

A review of the status of water fluoridation within the European Community

Douglas Cross¹ (14th February 2008)

1. Introduction

Fluoridated water is supplied to many millions of people worldwide, with the objective of reducing or preventing the development of dental caries. Young people are the main target, although it is sometimes claimed that fluoride may also be of benefit to older people. Its efficacy and safety are contentious, and claims and counter-claims about the dental, medical and toxicological aspects of fluoridation have become increasingly heated. Fluoride is not essential for human growth and development, and the fluoride content of the body is not under physiological control.² The sole reason for its addition to public water supplies is for dental prophylaxis – the prevention of the development of dental caries in young children.

The fluorine chemical industry has grown very rapidly in recent years, with applications including pesticides, anaesthetics, drugs and cosmetics. Yet the impacts of releases of fluorides and of complex organic fluorochemicals to the environment are poorly understood. Only about a dozen naturally occurring organofluorine chemicals are known. Of these fluoroacetate, found in more than 40 plant species, is the most ubiquitous. It is a breakdown product of a number of fluorinated pesticides, and may be concentrated by factors of over 250 in the growing tips of vegetation. It has been responsible for a number of livestock mortalities. However, recently it has been discovered that fluoroacetate may enter biological systems directly from inorganic fluorides in the environment. An enzyme capable of converting inorganic fluoride to a fluoromethyl group, a precursor of more complex fluorochemicals, has been found in a bacterium³.

At least 99% of the fluoride in domestic water is discharged directly into domestic and industrial drains without being drunk by consumers, and it also passes unchanged through sewage treatment works. The effluents from such works may have higher levels of fluoride than is present in their main source of water, from fluorides originating from foods and drinks. Consequently, increased fluoride contamination may occur in rivers that have a number of sequential local abstraction and discharge operations from communities relying on river abstractions as their primary source of water supply.

The discovery that inorganic fluoride can enter the food chain through bacterial action implies that increasing discharges of fluoridated effluents to surface waters could result in more fluoroacetate entering ecosystems and the human food chain, yet this potential impact of the extension of water fluoridation is rarely if ever considered.

Medical effects of increased fluoride uptake

¹ Independent Consultant Environmental Analyst. Contact - maverick65@tiscali.co.uk (Tel 01229 885420)

² European Food Safety Agency (2005). Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride. The EFSA Journal (2005) 192, 1-65

³ O'Hagan et al (2002). Enzyme catalysed organofluorine synthesis, *Nature*, **416**, 279-280).

Dental fluorosis is the most widely recognised side-effect of water fluoridation. It is the only visible indicator of an excess of fluoride intake, and presents as a discolouration of the teeth resulting from the incorporation of fluoride into the enamel. In severe cases it is a psychologically damaging disfigurement, and may require expensive corrective cosmetic dentistry to conceal. Such treatment is expensive and has to be repeated through life. The severity of dental fluorosis is directly proportional to the amount of ingested fluoride, and in fluoridated countries its prevalence has grown rapidly. Half or more of the population is affected in fluoridated areas of Ireland and parts of the USA.

Indications of the biochemical damage resulting from an excess of fluoride intake are widely reported in the toxicological research literature. Of particular concern is the high level of risk to those individuals in the population who are particularly sensitive to fluoride intoxication, and it is clear that the safety margin between the supposed 'optimal' level for the claimed dental benefits of fluoride and the development of both the disfigurement by dental fluorosis and the development of other fluoride-related conditions in the most vulnerable members of the population is very narrow, or even none at all.

Topical application of fluoride to the teeth, in toothpaste, is considered to be the most effective method of preventing dental caries, whilst the evidence that ingestion is beneficial is far less well substantiated. Yet remarkably, pressure to expand the fluoridation of public water supplies is increasing. Since fluoride is commonly found in many foods, the total dietary exposure to fluoride has to be taken into account in any discussion of the tolerable upper intake level for fluoride and the safety of adding it to the public water supply.⁴

Ethical constraints versus legal permissibility.

Social, ethical, and political debates over water fluoridation are invariably diverted into arguments on indeterminate aspects of civil liberties, human rights and the supposed relative rights of different sectors of the public to receive or reject the claimed benefits of public medication. It is alleged that alleviating dental decay in the young over-rides public and individual objection to public medication, even when over 90% of the population is not at risk. The bizarre ethical basis adopted by fluoride proponents is exemplified by extreme statements claiming that it is unethical to prevent young people from receiving the 'benefits of fluoride', irrespective of the known medical risks and the absence of any acceptable safety margins. It is even denied that fluoridation is not public medication, for reasons ranging from the absurd (it is too dilute to be a medicine) to the ingenuous (fluoride is an essential nutrient). Such argument has no relevance to the examination of the primary issue – that of whether or not the practice of water fluoridation is actually permissible in law.

Inevitably, where there is doubt regarding the legitimacy of a practice that carries a risk of directly and physically affecting the health of most, if not all individuals in a large population, the question of the liability of proponents and manufacturers of the product for medical damage emerges. In this case, indemnity has been conditionally offered to water undertakers by the British Government, but the question then arises, can it be permissible to offer indemnity if fluoridation is in violation of the law? Another problematic area is the proposal that communities should be consulted before any new scheme is introduced – again, is it permissible to consult on any action that may be contrary to law? These issues are examined in outline at the end of the analysis.

⁴ EFSA (2005) op.cit p1.

2. Fluoridation in the European Community

This analysis is the first to examine the legal framework under which water fluoridation is practiced in the UK (and, in less detail with respect to national legislation, in the Republic of Ireland) under the umbrella of the legal framework established by the European Community. It relies upon primary European Community legislation and decisions by the European Court of Justice (ECJ) which, whilst not themselves enforceable in English law, are required to be transposed into compatible national legislation by all Member States.

The central issue that emerges is that the English law nominating fluorosilicates as the active substances that may be used to fluoridate public water supplies is incompatible with EC Directives and Regulation, and therefore with the English legislation derived from them, on drinking water, medicines, foods, food supplements and food additives. In addition, the Water Act is itself incompatible with the pre-existing national legislation prohibiting the administration of fluorosilicates and related substances to the public.

Despite the extent to which fluoridation is employed around the world, very few studies have actually addressed the regulatory framework within which it is applied. In this analysis European Community (EC) Directives and Regulations that govern the supply of medicines, food products and cosmetics are examined, and their relevance to the practice of water fluoridation in those few countries within the EC in which it is still employed is assessed. Other fluorine-containing substances are commonly administered orally, but are not considered here; this analysis is concerned solely with the legitimacy of water fluoridation within the current regulatory framework of the EC.

Within the EC, Great Britain and Ireland are the only Member States that permit fluoride to be added to the public water supply on a significant scale. In Britain, the practice was voluntary until the passing of the Water Act in 2003. This gave Strategic Health Authorities (SHAs) the power to order local private sector water suppliers to fluoridate the public water supplies if, in the opinion of the SHA, this would improve dental health in the area. This power is apparently moderated by provisions for local consultation, but this is illusory – in practice the ultimate decision on whether or not to fluoridate a specific area still rests with the Secretary of State for Health; there is no guarantee of respect for the opinion of local consumers.

