The implications of the European Court of Justice decision on the regulation of 'functional drinks' with regard to the practice of water fluoridation. [1]

Douglas Cross [2]
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Abstract

In a landmark decision of the European Court (ECJ) in the case of Warenvertriebs and Orthica, on the regulation of foods that appear to be on the borderline between foods and medicines, the Court ruled

- Where a product appears to be both a food and a medicinal product, the medicinal legislation must take precedence, and the product is subject to regulation as a medicine
- National Regulators can not decline to recognise such products as medicines, and must subject them to pharmaceutical scrutiny with a view to issuing a marketing authorization
- Such 'functional drinks' must not be used to prepare foodstuffs, nor may food containing them be exported to other European Community (EC) member states.

The ruling must be applied to fluoridated water. It establishes that

- Fluoridated water, as a 'near-water drink containing added minerals', is a functional food with recognisable pharmaceutical properties. As such, it must be regulated as a medicinal product.
- In the absence of a relevant medicinal marketing authorization for its supply to the public, fluoridation of public water supplies in the UK and Ireland must stop immediately
- All plans to further expand fluoridation in the UK must be suspended, pending mandatory review of its efficacy and safety and a decision on the propriety of awarding it a marketing authorization as a medicinal product.
- Fluoridated water must not be used in the preparation of any food for retail or wholesale purposes in the UK or Ireland
- Irrespective of any possible future award of a marketing authorization, no UK or Irish food manufacturer using fluoridated water in the preparation of their products may export them to any other EC country.
- No food manufacturer in external states practicing water fluoridation may export their products to any EC country if they use it to prepare their products.

This decision of the Court is binding on all EC member states, and is immediately enforceable in the national legislation of member states.

Analysis

A central argument in the dispute over the legality of water fluoridation is the claim by the Medicines and Healthcare Products Regulatory Authority (MHRA) in the UK, and the Irish Medicines Board (IMB) in the Irish Republic, that fluoridated water is a 'borderline product'. These regulators hold that "water is a normal part of the human diet", and therefore, in their opinions, it is a food and not subject to medicinal regulation. Within the Commission itself there is also evidence of a persistent and inexplicable reluctance to apply relevant Case Law rulings by the European Court to the highly controversial practice of water fluoridation in the UK and Ireland.

Fluoridated water is a 'functional food', and therefore a medicine.

However, in this crucial decision in 2005, the Court ruled that foods that are formulated to have both a nutritive and a medicinal function ('functional foods') must always be regulated as medicines, and subject to full prior marketing authorization (product licencing). Such functional foods include

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1 HLH Warenvertriebs and Orthica (Joined Cases C-211/03, C-299/03, C-316/03 and C-318/03) 9 June 2005

2 Douglas Cross. Independent Consultant in Environmental Analysis. Email maverick65@tiscali.co.uk

'near-water drinks with minerals added'[3], and fluoridated water falls firmly within the scope of this ruling. This decision reflects the principle of non-cumulation of legislation[4] – where a product appears to fall under two disparate legislative codes, one must take precedent over the other. As a general principle, medicinal law is always the relevant code where a product has, or is marketed as having, medicinal effects on the consumer.

Fluoridation proponents claim that fluoridated water has the mineral fluoride added to it, to 'fortify' a supposed deficiency in natural (calcium) fluoride. The purpose of this 'supplementation' is specifically to prevent dental caries, and the product is marketed with this claim as the sole justification for its supply. In fact this practice is fundamentally unlawful, since the source material - fluorosilicic acid - is not included in the positive list of permissible sources of 'fluoride' that may be added to human foods, as set out in Annex II of the food additives legislation[5].

However, even if fluorosilicates were permissible sources of fluoride under the EC legislation, fluoridated water is a 'functional food', and as such is therefore entirely subject to this ECJ decision. The Medicines Directive (65/65/EEC) clearly established the classification criteria that must be applied to product that are medicinal either by presentation or function, and this recent ruling simply clarified its application to functional foods.

It has in fact clearly been the case that since 1965 fluoridated water met both criteria that define a product as medicinal. This ruling exposes the failure of the UK and Irish regulators to designate fluoridated water as a medicinal product, in violation of the EC legislation since the transposition of the Directive into national law. It implies that regulators who have failed to comply with that legislation have been in breech of the Directive for the whole of the subsequent period.

Removal of regulators' discretion to designate medicinal products

The ruling states that regulators in member states can no longer exercise discretion in applying (or in the case of the UK and Ireland, refusing to apply) the provisions of the Medicinal Products Directive [6] to such 'borderline' products, thus avoiding regulating them under medicinal legislation. In effect with this ruling the concept of such dual function – and therefore legally ambiguous - 'borderline products' has been abolished from European law.

