developmental neurotoxicants

New toxicological methods now allow a rational strategy for the identification of developmental neurotoxicants based on a multidisciplinary approach.¹⁰⁴ A new guideline has been approved as a standardised approach for the identification of developmental neurotoxicants.¹⁰⁵ However, completion of such tests is expensive and requires the use of many laboratory animals, and reliance on mammals for chemicals testing purposes needs to be reduced.¹⁰⁶ US governmental agencies have established the National Center for Computational Toxicology and an initiative—the Tox 21 Program—to promote the evolution of toxicology from a mainly observational science to a predominantly predictive science.¹⁰⁷

In-vitro methods have now reached a level of predictive validity that means they can be applied to neurotoxicity testing.¹⁰⁸ Some of these tests are based on neural stem cells. Although these cell systems do not have a blood-brain barrier and particular metabolising enzymes, these approaches are highly promising. As a further option, data for protein links and protein-protein interactions can now be used to explore potential neurotoxicity in silico,¹⁰⁹ thus showing that existing computational methods might predict potential toxic effects.¹¹⁰

In summary, use of the whole range of approaches along with clinical and epidemiological evidence, when available, should enable the integration of information for use in at least a tentative risk assessment. With these methods, we anticipate that the pace of scientific discovery in developmental neurotoxicology will accelerate further in the years ahead.

Conclusions and recommendations

The updated findings presented in this Review confirm and extend our 2006 conclusions.⁶ During the 7 years

since our previous report, the number of industrial chemicals recognised to be developmental neurotoxicants has doubled. Exposures to these industrial chemicals in the environment contribute to the pandemic of developmental neurotoxicity.

Two major obstacles impede efforts to control the global pandemic of developmental neurotoxicity. These barriers, which we noted in our previous review⁶ and were recently underlined by the US National Research Council,¹¹¹ are: large gaps in the testing of chemicals for developmental neurotoxicity, which results in a paucity of systematic data to guide prevention; and the huge amount of proof needed for regulation. Thus, very few chemicals have been regulated as a result of developmental neurotoxicity.

The presumption that new chemicals and technologies are safe until proven otherwise is a fundamental problem.¹¹² Classic examples of new chemicals that were introduced because they conveyed certain benefits, but were later shown to cause great harm, include several neurotoxicants, asbestos, thalidomide, diethylstilboestrol, and the chlorofluorocarbons.¹¹³ A recurring theme in each of these cases was that commercial introduction and wide dissemination of the chemicals preceded any systematic effort to assess potential toxicity. Particularly absent were advance efforts to study possible effects on children's health or the potential of exposures in early life to disrupt early development. Similar challenges have been confronted in other public health disasters, such as those caused by tobacco smoking, alcohol use, and refined foods. These problems have been recently termed industrial epidemics.¹¹⁴

To control the pandemic of developmental neurotoxicity, we propose a coordinated international strategy (panel). Mandatory and transparent assessment of evidence for neurotoxicity is the foundation of this strategy. Assessment of toxicity must be followed by governmental regulation and market intervention. Voluntary controls seem to be of little value.¹¹

Panel: Recommendations for an international clearinghouse on neurotoxicity

The main purpose of this agency would be to promote optimum brain health, not just avoidance of neurological disease, by inspiring, facilitating, and coordinating research and public policies that aim to protect brain development during the most sensitive life stages. The main efforts would aim to:

- Screen industrial chemicals present in human exposures for neurotoxic effects so that hazardous substances can be identified for tighter control
- Stimulate and coordinate new research to understand how toxic chemicals interfere with brain development and how best to prevent long-term dysfunctions and deficits
- Function as a clearinghouse for research data and strategies by gathering and assessing documentation about brain toxicity and stimulating international collaboration on research and prevention
- Promote policy development aimed at protecting vulnerable populations against chemicals that are toxic to the brain without needing unrealistic amounts of scientific proof

The three pillars of our proposed strategy are: legally mandated testing of existing industrial chemicals and pesticides already in commerce, with prioritisation of those with the most widespread use, and incorporation of new assessment technologies; legally mandated premarket evaluation of new chemicals before they enter markets, with use of precautionary approaches for chemical testing that recognise the unique vulnerability of the developing brain; and the formation of a new clearinghouse for neurotoxicity as a parallel to the International Agency for Research on Cancer. This new agency will assess industrial chemicals for developmental neurotoxicity with a precautionary approach that emphasises prevention and does not require absolute proof of toxicity. It will facilitate and coordinate epidemiological and toxicological studies and will lead the urgently needed global programmes for prevention.