The foundation of the British and Irish Governments' policy to impose fluoridation is the claim that it does not constitute public medication. In Scotland, this has been rejected; the practice was confirmed as being a medicinal intervention by Lord Jauncy⁵,

(P.370) "Fluoride is intended to produce a positive effect on the body of the consumer after ingestion. Thus the water instead of being the object of treatment becomes the means whereby fluoride is carried into the consumer's body to effect a result which could also be achieved by the consumption of fluoride pills or of food and drink containing high levels of fluoride. . . It would necessarily involve a restriction on the freedom of choice of the individual who would have little alternative but to consume the fluoridated water whether he liked it or not."

In this case, it was ruled that fluoridation was *ultra vires* the remit of the water supplier, and consequently it is no longer practiced in Scotland. This interpretation appears not to be accepted

⁵ Mrs. Catherine McColl v Strathclyde Regional Council 1983, High Court of Scotland.

by the health sector in England, however, and this part of the judgment is invariably ignored by proponents of fluoridation.

In Ireland, fluoridation is mandatory wherever practicable, and three quarters of the population receives fluoridated water. Very few other locations in the EC are exposed to artificially fluoridated water, although people traveling around Europe inevitably encounter the product if they visit such areas.

3. The status of fluoridation chemicals in UK and EC legislation.

The fluorosilicates used for water fluoridation are complex inorganic derivatives of hydrofluoric acid (HF). HF is a very toxic and corrosive poison, and its derivative, the fluorosilicic acid used very widely to fluoridate public water supplies, is a very hazardous substance whose handling, transport and use are strictly regulated under the Control of Substances Hazardous to Health (COSHH) Regulations 2002. Sodium fluorosilicate ('silicofluoride') is a Part II poison whose administration to any person is forbidden under the Poisons List Order 1982, whilst fluorosilicic acid contains up to 15% by volume of HF, which is also a listed Part II poison under the Act. The administration of either substance, or of any substance containing them, to the public is forbidden under the Poisons Act 1972, and constitutes an assault under the provisions of the Offences Against the Person Act 1861.

Other inorganic fluorides have specific permissions for use under EC and UK foods, medicines and cosmetics regulations. Sodium and potassium fluorides are authorized for use as minerals in the Food Supplements Directive (2002/46/EC), and in special foods authorized under the Dietary Foods for Special Medical Purposes Directive (1999/21/EC). Twenty compounds containing fluoride may be included as ingredients in specific oral hygiene preparations classified as cosmetics products (Annex III part1 of Directive 76/768/EEC, as amended), but cosmetic products used for the purpose of oral hygiene may not be ingested.

The only specific references to fluorosilicates in the European Directives and Regulations are to the maximum permissible concentrations of four types of fluorosilicates in some types of oral hygiene products. Fluorosilicic acid, as a complex derivative of HF, is specifically banned for such use. Fluorosilicates are not permissible additives in any form of ingestible product, and only appear as nominated substances for water fluoridation in the British and Irish domestic water legislation. Sodium fluorosilicate and fluorosilicic acid are the only chemicals that are used to fluoridate public water supplies, as specified under the provisions of the UK's Water Act 2003.

4. The application of the water quality Directive (98/83/EC) to fluoridated water.

The quality of water intended for human consumption is regulated by Directive 98/83/EC. The maximum permissible level of fluoride in drinking water is specified as 1.5 mg/litre in Article 5(1), and Member States are required to set their own national limits at or below this level. The concentration for 'optimally fluoridated water' recommended by proponents of fluoridation is 1 mg/litre, and this is generally adopted as the target concentration for public water supplies in both Britain and Ireland. In warmer countries, the recommended 'optimum' concentration is reduced to 0.7 mg/litre, although in Ireland a reduced concentration of 0.7mg/l is now being recommended, and there have recently been moves to reduce the limit of fluoride in drinking water to 0.7mg/l in Ireland,

The apparent legitimacy of the practice of water fluoridation as it is applied in Britain and Ireland therefore rests on the assumption that the setting of a maximum admissible concentration of a contaminant constitutes licence to the State to supplement any naturally occurring concentration up to that maximum limit. This is a fallacy. The fundamental objective of the Directive, and of dependent national water quality standards, is to ensure the best possible quality of drinking water, not the worst permissible. The protection of public health is of paramount concern..

Uncertainty over whether or not fluoridated water should be regulated under the water or medicinal legislation can be traced back at least as far as the 1980 water quality Directive (80/778/EEC). Article 1 states that

'This Directive shall not apply to . . . waters which are medicinal products within the meaning of Council Directive 65/65/EEC . . . relating to medicinal products.'

But Article 4 then qualifies this by stating that the Directive

*'shall not apply to: . . . medicinal waters **recognized as such** by the competent national authorities.'* (My emphasis added)

This loophole allowed a national authority to refuse to recognize fluoridated water as a medicinal product. It could then be regulated by default as potable water. However, in Directive 98/83/EC, which replaced 80/778/EEC, this exemption is absent. In effect, from 1998 national authorities could no longer claim that fluoridated water was not a medicinal product simply by refusing to recognize it as such.

The critical issue is therefore whether or not fluoridated water is a medicinal product. Much of the promotional material issued by proponents of fluoridation contains claims, both explicit and implicit, that its regulation falls under one or more of the Directives dealing with foods, food supplements, medicinal foods, and cosmetics. Some even argue that it is one of the ill-defined 'borderline products' that may be a combination of two, or even all three of these three types of product. So if there is doubt that 98/83/EC does apply to fluoridated water, precisely what is its appropriate designation? The answer lies in a poorly understood section of 98/83/EC dealing with products that may be exempt from control under the Directive.

Article 3 permits member states to exempt drinking water from the water quality directive under specific conditions. The Directive does not apply to any waters that are either natural mineral waters or those that are classed as a medicinal product under 65/65/EEC and its successors. But it goes further than this. Article 3.2 (a) states that

Member States may exempt from the provisions of this Directive:

(a) water intended exclusively for those purposes for which the competent authorities are satisfied that the quality of the water has no influence, either directly or indirectly, on the health of the consumers concerned

The general assumption appears to be that this exemption may be invoked if 'supplementation' of 'natural fluoride' has no adverse effect on health, and this may account for proponents' claims that the only adverse effect is dental fluorosis, an "insignificant" and "cosmetic effect". This is fallacious - no substances may be added to drinking water if they have any direct or indirect effect, **even if that effect is beneficial**. If proponents claim that fluoridation improves the dental health of the population, then this immediately excludes the product from exemption under 98/83/EC, and requires that it be controlled under the foods regulations. But it does more than this. In claiming medicinal properties for fluoridated water, it is mandatory that it be classified as a medicinal product. The resolution of the legal status of the product, whether it be regarded as a medicine or a food, is discussed in the following sections.

5. Medicines law

5.1 The EC medicines Directives

In 2001 the European Commission published its proposals to amend the body of legislation covering both the human and veterinary medicines regulatory regimes (Regulation 2309/93 and its associated Directives 2001/82/EC on veterinary medicines and 2001/83/EC on human medicines). The agreed texts were adopted by the Council and the European Parliament on 31 March 2004 as–

- Regulation (EC) No. 726/2004, replacing Regulation 2309/93
- Directive 2004/27/EC on human medicines, amending Directive 2001/83/EC
- Directive 2004/28/EC on veterinary medicines, amending Directive 2001/82/EC

Regulation 726/2004 is directly applicable in all EC national law, and its main provisions applied in the UK as from 20 November 2005. For human medicines, States were required to adopt the legislation necessary to transpose Directive 2004/27/EC by 30 October 2005.

5.2 EC Definition of a medicinal substance

The definition of a medicinal substance originally included in the Medicines Directives 65/65/EEC and 2001/83/EC was amended by 2004/27/EC to:

‘Article 1. ‘2. Medicinal product:

- (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*
- (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.’*

In relation to the practice of water fluoridation, this definition of a medicinal substance is effectively the same as that presented in 2001/83/EC. Substances covered by this definition are generally referred to as medicinal by presentation and/or medicinal by function, and the efficacy of the product is not a relevant issue. A European Court of Justice (ECJ) judgment⁶ held that:

‘Any product satisfying either set of criteria laid down in Article 1(2) of Directive 65/65/EEC is a medicinal product. Such products are subject to the relevant legal rules relating to proprietary medicinal products . . . ‘

In the Ter Voort decision ⁷(C219,91) the ECJ stated

‘A product which is recommended or described as having preventive or curative properties is a medicinal product . . . even if it is generally considered as a foodstuff and even if it has no known therapeutic effect in the present state of scientific knowledge’.

The updated definition of a medicinal substance in 2004/27/EC incorporates these ECJ rulings, and is relevant to any product, irrespective of whether or not it actually has a marketing authorization, or is effective as a medicine. A number of ECJ rulings⁸ affirm that the intent to

⁶ Official Journal of the European Communities, 1989, C112, 89.

⁷ Official Journal of the European Communities, 1991, C219, 91.

⁸ Case C-60/89, 21 March 1991, re Monteil and Samanni, European Court Reports 1991;I:1547.

Case C219-91 28 October 1992 re Ter Voort, European Court Reports 1992;I:5485.

Case C368-88 21 March 1991 re Delattre, European Court Reports 1991;I:1487.

Case C227-82 30 November 1983 re van Bennekom, European Court Reports 1983;3883.)

medicate, or even the intent to give an impression that a substance has medicinal properties, is the key factor in defining a substance as ‘medicinal’:

‘if a product is represented to the public so that any averagely well-informed person gains the impression that the substance might have a beneficial effect on some medical condition, then that substance is a medicine under the terms of this Directive’.

In both the UK and Ireland, fluoridated water is a medicine by both presentation and function as defined by the EC Directive and the ECJ rulings. The fluoridation policies of these Governments are unquestionably aimed at carrying out a medical intervention, and are promoted vigorously as such. This is intent to medicate by presentation.

The concentration of fluoride in fluoridated water is that which is claimed to produce the required remedial or prophylactic effect on tooth decay. Arguments that it is too dilute to be a medicine are clearly irrelevant, since the product is distributed to the public at a concentration that is asserted to be the optimum for achieving the claimed beneficial effect. For example, vaccines may contain no more than microgramme amounts of active ingredient, but they are still medicines in law, and require medicinal licenses. In this context, it is worth reflecting of the fact that, despite having no active ingredients and with no therapeutic properties, even sterile water for injection still requires - and has - a marketing authorization, because it is used with the intent to perform a medicinal intervention. Fluoridated water is therefore also medicinal by function.

5.3 Manufacture of medicinal products

Water, whether fluoridated or not, is a product. Directive 2004/27/EC requires that all medicinal products must be manufactured under pharmacological conditions. This applies to all stages of manufacture, and includes the import of an active ingredient.

‘Article 2. This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

‘Article 46a 1. manufacture of active substances used as starting materials shall include both total and partial manufacture or import of an active substance used as a starting material . . . and the various processes of dividing up, packaging or presentation prior to its incorporation into a medicinal product, including repackaging or re-labeling, such as are carried out by a distributor of starting materials.

In the UK the industrial manufacture of fluorosilicates for use under the provisions of the Water Industry Act 1991 is controlled under British Standards (BS) EN 12174 and 12175 for sodium hexafluorosilicate and hexafluorosilicic acid respectively (although in practice almost all fluorosilicic acid is imported). This is accepted by the Drinking Water Inspectorate as meeting the requirements for chemicals used in water treatment processes.

However, compliance with these Standards does not constitute authorization of their use as medicinal substances. As Lord Jauncy pointed out, “the water instead of being the object of treatment becomes the means whereby fluoride is carried into the consumer's body”⁹. Water fluoridation is not a ‘water treatment process’, as has been claimed, but one designed to ‘treat’ the consumer, by medication.

⁹ Jauncy op.cit page 4

All batches of medicinal chemicals, and of the finished product, must be subjected to batch testing under pharmacological industry conditions. All materials used must have been produced using pharmacological grade starting ingredients, and the final product as formulated at water treatment works should be manufactured under the supervision of Qualified Persons within the pharmacological industry. At present, the manufacture of fluoridated water fails to comply with all of these requirements.

5.4 Registration of medicinal products.

Although fluoridated water is quite clearly a medicinal product, it is not recognised as such in the UK or Ireland, or indeed in many other countries where fluoridation is still practiced. In the UK, the decision as to whether or not a marketing authorization should be issued is made by the Medicines and Healthcare products Regulatory Agency (MHRA – formerly the Medicines Control Agency, MCA), and in Ireland by the Irish Medicines Board (IMB). The MHRA

“reaches a determination on whether a product is or is not a medicinal product on a case by case basis, and in the light of:

- *the definitions set out in paragraph 8 above;*¹⁰
- *relevant ECJ and domestic Court precedents; and*
- *following an assessment of all the available evidence.*

So whilst the MHRA accepts the definition set out in Article 1 of Directive 2001/83 (*and now 2004/27/EC*), it then qualifies this;

“Although the above definition must be applied throughout the EC, it is for individual Member States to do so in respect of products within their borders. This is the basis on which the MHRA, on behalf of the UK Licensing Authority, determines (subject to review by the courts) whether a product is a medicinal product. The Agency’s power to do so has been confirmed by a judgment of the Court of Appeal (R. v. Medicines Control Agency ex parte Pharma Nord (UK) Limited 1998). The Master of the Rolls, Lord Woolf, and his colleagues did not accept the argument that only a court could decide what is or is not a medicinal product. The judgment included the following;

“The approach of the European Court is equally consistent with the initial decision being made by the licensing authority and that decision being reviewed by whatever are the appropriate courts within a particular member state.”¹¹ ”

This is clearly perverse. The arguments of those challenging the MHRA’s decision not to license fluoridated water as a medicine are not that it does not have the authority to decide if a product is medicinal. The ECJ decisions make it quite clear that it is a medicinal product. The MHRA’s decision to refuse to designate the product as medicinal is clearly incompatible with the definition of such products within the Directive and the decisions issued by the ECJ.

