IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

CIV-2014-485-4138

UNDER THE	Judicature Amendment Act 1972 and the Declaratory Judgments Act 1908
IN THE MATTER OF	An application for judicial review and an application for a declaration
BETWEEN	NEW HEALTH NEW ZEALAND INC
	Plaintiff
AND	ATTORNEY-GENERAL FOR AND ON BEHALF OF THE MINISTER OF HEALTH
	Defendant

STATEMENT OF DEFENCE

12 May 2014

CROWN LAW
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The defendant by his solicitor in response to the statement of claim dated 2 April 2014 says:

Parties

1. Admits paragraph 1.

2. Has insufficient knowledge of and therefore denies paragraph 2.

3. Admits paragraph 3 but says the Minister of Health should be substituted as the defendant.

4. Admits that the Minister of Health is under the Medicines Act 1981 responsible for the regulation of products used for a therapeutic purpose as defined in that Act and that the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), a business unit of the Ministry of Health, is the regulatory authority responsible for administering those functions.

The plaintiff

5. Has insufficient knowledge of and therefore denies paragraph 5.

Fluoridation of water supplies

6. Admits paragraph 6 and further says:

    6.1 The naturally occurring fluoride level in New Zealand water supplies is usually between 0.1 and 0.3 parts per million (ppm);

    6.2 For oral health reasons, the Ministry of Health specifically recommends the fluoride content for drinking-water be in the range of 0.7 – 1.0 ppm;

    6.3 Currently approximately 56 percent of people on minor or larger water supplies receive water in which the fluoride levels has been adjusted to the recommended level;

    6.4 The power of local authorities to add fluoride to their drinking water supplies arises under the Local Government Act 2002 and the Health Act 1956;

6.5 The drinking water standard issued under the Health Act 1956, Drinking-water Standards for New Zealand 2005 (Revised 2008), specifies the maximum acceptable value for fluoride is 1.5 parts per million (ppm).

7. Admits paragraph 7 and further says:

7.1 Hydroflurosilicic acid, or HFA is a liquid and Sodium silicofluoride, or SSF is a solid, both contain fluoride ions that are no different to the fluoride found naturally in water and once HFA or SSF is mixed with water the fluoride ions are released;

7.2 The chemical compounds HFA and SSF are both hazardous substances for the purposes of the Hazardous Substances and New Organisms Act 1996 and that Act accordingly regulates how HFA and SSF must be treated, including their handling, packaging and labelling, storage and transport.

8. Admits paragraph 8 and further says:

8.1 In some manufacturing plants, the scrubbing process in the production of phosphate fertilisers produces HFA in a form suitable for water fluoridation, thereby making it a profitable by-product.

9. Admits paragraph 9.

10. Admits paragraph 10 and further says:

10.1 The Ministry of Health is the government's agent and key advisor on health issues and recommends water fluoridation as a safe, effective and affordable way to prevent and reduce tooth decay.

11. Admits paragraph 11 and further repeats paragraph 10 above.

12. Has insufficient knowledge and therefore denies paragraph 12 and further says:

12.1 Fluoride is a natural element and is naturally occurring (at varying concentrations) in the air, soil, plants and water and he repeats paragraph 6.1 above;

12.2 Fluoride is not harmful to health at the resulting concentrations added to drinking water supplies, rather fluoride, like many other elements, is only harmful at high concentrations and he repeats paragraphs 6.2 to 6.5 above;

12.3 Hundreds of peer reviewed and scientific studies over many decades have found water fluoridation is safe;

12.4 The Ministry of Health considers that fluoridation of drinking water supplies is an effective way of preventing and reducing tooth decay and this view is shared by other public health authorities and medical science bodies and international organisations which include the New Zealand Dental Council, the New Zealand Medical Association, the World Health Organisation and the World Dental Federation;

12.5 Fluoride compounds added to water supplies may contain heavy metal contaminants including arsenic, mercury and lead, all of which may occur naturally in water, soils, and drinking-water reticulation systems. The addition of fluoride compounds must conform with the drinking water standard issued under the Health Act 1956, Drinking-water Standards for New Zealand 2005 (Revised 2008) and those standards specify a maximum acceptable value for heavy metal contaminants including arsenic, mercury and lead. Accordingly, the resulting concentrations of any heavy metal contaminants following the addition of fluoride compounds to water supplies is safe as they cannot exceed the maximum acceptable values in the drinking water standards.