These new approaches must reverse the dangerous presumption that new chemicals and technologies are safe until proven otherwise. They must also overcome the existing requirement to produce absolute proof of toxicity before action can be started to protect children against neurotoxic substances. Precautionary interpretation of data about developmental neurotoxicity should take into account the very large individual and societal costs that result from failure to act on available documentation to prevent disease in children.¹⁴ Academic research has often favoured scepticism and required extensive replication before acceptance of a hypothesis,¹⁴ thereby adding to the inertia in toxicology and environmental health research and the consequent disregard of many other potential neurotoxins.¹⁵ Additionally, the strength of evidence that is needed to constitute “proof” should be analysed in a societal perspective, so that the implications of ignoring a developmental neurotoxicant and of failing to act on the basis of available data are also taken into account.

Finally, we emphasise that the total number of neurotoxic substances now recognised almost certainly represents an underestimate of the true number of developmental neurotoxins that have been released into the global environment. Our very great concern is that children

Search strategy and selection criteria

We identified studies published since 2006 on the neurotoxic effects of industrial chemicals in human beings by using the search terms “neurotoxicity syndromes”[MeSH], “neurotoxic”, “neurologic”, or “neuro*”, combined with “exposure” and “poisoning” in PubMed, from 2006 to the end of 2012. For developmental neurotoxicity, the search terms were “prenatal exposure delayed effects”[MeSH], “maternal exposure” or “maternal fetal exchange”, “developmental disabilities/chemically induced” and “neurotoxins”, all of which were searched for with the limiters “All Child: 0–18 years, Human”. We also used references cited in the publications retrieved.

worldwide are being exposed to unrecognised toxic chemicals that are silently eroding intelligence, disrupting behaviours, truncating future achievements, and damaging societies, perhaps most seriously in developing countries. A new framework of action is needed.

Contributors

Both authors did the literature review, wrote and revised the report, and approved the final version.

Conflicts of interest

PG has provided paid expert testimony about mercury toxicology for the US Department of Justice. P.J.L. has provided paid expert testimony in cases of childhood lead poisoning. We declare that we have no other conflicts of interest.

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Impact of fluoride on neurological development in children

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July 25, 2012 — For years health experts have been unable to agree on whether fluoride in the drinking water may be toxic to the developing human brain. Extremely high levels of fluoride are known to cause neurotoxicity in adults, and negative impacts on memory and learning have been reported in rodent studies, but little is known about the substance's impact on [children's neurodevelopment](#). In a meta-analysis, researchers from Harvard School of Public Health (HSPH) and China Medical University in Shenyang for the first time combined 27 studies and found strong indications that fluoride may adversely affect cognitive development in children. Based on the findings, the

authors say that this risk should not be ignored, and that more research on fluoride's impact on the developing brain is warranted.

The study was published online in *Environmental Health Perspectives* on July 20, 2012.

The researchers conducted a systematic review of studies, almost all of which are from China where risks from fluoride are well-established. Fluoride is a naturally occurring substance in groundwater, and exposures to the chemical are increased in some parts of China. Virtually no human studies in this field have been conducted in the U.S., said lead author Anna Choi, research scientist in the Department of Environmental Health at HSPH.

Even though many of the studies on children in China differed in many ways or were incomplete, the authors consider the data compilation and joint analysis an important first step in evaluating the potential risk. "For the first time we have been able to do a comprehensive meta-analysis that has the potential for helping us plan better studies. We want to make sure that cognitive development is considered as a possible target for fluoride toxicity," Choi said.

Choi and senior author Philippe Grandjean, adjunct professor of environmental health at HSPH, and their colleagues collated the epidemiological studies of children exposed to fluoride from drinking water. The China National Knowledge Infrastructure database also was included to locate studies published in Chinese journals. They then analyzed possible associations with IQ measures in more than 8,000 children of school age; all but one study suggested that high fluoride content in water may negatively affect cognitive development.