Both the UK and Irish authorities have repeatedly stated that in their opinion neither the fluorosilicates added to drinking water nor the resulting fluoridated water are medicinal products as covered by the Directive, and that therefore they do not require a marketing authorizations. A medicinal product may have no authorization for two reasons. There may never have been an application for it to be registered; it may be extremely rarely or never prescribed or administered, or the company producing it may have avoided requesting such a decision from the authorities. Alternatively, the regulatory authority may have decided unilaterally that the product is not a

¹⁰ This appears to be a misprint, and should read ‘paragraph 11 above’, in which the definitions set out in the Directive are reproduced

¹¹ MHRA (2003) ‘A guide to what is a medicinal product.’ MHRA Guidance Note No. 8 (previously MAL 8) April 2003

medicinal product, and declined to register it as such. However, since the definition of what constitutes a medicinal product is founded in law, the refusal of the MHRA and IMB to issue a licence merely establishes that fluoridated water is, in law, an unlicensed medicinal product.

In both the UK and Ireland fluoridated water is administered widely – indeed, it is undoubtedly the largest medicinal product by volume on the market. Both the MHRA and the IMB have repeatedly been challenged to designate it as a medicinal product, but have refused to do so.

5.5 Prohibition on advertising unlicensed medicines.

This is clearly perverse, and it places both agencies firmly in a ‘Catch 22’ situation. The advertising of medicines – including unlicensed products – was covered originally by Directive 92/28/EEC on the advertising of medicinal products for human use. This is now incorporated into 2004/27/EC.

‘Article 87: Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law.’

Despite the clear guidance indicating that an authorization should be automatically required for fluoridated water, and in spite of challenges from the public, this product has been used without authorization for many years. Its use is therefore incompatible with the European medicines legislation.

If a marketing authorization were to be issued, then the safety and efficacy of the starting substances and of the product as marketed to the public would first need to be firmly established. So far, no assessment of these has been carried out under the strict protocols required for clinical trials, and upon which applications for authorization must be founded. In the current state of scientific uncertainty it is unlikely that authorization would be given, particularly in view of the recent disclosure of strong evidence of the carcinogenic nature of fluoridated water at the concentrations employed in the public water supplies.¹²

On the other hand, without such authorization it is unlawful to manufacture, supply or even promote it as having any medicinal properties. In the UK, the Medicines (Advertising) Regulations 1994 states:

‘Article 3.—(1) Subject to paragraph (2), no person shall issue an advertisement relating to a relevant medicinal product in respect of which no product license is in force.’¹³

The ECJ decision clearly indicates that ‘presentation’ includes the promotion and advertising of any substance or product to the public as having medicinal properties, and this is also made clear in MHRA Guidance Note No.8. ‘Presentation’ covers any statement that is designed to give this impression to the public, and a list of phrases that are of this nature is provided in Appendix 1. ‘Presentation’ can be in printed (including pictorial), verbal or electronic format, and includes any such claims shown on a web site, or issued at a conference or other public meeting.

In its current ‘Blue Guide’¹⁴ the MHRA warns manufacturers that it is prohibited to issue advertisements which relate to unlicensed medicines. Yet Health Sector and professional medical and dental associations repeatedly advertise and promote the alleged benefits and ‘complete safety’ of the product. Its alleged efficacy and safety are recommended by individuals whom the

¹² Bassin EB. (2001). Association Between Fluoride in Drinking Water During Growth and Development and the Incidence of Osteosarcoma for Children and Adolescents. Doctoral Thesis, Harvard School of Dental Medicine.

¹³ The reference to ‘paragraph 2’ refers to homeopathic remedies

¹⁴ MHRA (2005) Blue Guide: Advertising and promotion of medicines in the UK’. MHRA London

public is encouraged to regard as having specialized professional knowledge, and upon whom it can rely. The prohibition on the use and advertisement of unlicensed medicinal products applies to all such sources of information, and has important implications for those promoting fluoridation as a prophylactic or cure for dental caries, especially when that promotion is aimed at children.

A key factor is public perception and trust. Much of the pro-fluoridation promotion is clearly designed to give the public the impression that the product has substantial and well proven beneficial effects on dental caries. Despite severe criticism of the validity of much of the scientific research in the field,¹⁵ public understanding of the issues raised by water fluoridation has been subverted by repeated misinformation and inflated claims about the efficacy and 'complete safety' of water fluoridation. Effective and balanced public debate is now impossible, and attempts to seduce the public into acceptance of the practice of water fluoridation through 'public consultation' are hopelessly compromised. The British Fluoridation Society (BFS) is an influential source of pro-fluoridation propaganda, and until last year was backed financially by the British Government, and by the Welsh and Northern Ireland Assemblies and, paradoxically, even by the Scottish Assembly, despite the Jauncey statement. Up to last year the BFS received over £100,000 per year in funding from these sources.

Since the product has no authorizations, the BFS publications promoting the product appear to be in violation of the intent of the European and UK legislative frameworks. They are circulated only by the highly questionable authority of the MHRA's controversial refusal to designate the product as medicinal and the Government's explicit policy of the widespread imposition of community fluoridation. If the MHRA's decision were to be challenged successfully in the Courts, then all such propaganda would automatically be shown to be incompatible with the legislation. In strictly legal terms, however, any promotion of fluoridated water is already illegal, and constitutes a statutory criminal offense.

5.6 Poisons used for medicinal purposes

The sale of poisons is regulated in the UK under the Poisons Act 1972. Some poisons have recognised medicinal uses, and are required to have a relevant medicinal authorization for that specific use. Sodium and potassium fluorides are Part II poisons ('alkali metal fluorides') under the Poisons List Order 1982, but have medicinal authorization for use in dental preparations and cosmetic products. Sodium fluoride is also regarded as a pesticide under the 1982 Order, but fluorosilicates are not recognised as pesticides under the Water Supply (Water Quality) Regulations 2000, since the definition in Section 2 (Interpretation) of those Regulations refers only to organic pesticides.

If no medicinal marketing authorization for a specific use is issued for a poison, then it remains a poison in law, and subject to the conditions of sale specified in the Poisons Act. Administering a registered poison indiscriminately to the public without compliance with the restrictions set out in this Act is an offence. Sodium fluorosilicate (listed in Part II of the Order as 'sodium silicofluoride') is such a poison. It has no exemption for its medicinal use in the manufacture of fluoridated water, and in this respect at least its use contravenes the Poisons Act. In the EC legislation its status is solely that of a permissible (limited) contaminant of cosmetics under the cosmetics legislation. It has no medicinal authorization.