In both European law and the English (and Irish) laws derived from it, such 'medicinal waters' have long been excluded from regulation as water for human consumption ('drinking water')[7]. They may also not be used in the preparation of foodstuffs[8]. This ruling substantiates my previously published opinion[9] that the product does not fall within the scope of the foods or the drinking water legislation. In addition there is strong evidence that water fluoridation results in a significant increase in the background prevalence of

3 See commentary by Craig Simpson and Darren Abrahams, Steptoe & Johnson LLP (Brussels), on 'Functional drinks: an uncertain future' PLC Cross-border Life Sciences Handbook 2005/06 *www.practicallaw.com/3-201-2759* accessed 5 May 2009, and *http://www.steptoe.com/assets/attachments/1048.pdf* accessed 12 May 2009

4 For a detailed explanation of the application of non-cumulation in this context, see 'Guidance document on the demarkation between the Cosmetics Directive 76/78 and the Medicinal Directive 2001/83 as agreed between the Commission Services and the competent authorities of member states.' This also comments on the regulation of functional foods and drinks. http://ec.europa.eu/enterprise/cosmetics/doc/guidance_doc_cosm-medicinal.pdf

5 1925/2006/EC on the addition of vitamins and minerals and of certain other substances to foods http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0026:0038:EN:PDF

6 Medicinal Products Directive 2001/83/EC, as amended by 2004/27/EC

7 Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. Also, the Water Supply (Water Quality) Regulations 2000. SI 2000 No. 3184

8 Food Safety (General Food Hygiene) Regulations 1995. SI 1995 No. 1763

9 Cross DW, Carton RJ. Fluoridation: a violation of medical ethics and human rights. Int J Occup Environ Health. 2003 Jan-Mar; 9(1):24-9.)

chronic fluoride poisoning, which may be revealed as dental fluorosis in up to half of all people living in fluoridated water areas[10]. The legislation dealing with the use of minerals in foodstuffs stipulates that if

> ***"a harmful effect on health has been identified, the substance and/or the ingredient containing the substance shall . . . be placed in a list of prohibited substances, and its addition to foods or its use in the manufacture of foods shall be prohibited"***[11]

The Court ruling confirms that there is an absolute requirement for all such 'functional drinks' to be subject to the same level of strict scrutiny that must be applied to the consideration of any licence application for a pharmaceutical product. In the present state of scientific knowledge of the hazards of fluoride generally, it would be impossible to justify the award of such a licence (and no fluoridated state has yet made such an award), and the fluoridation of public water supplies must cease immediately.

Fluoride – in any form or product - must now be placed on a list of ***"Substances under Community scrutiny"*** and subject to further scientific review, reflecting the mandatory application of the precautionary principle which is now entrenched in EC food law under the General Foods Regulations.[12]

Application to naturally fluoridated water supplies.

This prohibition applies to water supplied for human consumption to which 'fluoride' from any source material has been intentionally added, including those fluorides (of sodium and potassium) that are listed as permissible source materials in the Annex, but are not generally used for this purpose in the UK or Ireland. Indeed, even water that contains appreciable amounts of 'natural' fluoride may now be subject to medicinal regulation, since artificial fluoridation is aimed at 'correcting' any supposed 'deficiency' in the background level of fluoride in drinking water, with purely medicinal (prophylactic) intent.

It is well-established that the development of a number of adverse pharmacological reactions to fluoridated water is associated primarily (but not exclusively) with the presence of the fluoride ion, and that water containing sufficient fluoride to influence tooth decay also produces the same adverse medical reactions that are develop from consumption of artifically fluoridated drinking water. Moreover, the existence of a dose-dependent response in the development of a number of adverse medical reactions confirms that it has specific pharmacological effect on the human body at the recommended concentration. Evidence that fluoride at the so-called 'optimum' concentration (0.7 to 1.0 parts per million) causes harm, regardless of its origin, comes from all populations using water that contains naturally-occuring calcium fluoride at sufficient concentrations, as well as from those that drink water deliberately dosed with fluorosilicates or sodium fluoride.

Fluoridated populations in both the UK and Ireland have high rates of dental fluorosis, although data on this condition are collected officially only in Ireland. The refusal of the regulators in these two states to classify fluoridated water as a medicinal product appears to be the result of political pressure on them to preserve the *status quo*, rather than the result of an impartial application of the medicinal rules that govern the use of such products in the EC.

Urgency of action

Exposure of infants to fluoridated water for even a few months at critical stages of development can result in permanent damage to both primary and secondary dentition, as well as long-lasting and severe

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10 McDonagh et al, 2000. A Systematic Review of Public Water Fluoridation, Centre for Reviews and Dissemination, University of York. http://www.york.ac.uk/inst/crd/fluores.htm accessed 15th December 2008

11 Article 8 (2)(a)(i) of 1925/2006/EC, on the addition of vitamins and minerals and of certain other substances to foods

12 Regulation No 178/2002, laying down the general principles and requirements of food law, establishing the European Food SafetyAuthority and laying down procedures in matters of food safety

psychological harm and distress to many. It may also lead to other chronic, and sometimes fatal conditions, including the bone disease, osteosarcoma. Prevention of such damage in the future can only be achieved by an immediate withdrawal of the product from public distribution.

Failure of regulators to implement the Medicines for Human Use Directive.

The designation of fluoridated water as a medicinal product is now clearly compulsory and inescapable. The MHRA's and IMB's continued failure to implement the various rulings of the Court establishing the classification of medicinal products must be subject to immediate investigation, since the mandatory designation of the product has been evident for many years.