Plaintiff's legal challenge to fluoridation

13. Admits paragraph 13.

14. Admits paragraph 14.

15. Admits paragraph 15 and further says:

15.1 In that decision Rodney Hansen J held there is an implied power to fluoridate in the Local Government Act 2002, fluoride may be added

to drinking water in accordance with drinking water standards issued under the Health Act 1956, fluoridation of water is not medical treatment for the purpose of s 11 of the New Zealand Bill of Rights Act 1990 (the right to refuse medical treatment) and even if it did engage that right it was a justified limit in terms of s 5 of that Act.

16. Admits paragraph 16.

17. Admits paragraph 17.

18. Denies paragraph 18 and further says:

18.1 Rodney Hansen J did not find that water fluoridation has a therapeutic purpose as defined in s 4 of the Medicines Act 1981;

18.2 Whilst chemical compounds such as HFA and SSF and others such as chlorine are added to water supplies for public health reasons it does not follow that such compounds necessarily will come within the definition of medicine under the Medicines Act 1981, including because the treatment of water supplies is regulated under the Health Act 1956.

19. Denies paragraph 19 and relies on the definition of "medicine" in s 3 of the Medicines Act 1981 in its entirety, which includes the preface "unless the context otherwise requires".

20. Admits paragraph 20.

21. Denies paragraph 21 and further says:

21.1 He relies on the definition of "therapeutic purpose" in s 4 of the Medicines Act 1981 in its entirety, which includes the preface "unless the context otherwise requires".

22. Admits paragraph 22 and further says:

22.1 Section 2 of the Medicines Act 1981 defines "disease" as including any injury, ailment, deformity, disorder, or adverse condition, whether of body or mind.

23. Admits HFA and SSF are sold to some local authorities and used by them solely for the purpose of fluoridating the community water supply to prevent dental decay but otherwise denies paragraph 23.

24. Denies paragraph 24 and further says:

    24.1 He relies on s 17(1) of the Medicines Act 1981 in its entirety, which provides exceptions to the requirement for a manufacturer of a medicine to obtain a licence.

25. Admits paragraph 25.

26. Admits paragraph 26 and further says:

    26.1 No such licence has ever been sought from the Director-General;

    26.2 Nor is a licence required under the Medicines Act 1981 for the manufacture of either HFA or SSF because neither compound comes within the definition of a "medicine" in s 3 of that Act, including because the context requires otherwise and the use of these compounds is controlled under the Health Act 1956 and the Hazardous Substances and New Organisms Act 1996.

27. Denies paragraph 27 and further says:

    27.1 Section 20 of the Medicines Act 1981 only applies (subject to certain exceptions) to any "new medicine" as defined in s 3(3) of the Act;

    27.2 He relies on ss 3(3) and 20 of the Medicines Act 1981 in their entirety.

28. Admits paragraph 28.

29. Admits paragraph 29 and further says:

    29.1 That is for the Minister's consent under s 20 which applies to any "new medicine";

    29.2 Repeats paragraph 27 above.

30. Admits paragraph 30 and further says:

30.1 No such consent has ever been sought from the Minister;

30.2 Nor is consent required under the Medicines Act 1981 for the sale or supply of either HFA or SSF including because neither compound comes within the definition of a "medicine" or "new medicine" in s 3 of that Act, including because the context requires otherwise and the use of these compounds is regulated under the Health Act 1956 and the Hazardous Substances and New Organisms Act 1996.

This document is filed by Jane Foster, solicitor for the defendant, of Crown Law.

The address for service of the defendant is Crown Law, Level 3, Justice Centre, 19 Aitken Street, Wellington 6011. Documents for service on the defendant may be left at this address for service or may be:

(a) posted to the solicitor at PO Box 2858, Wellington 6140; or

(b) left for the solicitor at a document exchange for direction to DX SP20208, Wellington Central; or

(c) transmitted to the solicitor by facsimile to 04 473 3482; or

(d) emailed to the solicitor at Jane.Foster@crownlaw.govt.nz