Fluorosilicic acid – the main chemical used for fluoridation in the UK - is at least as toxic as its sodium salt, and is a highly corrosive poison, yet paradoxically it is not included in the list of

¹⁵ McDonagh M, Whiting P, Bradley M et al. A systematic review of public water fluoridation. 2000; York, Report number 18 University of York.

restricted substances in the Poisons List, even though it is included in other Poisons legislations, such as those of Australia and Singapore. However, the material supplied to water companies for fluoridation purposes contains a significant proportion of hydrogen fluoride (HF) which is specifically included in the schedule of the Poisons List Order. Its use for medicating the public water supply therefore contravenes the Poisons Act, since this prohibits not only the supply of the listed poisons, but also of substances containing them.

The regulations governing the packaging and labeling of poisons at point of sale are set out in the Poisons Act and the Poisons List Order. Poisons may only be sold in registered premises by qualified and registered individuals. The administration to the public of any 'noxious or poisonous substances' (there is no special list of these), whether in a food or in the water supply, is an offence under section 23 of the Offences Against the Person Act 1861.

The State-mandated addition of a poisonous substance to the public water supply raises an important ethical and legal issue. Its purpose is to bring about a physiological change in the bodies of consumers, without securing either authorization or consent. It appears not to differ in principle from an action to achieve an equivalent effect that is currently proscribed under anti-terrorism legislation in place in the UK and elsewhere. It also raises important issues relating to human rights¹⁶, particularly with respect to the prohibition on physical ill-treatment such as State-imposed medication. Should the principle be established that the State may medicate the public regardless of consent - and especially using unlicensed substances - then it would set a precedent whose future consequences and limitations are entirely unpredictable, and profoundly disturbing.

¹⁶ Cross DW and Carton RJ. Fluoridation - a violation of medical ethics and human rights. 2003; *International Journal of Occupational and Environmental Health* 2003;9:24-29 Republished in *Japanese Journal of Fluoride Research* (Nov 2003) 22: 52-60.

6. Food law

The nature of fluoridated water as a medicinal product is clearly established by the relevant definitions included in, and rulings arising from, the medicines directive and the ECJ decisions. However, fluoridation proponents also claim that fluoridated water is a food and is regulated under the foods legislation. Whilst this is inconsistent with the EC's decision on the criteria applicable for medicinal products, it is instructive to examine precisely what the legal position of the product would be were it to be regarded as a food under the current systems of legislation on foods and food products. Until the MHRA revises its decision that fluoridated water is not a medicinal product, the alternative arguments can be examined to identify the legal implications for manufacturers and health authorities in claiming that it is a food product.

6.1 Definition of a food

Food is defined in EC Regulation No 178/2002 on the general principles and requirements of food law.

'Article 2. 'food' (or 'foodstuff') means any substance or product . . . intended to be, or reasonably expected to be, ingested by humans. 'Food' includes drink . . . It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC . . . '

Food shall not include

(d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;

(e) cosmetics within the meaning of Council Directive 76/768/EEC'

Directive 2000/13/EC on the labeling, presentation and advertising of foods prohibits attributing any preventing, treating or curing properties to foods. This has been interpreted by the ECJ as banning all health claims relating to human diseases¹⁷

6.2 Fluoridated water and the food legislation.

An important source of confusion in the fluoridation debate is whether or not fluoridated drinking water is regulated under food or water law. The simple answer is that it is covered by neither. Water is a food under the terms of the Food Regulations (178/2002). Any water, even that which naturally contains fluoride derived from the geology of the areas from which it is collected, is a food ***provided that it does not have any substance added to it with medicinal intent***. In such a 'natural' state, its chemical quality is indeed regulated under the Drinking Water Regulations (Directive 98/83/EC).

But Article 3 of 98/83/EC states:

'Exemptions: This Directive shall not apply to . . . waters which are medicinal products within the meaning of Council Directive 65/65/EEC . . . relating to medicinal products.'
(This would, of course, now be governed under 2004/27/EC)

However, if fluoride, in any form whatever, is added with the intent to medicate dental caries in consumers, then such water immediately and irrevocably becomes a medicine, under the provisions of 2004/27/EC, and its regulation falls outside the scope of the water quality regulations. This would apply even if 'natural' calcium fluoride were used as the added source of fluoride, instead of fluorosilicates or any other form or source of fluoride. Once again, intent to medicate is the deciding factor.

¹⁷ Case C221-00, Austria v Commission.

6.3 Food supplements – vitamins, minerals and 'certain other substances'

It has been argued that adding fluoride to water is permissible since its purpose is to supplement what is described as a 'dietary deficiency' in fluoride. Since there is no such condition, this claim has no scientific validity. However, it is instructive to examine the food supplements Directive because this exposes yet another instance where the arguments of those promoting water fluoridation are erroneous.

The addition of specific vitamins and mineral substances to foods is permitted under the Food Supplements Directive (2002/46/EC). The use of the term supplements needs to be clarified. This Directive refers to supplementary sources of specified nutrient substances that are normally present in foods, and that are derived from a manufacturing process using chemical substances. The product must be presented in dose form – i.e., tablets, capsules, drops, etc. and labelled in accordance with the Directive.

For argument's sake, the implication of referring to fluoride and fluoridated water as a supplementary source of the mineral fluoride can be examined under this heading, despite the lack of conformation of the product with the supplements Directive specifications relating to dose and packaging.

*'Preamble, (9) 'Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore, it is appropriate to establish a **positive list** of those vitamins and minerals.'*

However, it was argued by some Member States that additional source materials for supplements were in use at the time that the Directive was formulated. This was acknowledged in the Directive, and provision was made for these to be submitted for authorization for their continued use in food supplements.

Article 4. 6. By way of derogation from paragraph 1 and until 31 December 2009, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that: (a) the substance in question is used in one or more food supplements marketed in the Community on the date of entry into force of this Directive,

(b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 12 July 2005.

Therefore manufacturers (Water Companies) had until 12 July 2005 to submit dossiers to obtain approval for the numerous substances (approximately 300) that are sources of vitamins and/or minerals already on the market in various Member States but which are missing from the Annexes of the directive. At the time of writing, it appears that no such applications and dossiers for authorizing the use of fluorosilicates as a supplementary source of the mineral fluoride in drinking water have been submitted to the EC. The deadline for marketing fluoridated water as a food supplement has therefore expired.

Article 1.1 states that all food supplements must be delivered to the consumer in pre-packed form, unless they are registered as medicinal products under 2001/83/EC. Also,

'Article 6 , no food supplement - including any mineral - may be presented to the public as having medicinal properties.'

In this Directive, fluoride is classified as a mineral, although no naturally occurring mineral 'fluoride' exists in isolation – it is always combined with some other element or compound. The '*positive list*' in Annex II of 2002/46/EC identifies specific compounds (and only those compounds) that are permissible sources of dietary 'minerals'. For fluoride, these are the fluorides of sodium and potassium; fluorosilicates are not permissible sources.

Therefore, water containing fluorosilicates is not an authorized source of fluoride, nor is it presented in the pre-packaged form specified for mineral supplements under this Directive. The fluorosilicates used in water fluoridation in the UK and Ireland have not been authorized by the EC under the 'grace period' provision, and their continued use in these countries is therefore illegal. In addition, fluoridated water is promoted with a specific medical claim relating to its efficacy in preventing dental caries. It is therefore a medicinal product, and cannot therefore be held to be a source of 'supplementary' fluoride; advertising it as such contravenes this Directive.

