



## Water Fluoridation in the EU: the European Commission's 10 years of regulatory failure

9<sup>th</sup> June 2009

- 1999 Environment Commissioner Margot Wallström admits the industrial waste from which fluorosilicic acid is derived for the purpose of fluoridating drinking water consumed by 9 million people in Ireland and the UK, has not been assessed for its risk to public health nor has it been toxicologically tested in the EU. Yet the Commissioner fails to enforce the *Drinking Water Directive* (98/83/EC) prohibiting its use.
- 2000 UK *NHS Systematic Review* of water fluoridation fails to demonstrate the safety of fluoridation, yet confirms the high risk of dental fluorosis and the low quality evidence for adding fluoride to drinking water.
- 2002 EU general food law (Regulation 178/2002/EC) came into force EU-wide on 21 February and introduced the 'precautionary principle' to EU food law, yet has never been invoked despite known risks of fluoride in drinking water, soft drinks and foods made using fluoridated municipal tap water.
- 2003 Basel (Switzerland) is last continental European city to stop fluoridation of the water supply after 40 year experience which demonstrated lack of effectiveness and unacceptable increase in dental fluorosis.

Irish North South Oral Health Survey in Children 2002 reveals a 700% increase in fluorosis from 1984 to 2002, now affecting 37% of 15-year-olds. Only 63% of this age group living in fluoridated areas of Ireland have normal tooth enamel.

The World health Organization (WHO), at the EU Drinking Water Seminar (Oct 2003) promises to publish in "early 2004" a risk assessment of hydrofluorosilicic acid as used in fluoridation programmes in Ireland and the UK. It has yet to be published.

An amendment (*Directive 2004/27/EC*) to the *Medicines Directive (2001/83/EC)* becomes effective on 30<sup>th</sup> October, classifies all products which are presented to "treat or prevent" disease, or which have a "pharmacological, immunological or metablic action", as medicinal products. The only exemptions are products which are "clearly" foods, food supplements, etc. The amending directive makes clear that "in cases of doubt" (i.e. 'borderline products'), medicinal law shall have supremacy over any other EU law. Under these terms, hydrofluorosilicic acid, used with the purpose of preventing a disease (dental caries) must be regarded as medicinal. However, drinking water which is medicated with fluoride has yet to be classified as a medicinal product by the European Commission, European Medicines Agency or the UK and Irish governments.

For more information:

- 5<sup>th</sup> June, European Court of Justice (*HLH Warenvertriebs and Orthica [Joined Cases C-211/03, C-299/03, C-316/03 and C-318/03*]) confirms that borderline products must be reclassified as medicines under *Directive 2004/27/EC* Commission still fails to act.
- 2006 Regulation 1925/2006/EC ('Food 'Fortification Regulation') allows the addition of sodium and potassium fluoride to manufactured foods and drinks, including water (e.g. bottled waters, soft drinks). Yet Article 8 contains provisions under which substances identified as having harmful effects should be added to a prohibited list of substances which are prohibited, restricted or under Community scrutiny. Despite the known risks of fluoride, no form of fluoride has been added to any of these lists.
- Voice of Irish Concern for the Environment (VOICE) submits petition on concerns regarding the addition of the hydrofluosilicic acid to Irish drinking water to the European Parliament's Petitions Committee (Petition 210/2007). The petition highlights the negligence of the Irish government in not assessing: a) the toxicity of fluorosilicic acid or b) total fluoride intake levels in the population. Commission Reply of 29.11.2007 was rebutted at Petition Committee.
- 2008 Environmental and health groups appeal to the European Commission's DG SANCO (Directorate General for 'Health and Consumers') over its inaction given that the *Hazardous Waste Directive* (91/689/EEC) classifies fluorosilicic acid as hazardous waste. Under this Directive, hazardous waste may not be disposed of in either ground water or in drinking water.
- 2009 March: DG SANCO issues a public call for information, requesting that the Scientific Committee on Environmental Health Risks (SCHER) critically reviews the health effects of fluoride and the most common drinking water fluorides, including fluorosilicic acid.

May: European members of International Society of Doctors for the Environment (ISDE <a href="https://www.isde.org">www.isde.org</a>) advise the European Commission that SCHER is not qualified to risk assess health effects of fluoride in drinking water due to its inappropriate range of scientific expertise.

## Summary of unenforced European laws relating to the addition of fluorosilicic acid to Irish and UK drinking water

Directive or Regulation	Directorate General	Commissioner
Drinking Water Directive (98/83/EC)	Environment	Stavros Dimas
General Food Law Regulation (178/2002/EC)	Health and Consumers	Androulla Vassiliou
Medicines Directive (2001/83/EC, amended by 2004/27/EC)	Enterprise and Industry	Günter Verheugen
Food Fortification Regulation (2006/1925)	Health and Consumers	Androulla Vassiliou
Hazardous Waste Directive (91/689/EC)	Environment	Stavros Dimas

For more information: