

WRITTEN QUESTION P-2159/10
by Caroline Lucas (Verts/ALE)
to the Commission

Subject: Fluoridation of drinking water in Southampton, UK

On 26 February 2009, the UK South Central Strategic Health Authority (SHA) took the decision to artificially fluoridate the drinking water of approximately 195 000 residents of Southampton and adjacent areas. The scheme is in preparation and was originally scheduled to start in March 2010.

The chemical compound proposed for use in the Southampton scheme is hexafluorosilicic acid, not currently subject to any requirement to licence it as a medicinal product in the UK. Article 1 of Directive 2001/83/EC¹ as amended, defines a 'medicinal product' as:

- (a) 'Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; ['the first limb'];
- (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' ['the second limb'].

In respect of Directive 2001/83/EC as amended, the European Court of Justice emphasised the importance of the impression that consumers are likely to form as a result of the product's presentation: 'It is necessary to take the view that a product is presented for treating or preventing disease, whenever any averagely well informed consumer gains the impression, that the product in question [has] an effect such as is described by the first part of the EC definition [i.e. having properties for treating or preventing disease in human beings], *Case C227-82 30 November 1983 re van Bennekom, European Court Reports 1983;3883*.

In information presented to the public by the South Central Strategic Health Authority in the document entitled 'Public consultation on the proposal for water fluoridation in Southampton and parts of south-west Hampshire', September 2008, the public were given the clear impression that hexafluorosilicic acid has properties for treating and preventing dental caries – see http://www.southcentral.nhs.uk/document_store/12520754911pQN_consultation_document_-please.pdf.

Does the Commission consider that hexafluorosilicic acid is being presented as having properties for treating or preventing disease in human beings and, therefore, meets the definition of a medicinal product?

¹ JO L 311, 28.11.2001, p. 67.