6.4 Specially medicated foods, or foods for particular nutritional purposes

'Dietary foods' is a category of foods for particular nutritional uses. Some are 'medical foods', and defined and specified by the Dietary Foods for Special Medical Purposes Directive (1999/21/EC), They are

'specially processed or formulated, and are intended for the dietary management of patients. They must be used under medical supervision.'

Others are defined and specified by Directive 2001/15/EC (substances that may be added for specific nutritional purposes in foods for particular nutritional uses). All such foods must be pre-packaged;

'The labeling and the labeling methods used, the presentation and the advertising of the products referred to in Article 1 shall not attribute properties for the prevention, treatment or cure of human disease to such products or imply such properties. . . the packaging shall completely cover the products'.

As in the food supplements Directive, fluorosilicates are not permissible sources of fluoride in either of these Directives; only sodium and potassium fluorides are so authorized. Contrary to the labeling requirements, fluoridated water is marketed with specific medicinal claims, but it is not sold in any form of packaging, nor is it used under medical supervision. Its supply is therefore incompatible with both of the above Directives.

It is commonly argued that the addition of fluoride to water is comparable to, for example, the addition of the registered vitamin folic acid to bread under 1999/21/EC, to prevent spina bifida. Such arguments are ill-founded. Firstly, deficiency of folic acid is a known cause of this condition. Bread supplemented with it is marketed in packaged form, and its presence is clearly indicated on the outside of the packaging. There is no equivalent human disease caused by a 'deficiency' of fluoride in the diet, nor is fluoridated water supplied in the mandatory packaged form bearing the required information required under this Directive. Secondly, fluorosilicates are not identical – either chemically or legally – to those fluorides that are authorized sources of fluoride under these regulations. The comparison is therefore both scientifically and legally false.

In fact, the inclusion of fluoride as a mineral under the umbrella of this Directive is anomalous. The European Food Standards Agency (EFSA) opinion on permissible upper intake levels of fluoride in the diet¹⁸ states the case categorically in its opening statement – 'Fluoride is not essential for human growth and development'. Therefore the human body cannot be in a state of 'fluoride deficiency' and the use of the term 'supplement' has no scientific validity when applied

¹⁸ EFSA 2005, op. cit. – see footnote page 1

to fluoride. It is improper to refer to fluoride as a nutrient or classify it, by association, as a mineral within this Directive. The inclusion of fluoride within the list of 'minerals' in the food supplements Directive is therefore anomalous and inappropriate.

Unlike true vitamins and minerals that play an essential role in maintaining the human body in good health, the role of fluoride in the diet is solely that of a contaminant and cumulative poison, to which medicinal claims have been attached by the proponents of water fluoridation. Like other toxic substances (for example, arsenic, cadmium or lead), in very limited quantities as a natural contaminant of foods, it is undesirable but can be tolerated. But the extent of the development of dental fluorosis -indicative of at least incipient systemic fluoride poisoning - in fluoridated areas indicates that the safety margin between tolerable and unacceptable dietary intakes of fluoride is extremely narrow. Any amount of 'supplementation' of its presence in the diet is liable to result in an incipient toxic overload.

6.5 Food additives.

Since fluorosilicates added to water are not marketed in the mandatory pre-packaged form, it could be argued that they are instead food additives. Directive 95/2/EC on food additives other than colours and sweeteners has been repeatedly amended to permit minor changes in the definitive lists of such substances, and has recently been updated as 2006/52/EC on the addition of vitamins and minerals and of certain other substances to foods. Permissible additives are listed in Annex I and accorded specific E-numbers identifying them positively. Article 3.1 states

Member States shall bring into force by 15 February 2008 the laws, regulations and administrative provisions necessary to comply with this Directive in order to:

(a) permit trade in and the use of products complying with this Directive by 15 February 2008;

(b) prohibit trade in and use of products which do not comply with this Directive by 15 August 2008.

However, products placed on the market or labeled before 15 August 2008 which do not comply with this Directive may be marketed until stocks are exhausted.

In the preamble to the proposed new legislation (COM(2006) 428 final) the Commission further requires that

13. A food additive already approved under this Regulation which is prepared by production methods or starting materials significantly different from those included in the risk assessment of the Authority, or different than those covered by the specifications laid down, should be submitted for evaluation by the Authority for an evaluation with emphasis on the specifications.

(16) Food additives remain subject to the general labelling obligations as provided for in Directive 2000/13/EC and, as the case may be, in Regulations (EC) Nos 1829/2003 and 1830/2003. In addition, specific provisions on labelling of food additives sold as such to the manufacturer or to the final consumer should be contained in this Regulation.

The fluorosilicates used in water fluoridation comply with none of these requirements, and they are not included in Annex I (or indeed, any other Annex) of 95/2/EC or in 2006/52/EC. If fluoridated water retains its quasi-legal identity as a food, in the absence of a medicinal designation, then the addition of any form of fluorosilicate to it is not permissible. Since fluoridated water is incontrovertibly a product, but bears no label (or indeed, is not contained in any mandatory form of packaging) trade in and use of fluoridated water in the EC must cease by, at the latest, 15th August 2008.

7. Cosmetics law.

Dismissing dental fluorosis as a mere ‘cosmetic’ effect of fluoridation is a deliberate misdirection often used to argue that this widespread effect is not a serious issue. Dental fluorosis is not a ‘cosmetic effect’ - it is a disfigurement that results in high remedial costs and personal embarrassment to many people. The appropriate cosmetic intervention would be veneering the teeth to conceal the defect. It may also indicate an excessive body burden of fluoride and potential serious health consequences in later life.

Under the EC Cosmetics Directive 76/768/EEC, no cosmetic substance may be ingested. This is quite distinct from putting a cosmetic preparation into the mouth for dental or oral hygiene purposes. Providing it is not swallowed, an oral hygiene product remains a cosmetic substance, although it may also require medicinal authorization if it is marketed as having some medicinal property. The Preamble to the Cosmetics Directive (76/768/EEC) states that it

‘relates only to cosmetic products and not to pharmaceutical specialities and medicinal products . . . (it) is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease . . . Products containing substances or preparations intended to be ingested . . . do not come under the field of cosmetics’

The original Cosmetics Directive (76/768/EEC) has been updated repeatedly, and has recently been transposed into English Law as The Cosmetic Products (Safety) Regulations 2003. In the cosmetics Directive, hydrofluoric acid and its derivatives (‘No. 191 - Hydrofluoric acid, its normal salts, its complexes and hydrofluorides’) are included in Annex II in a list of banned substances. Fluorosilicic acid is a ‘complex derivative of hydrofluoric acid’, and as such is proscribed under the Cosmetics Directive. An exception is granted in Annex III, Part 1 for sodium, potassium, ammonium and magnesium fluorosilicates (substance nos. 40-43), which may be added in strictly controlled amounts in oral hygiene products. Identical provisions are included in the UK Act. Therefore, it is clear that, as understood in the terms expressed in the text of the Directive, fluorosilicic acid is a banned substance in terms of the cosmetics legislation. Any claim that fluoridated water containing fluorosilicic acid might have ‘cosmetic’ properties is therefore in breach of the legislation.