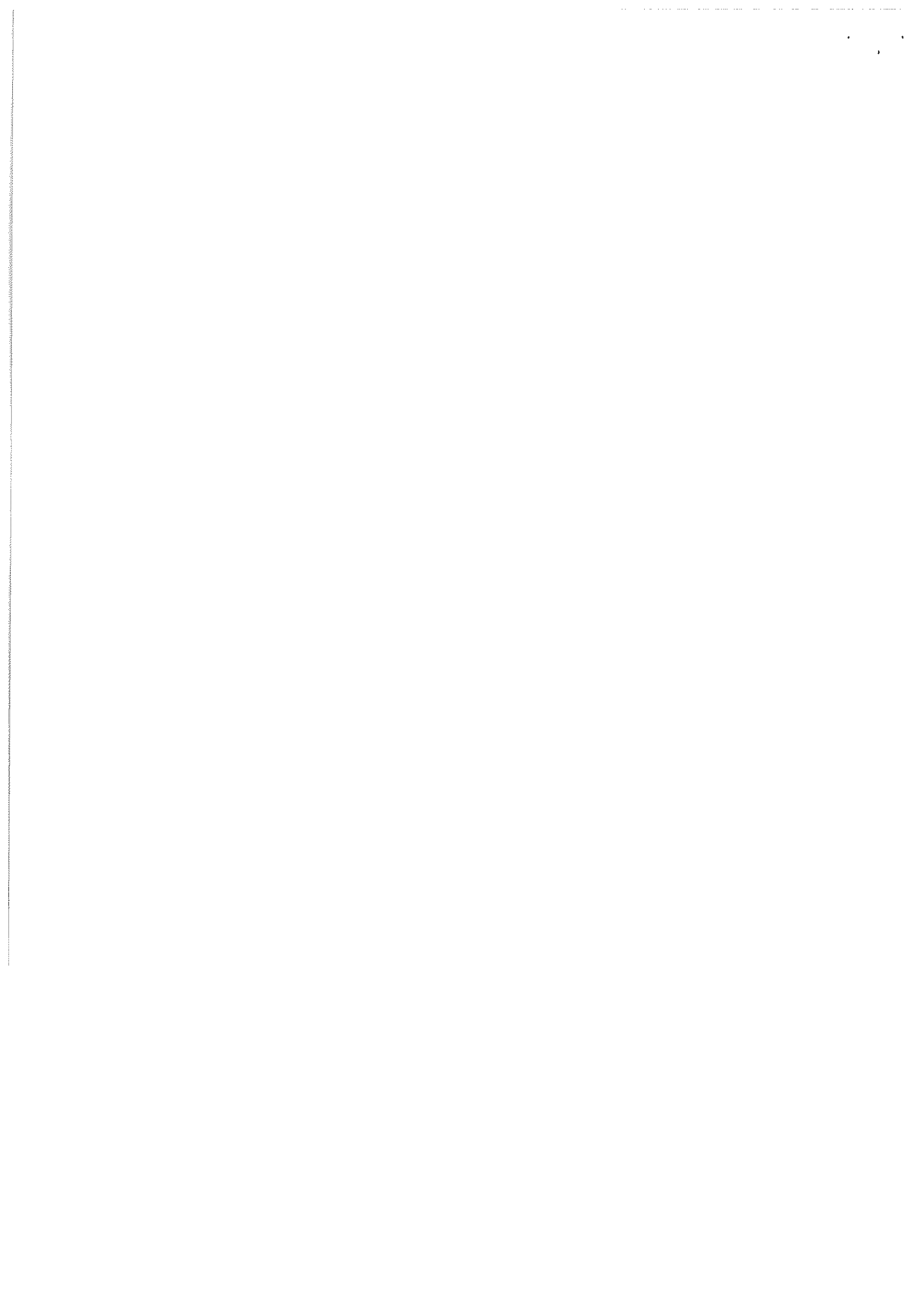
The average loss in IQ was reported as a standardized weighted mean difference of 0.45, which would be approximately equivalent to seven IQ points for commonly used IQ scores with a standard deviation of 15.* Some studies suggested that even slightly increased fluoride exposure could be toxic to the brain. Thus, children in high-fluoride areas had significantly lower IQ scores than those who lived in low-fluoride areas. The children studied were up to 14 years of age, but the investigators speculate that any toxic effect on brain development may have happened earlier, and that the brain may not be fully capable of compensating for the toxicity.

"Fluoride seems to fit in with lead, mercury, and other poisons that cause chemical brain drain," Grandjean says. "The effect of each toxicant may seem small, but the combined damage on a population scale can be serious, especially because the brain power of the next generation is crucial to all of us."

** This sentence was updated on September 5, 2012.*

Read a September 2012 statement by the authors.

*** Learn more about the IQ measurements by HSPH's Anna L. Choi and Philippe Grandjean in response to a letter to the journal published in the March 2013 (Vol. 121, No. 3) Environmental Health Perspectives.*



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