The MHRA and IMB insist that, in coming to their decisions on the status of fluoridation chemicals, they take into account all of the factors relevant to the use of the product. This distracting claim applies mainly to borderline cosmetic products, where there may be reasonable uncertainty whether or not a cosmetic product also has specific properties that may be considered to be aimed at correcting an external blemish or similar disease condition. But in the case of consumable fluoridated water, no such ambiguity exists – it is promoted as having specific prophylactic properties, and is intended to exert a direct pharmacological effect on the actions of cells in the tooth enamel that repair damage caused by decay.

The evidence that the fluoridation of drinking water is in violation of the medicines legislation and that it is accompanied by substantial public harm has been in the public domain for many years. It is now impossible for these two regulatory authorities to claim ignorance of the legal and medical evidence against the practice. The only credible interpretation of this remarkable instance of maladministration is that they have bowed to political pressure to support national water fluoridation policies, and placed it above their primary duty, the protection of public health and welfare against unacceptable and unlawful medicinal products.

Equally, the evident unfamiliarity of a number of European Commissioners, their advisers and officials, with the medicinal law of the EC, and their failure to correct this situation in these two member states is a matter of grave concern. Even the validity of the present study mandate to SCHER on water fluoridation chemicals is open to serious question - since the product is undoubtedly medicinal, the responsibility to scrutinise it rests directly with the European Medicines Evaluation Agency (EMEA). The failure of EMEA to meet this obligation in the case of water fluoridation is a matter of great concern, as also is the remarkable decision by DG-SANCO to call for scientific information on water fluoridation without requiring the involvement of the EMEA.

Conclusions.

Mandatory responses demanded under the Precautionary Principle

1. In the absence of a relevant medicinal product licence, the supply of fluoridated water to the public must cease immediately, and all new plans to expand fluoridation to new areas of the UK abandoned.

2. Measures must be taken to establish the true extent of the medical damage caused by the improper supply of this unlawful product to both the UK and the Irish populations. At present information on the prevalence and severity of dental fluorosis is available only in Ireland – although twice as many people (5-6 million) live in fluoridated water areas in England, no attempt has been made by the Dept of Health to record its prevalence in the UK, and the very

existence of the condition is disputed by fluoridation promoters, despite evidence that both moderate and severe fluorosis exist in the UK, just as in Ireland. An immediate study of the prevalence and severity of dental fluorosis in the UK is necessary to provide for remedial dental intervention to those who have been damaged by this improper state policy.

3. The use of fluoridated water in food preparation must cease immediately, irrespective of any possible attempt that might be taken to license fluoridation chemicals. As a 'functional food' its use in food preparation is prohibited, as also is the export of foods prepared in those facilities in the UK and Ireland to which fluoridated water is delivered for the purpose of food preparation.The ECJ ruling states that even if a product of this description is marketed legally as a food in one member state, it cannot be exported to another member state unless it has the relevant medicinal product licence. Since the product is formulated using an unauthorised and unlicenced source material, its supply to the general public is unlawful, and both domestic sales and the export of any food products containing fluoridated water to other EC member states is prohibited.

4. The ruling implies that processed foods prepared using fluoridated water in any country outside the EC is also prohibited from importation into the EC. This effectively indicates that the substantial trade in such food products from the USA, Australia, New Zealand and other fluoridated states to all member states in the EC is prohibited. An immediate review of the feasibility of this consequence of the ruling is imperative, since an international agreement to abandon all water fluoridation is the only practical solution to the avoidance of a very significant obstacle to the continuation of relevant trade between all those states involved.

5. In view of the evidence of the proven relationship between exposure to environmental fluorides in all forms and the current pandemic of chronic fluoride poisoning, the use of any form of fluoride in dual purpose functional products (including fluoridated water, food products prepared with it, and fluoride toothpastes and other dental preparations) must be subject to immediate review. The precautionary principle must be applied, to protect the public from the marketing of the innumerable products containing this substance, to which the public is currently exposed without monitoring or restraint.

6. The sole (and highly questionable) pretext of the administration of fluoride to humans in ingestible products is medicinal. Its anomalous inclusion as a mineral in the food additives legislation, and of attempts to register substances containing fluorine as a permissible ingredient in foods, are entirely unacceptable. Since there is no scientifically proven nutrient function of fluoride [13], its continued inclusion (in any form) in the list of authorised 'minerals' that may be added to foods should be subject to immediate revocation.

7. In this landmark ruling (Warenvertreibs and Orthica, 2005) the Court also stated that the concept of an 'upper safe level' for fluoride intake in Article 5(1)(a) of the Food Supplements Directive (2002/46/EC) is not relevant for the purposes of drawing a distinction between medicinal products and foodstuffs. It is therefore purely the toxicological characteristics of ingested fluoride that are relevant to the assessment of its medicinal properties, and these can only be examined by using recognised rigorous pharmacological standards that evaluate its safety and efficacy as a medicinal product.

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13 European Food Safety Agency. 2005. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride. Question number: EFSA-Q-2003-01.8 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620766918.htm