8. Indemnity against claims by the public

Section 58 of the Water Act 2003 amends the Water Industry Act 1991 in respect of the provision of indemnity against claims from the public:

90 Indemnities in respect of fluoridation.

(1) The Secretary of State may, with the consent of the Treasury, agree to indemnify any water undertaker in respect of liabilities which it may incur in complying with arrangements entered into by it pursuant to section 87(1) above.

In effect, pressure from water undertakers was exerted to ensure that the costs of any litigation for medical damages arising from the public as a result of an order from a Strategic Health Authority to fluoridate their water supplies would not attract financial penalties against the water undertakers themselves. Even more remarkably, s. 58 of the Water Act amended the Water Industry Act to stipulate that:

91 Pre-1985 fluoridation schemes

(1) With effect from the appointed day, relevant pre-1985 arrangements shall be treated for the purposes of this Chapter as if they were arrangements entered into by the water undertaker in question with the relevant authority under section 87(1) above.

The Government has therefore agreed (in principle, at least) to consider providing indemnity to water undertakers for any claims for damages that might arise from pre-existing fluoridation schemes. In England these currently serve approximately 6 million people. With the incidence of dental fluorosis 'of cosmetic concern' running at around 12% in many fluoridated populations, this suggests that up to one million people might already be able to press claims against water undertakers in the Midlands, North East and in two small areas in the North West. At an estimated annual cost for minimal cosmetic dentistry per head of £250, this implies a continuing liability for at least £250 million per year.

In real terms, the wording of these amendments does not actually guarantee that any such immunity will be provided, since the decision rests with the Secretary of State and the Treasury. The grant of such indemnity is optional, not compulsory. But since the practice of fluoridation violates both EC and national legislation, in fact no such indemnity can be provided; no indemnity is available for a criminal act against the public.

9. Consultation on fluoridation – negation of the democratic process.

The British Government has made provision for initiating a 3 month 'Consultation Period' before new fluoridation schemes are introduced. The Water Fluoridation (Consultation) (England) Regulations 2005 state:

Outcome of consultation

5. A Strategic Health Authority shall not proceed with any step regarding fluoridation arrangements that falls within section 89(2) of the Act unless, having regard to the extent of support for the proposal and the cogency of the arguments advanced, the Authority are satisfied that the health arguments in favour of proceeding with the proposal outweigh all arguments against proceeding.

However, no consultation process – whether with the public or with the health sector, as specified in the Water Act – is permissible that enables a State to consult on whether it may order private companies to commit an act of criminal assault upon their own customers. In the Isle of Man and in Ireland, where water supplies are provided by branches of central Government, the question of whether it is permissible for the State to allow one of its sectors to commit such an act of assault against the public raises a fundamental issue of democracy that needs to be challenged by the judiciary.

The issue of indemnity is of concern to individuals and organisations attempting to impose fluoridation on public water supplies. Since the manufacture and distribution of fluoridated water is an offence, regardless of whether it is claimed to be a medicinal product (unlicensed, and in breach of the packaging regulations) or a food containing an unauthorised additive, the manufacturers may be considered to be in breach of the various national Statutory Instruments through which penalties may be imposed. But they do so only because they are forced to comply with orders to commit such offences, issued by SHAs under the provisions of the Water Act 2003.

The question is therefore, is it acceptable for the State to order a private company, or individuals working for such companies, to commit a criminal offence? Clearly, such action cannot be endorsed, and water undertakers are at liberty to challenge fluoridation orders in the Courts. Indeed, it would be foolish not to do so. In the case of those undertakers who were fluoridating their product on a voluntary basis before 1985, and continue to do so, the issue is whether or not they should now cease the practice, and risk an order by the SHA to maintain the supply of fluoridated water to the public, despite its violation of the relevant medicinal and foods legislation. Again, the only available action is to desist and seek judiciary support for their action.

In fact, a precedent has already been set in this contentious issue. In 1998 Northumbrian Water declined a Health Authority's request to extend fluoridation¹⁹. The Health Authority argued that the relevant parliamentary acts governing water fluoridation were intended to encourage it, not merely enable it to be implemented if requested to by the Health Authority. The defendants argued that the water company had absolute discretion on whether or not to proceed with new water fluoridation schemes, that that this discretion was wide and unfettered, and that water companies had an overriding responsibility to their shareholders. Under the current law, no other consideration – not even public health - took precedence, and the water company had a right to turn down a reasonable request without giving a reason. Mr Justice Collins concluded that as a private company (which did not possess power solely for the public good), Northumbrian Water had unfettered discretion for the purposes of the (fluoridation) statute, and the action failed.

¹⁹ **R v Northumbrian Water** ex p. Newcastle and North Tyneside Health Authority. Queen's Bench Division. (Crown Office List), **Collins J.** (15 December 1998)

10. Conclusions

1. **Definition of a medicinal substance or product.** The definition of what constitutes a medicinal product is contained in the current EC Medicines Directives. It is supported by European Court of Justice decisions. Any substance is a medicine if it is supplied with the intent to treat or prevent a medical condition. The ECJ has ruled that efficacy is not a relevant issue. The Jauncey decision established that fluoridation is public medication in the UK.
2. Under these rules, fluoridated water is a medicinal product both by presentation and by function, regardless of whether or not it has any dental benefits.
3. The refusal of the MHRA to identify this product as medicinal is incompatible with the EC definition, and should be subject to challenge as a public interest issue.
4. **Marketing of medicinal products.** Nomination of the two fluorosilicates used to fluoridate water in the UK under the provisions of the Water Act 2003 does not constitute license to employ either for a medicinal purpose as defined by the EC legislation, even if they are manufactured in compliance with a relevant British Standard..
5. Fluoridated water, although supplied with the intent to prevent or treat a recognised medical condition (dental caries), has no marketing authorization in the EC as a whole, or in the UK and Ireland specifically. Its sale within the EC is therefore illegal.
6. Fluoridated water is supplied with the intent to medicate the public. Therefore, even if it had a medicinal authorization,
 - It would have to be supplied to the public in properly packaged and labeled containers that carry the mandatory information specified for medicinal products.
 - It would be subject to manufacture under conditions required for pharmaceutical products, and under the supervision of Qualified Persons.
 - Individual packages from each batch would need to be traceable back to the original production batch, to facilitate recovery of that consignment in the event of a defectAs presently supplied to the public, it meets none of these requirements, and its sale is therefore in breach of the medicines Directive.
7. **Advertising unlicensed medicines.** Advertising or promoting any medicinal substance or product that does not have a marketing authorization is prohibited. Promoting unauthorized fluoridated water to the public as a product that has beneficial effects upon dental caries is incompatible with EC and domestic legislation.
8. Organizations and individuals whom the public may reasonably expect to be professionally qualified to provide reliable and balanced medical or dental advice, and who promote or advertise an unlicensed product such as fluoridated water as having medicinal effects, commit a criminal offence under the Medicines (Advertising) Regulations. They may also be in breach of relevant professional Medical Codes of Conduct.
9. **Administration of poisons in domestic legislation.** Sodium fluorosilicate is a registered poison, and has no exemption for medicinal use. As a scheduled poison, its use is subject to the regulations imposed under the Poisons Act. The sale of water fluoridated with this substance is not compliant with such provisions, and its use is therefore unlawful, regardless of its nomination for this purpose under the UK's Water Act.
10. Fluorosilicic acid is a complex derivative of hydrofluoric acid. Its administration to the public in virtually unavoidable fluoridated water without a relevant medicinal authorization is a tort, and is in violation of the Offences Against the Person Act.

Relevance of the legislation on foods.

11. Any ingestible substance is either a food or a medicine. Under the food regulations,
 - Water is a food; ‘foods’ include drinks and, quite specifically, water. No food may be sold with a claim for any medicinal property.
 - Any food, including water, must be formulated in accordance with the foods, food supplements, or special dietary and medical foods Directives.
 - Water that has any substance added to it with medicinal intent is not regulated under the water quality Directive, but is a medicine, and controlled under the medicines Directive
 - Foods sold for specific dietary or medical purposes must be packaged and labeled in compliance with the relevant foods Directives.
 - Fluorosilicates are not authorized as nutrients, nor are they permissible sources of the 'mineral' fluoride as specified in the relevant food Directives
 - No fluorides or fluorosilicates may be used as food additives – this applies to drinking water.
12. Fluorosilicates may not be used in the preparation of foods (including water), food supplements, or foods for special dietary or medical purposes. Cosmetic products may contain limited amounts of specified fluorosilicates, but they may not be ingested.

11. Reference Sources

EC Regulation No.

- 2309/93 on human and veterinary medicines (OJ L 214, 21.8.1993, p. 1.)
258/97 on other substances added for specific nutritional purposes
(OJ L 43, 14.2.1997, p. 1.)
178/2002 on the general principles and requirements of food law.
(OJ No. L31, 1.2.2002, p.1.)
1642/2003 amending 178/2002 (OJ No. L245, 29.9.2003, p.4).
726/2004 on human and veterinary medicines (OJ L 136, 30.4.2004, p. 1.)

EC Directives

- 65/65/EEC on medicinal products (OJ No 22 of 9. 2. 1965, p. 369/65.)
75/319/EEC. Guide to Good Manufacturing Practices for Medicinal Products'
(OJ No L 147 of 9. 6. 1975, p. 13)
75/440/EEC on standards for surface water for the abstraction of drinking water
(OJ L 194, 25.7.1975, p.34)
76/768/EEC on cosmetic products (OJ L 262, 27.9.1976, p. 169)
79/112/EEC on the labeling, presentation and advertising of foodstuffs
(OJ L 33, 8.2.1979, p. 1.)
80/778/EEC on quality of water intended for human consumption (OJ L 229, 30.8.1980, p. 11)
89/107/EEC on food additives authorised for use in foodstuffs for human consumption
(OJ L 40, 11.2.1989, p. 27.)
89/398/EEC on foodstuffs for particular nutritional uses (OJ L 186, 30.6.1989, p. 27.)
92/28/EEC on advertising of medicinal products (OJ L 113, 30.4.1992)
92/73/EEC on homeopathic medicinal products (OJ L 297, 13.10.1992)
95/2/EC on food additives other than colours and sweeteners, as amended
(OJ L61, 18.3.1995 p1-40)
98/83/EC on the quality of water intended for human consumption
(OJ L 330, 05/12/1998 p. 0032 – 005)
1999/21/EC on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29)
2000/13/EC on labeling, presentation and advertising of foods (OJ L 109, 6.5.2000, p. 29.)
2001/15/EC on substances that may be added for specific nutritional purposes in foods for
particular nutritional uses (OJ L 052, 22.2.2001, p. 0019-0025.)
2001/20/EC good clinical practice in clinical trials on medicinal products for human use
(OJ L 121, 1.5.2001, p. 34).
2001/82/EC on veterinary medicines (OJ L 311, 28.11.2001, p. 1)
2001/83/EC Codified Directive on human medicines (OJ L 311, 28.11.2001, p. 67.)
2002/46/EC on Food Supplements (OJ L 183. 12.7.2002, p. 51.)
2003/15/EC amending Council Directive 76/768/EEC on cosmetic products
(OJ L 66, 11.3.2003 p 26)
2004/27/EC on human medicines (OJ L 136, 30.4.2004 p.34)
2004/28/EC on veterinary medicines (OJ L 136, 30.4.2004, p. 58).
2006/52/EC amending Directive 95/2/EC on food additives other than colours and sweeteners
and Directive 94/35/EC on sweeteners for use in foodstuffs
(OJ L204, 26.7.2006 p1-13)

UK Legislation

Offences Against the Person Act 1861
Poisons Act 1972 ISBN 0105466727.
Poisons List Order 1982 SI 218, ISBN 0110262182
Water Industry Act 1991 (SI 1991 No. 1837
Medicines (Advertising) Regulations 1994 (SI 1994 No. 1932)
Water Supply (Water Quality) Regulations 2000 (SI 2000 No. 3184)
Control of Substances Hazardous to Health (COSHH) 2002
Water Act 2003 (2003 Chapter 37) ISBN 0 10 543703 4.
The Cosmetic Products (Safety) Regulations 2003 (SI 2003 No. 835,)
The Contaminants in Food (England) Regulations 2004 (SI 2004 No. 3062)
The Water Fluoridation (Consultation) (England) Regulations 2005 (SI 2005 No. 921)

British Standards

BS EN 12174 Chemicals used for treatment of water intended for human consumption.
Sodium hexafluorosilicate.
BS EN 12175 Chemicals used for treatment of water intended for human consumption.
Hexafluorosilicic acid

ECJ Rulings

C112, 89 Judgment of 16/04/1991, Upjohn / Farzoo (Rec.1991,p.I-1703)
Case C-60/89, Judgment of 21/03/1991, Criminal proceedings against Monteil and Samanni
(Rec.1991,p.I-1547)
Case C219-91 Judgment of 28/10/1992, Criminal proceedings against Ter Voort
(Rec.1992,p.I-5485)
Case C369-88 Judgment of 21/03/1991, Criminal proceedings against Delattre
(Rec.1991,p.I-1487)
Case C227-82 Judgment of 30/11/1983, Van Bennekom (Rec.1983,p.3883)(ES1983/01027)
Case C221-00 Judgment of 23/01/2003 , Commission / Autriche (Rec.2003,p.I-1007)

Guidelines

Blue Guide: Advertising and promotion of medicines in the UK.
MHRA November 2005

Impending Directives

COM(2006) 428 final on food additives, 27.07.2006