30.8.2012

NOTICE TO MEMBERS

Subject: Petition 0210/2007 by Robert Pocock (Irish), on behalf of Voice of Irish Concern for the Environment, on concerns regarding the addition of the hydrofluosilicic acid (H2SiF6) into drinking water in Ireland

Petition 0211/2007 by Walter Graham (British), on behalf of Council of Northern Ireland against Fluoridation, on concern about the addition of hydrofluosilicic acid (H2SiF6) to drinking water in UK

1. Summary of petition 0210/2007

The petitioner expresses concern about the potential impact on public health of the industrial chemical contaminant hydrofluosilicic acid (H2SiF6) which is added to the drinking water in Ireland. The petitioner challenges the explanation of the Irish government that the H2SiF6 is added to water in order to prevent dental caries in human beings, pointing out that the chemical has not been authorized under the EU Directive 2004/27. Furthermore, the petitioner argues that the adding of H2SiF6 into raw water would be a breach of the EU Drinking water Directive (98/83) and an infringement of the individual's right to refuse medication. The petitioner asks the European Parliament to have the issue investigated.

Summary of petition 0211/2007

The petitioner argues against compulsory water fluoridation in the United Kingdom by the addition of hydrofluosilicic acid (H2SiF6), considering that this is a breach of fundamental human rights. The petitioner mentions a US study which identifies several adverse health effects of fluoride, including thyroid impairment and arthritis. The petitioner asks the European Parliament to intervene and have an impact assessment on the side-effects of this chemical compound conducted.

2. Admissibility

Declared admissible on 4 July 2007. Information requested from Commission under Rule 192(4).

3. **Commission reply**, received on 29 November 2007.

The Petitions

The petitioners express their concern on the adverse health effects of fluorosilicic acid and fluoride added to drinking water. They also consider fluoridation of drinking water a breach of human rights.

The Commission's comments to the petition

Hydrofluorosilicic acid (H_2SiF_6), also known as fluorosilicic acid, is the most frequently used substance for public water fluoridation. Hydrofluorosilicic acid is a dangerous substance when handled in a concentrated form. It is highly aggressive not only if swallowed but also when fumes are inhaled or when the substance comes into contact with eyes or skin.

However, these properties are of relevance for handling the substance, inter alia in the drinking water treatment plant, where concentrated H_2SiF_6 is added to drinking water. In municipal water fluoridation schemes, however, fluorosilicic acid is diluted over 110.000 times. Once diluted, the fluorosilicic acid decomposes, producing fluoride ions. The risks are similar to those related with handling of chlorine, which is added to drinking water for disinfection purposes. Chlorine is also very toxic in its concentrated form.

The WHO Guidelines for Drinking Water Quality[1] do not highlight any toxicological hazards related to the use of fluorosilicic acid in the preparation of drinking water and do not indicate a safety issue for the consumer. On this basis, the use of fluorosilicic acid does not seem to present a toxicological threat or an infringement of the Drinking Water Directive[2]. The Commission has, therefore, no plans to undertake a further toxicological review nor an impact assessment on the use of fluorosilicic acid as a source of fluoride in drinking water.

Concerning the resulting fluoride ion (F^-) in drinking water (which is the result of the decomposition of fluorosilicic acid), the Commission is aware that fluoride provides protection of teeth[3] against dental caries when this substance is present in drinking water in low concentrations. This particularly applies to children. Concentrations of 0.5 mg up to 2 mg F/litre lead to the development of teeth which are less prone to decay[4].

As the petitioner mentioned, fluoride can cause dental fluorosis or even dental or skeletal illnesses, in higher concentrations and depending upon the intake. In its Guidelines for Drinking Water Quality[3], WHO sets a guideline value of 1.5 mg F/litre. The Drinking Water Directive establishes a clear and legally binding standard (1.5 mg F/l), in line with the

[1] Guidelines for Drinking Water Quality, 2004, ISBN 92 4 154638 7.
[2] Council Directive 98/83/EC OJ 33032 of 5.12.98.
[3] Mainly because hydroxyapatite (in enamel) is converted into fluoroapatite.
[4] WHO Guidelines for Drinking Water Quality , Geneva 2004, ISBN 92 4 154638 7.

guideline value of the WHO. When the drinking water's fluoride content remains below the directive's maximum concentration after fluoridation, the Commission considers the drinking water in conformity with the directive.

It must be noted that adding fluoride to drinking water is a national decision which does not flow from any obligation under Community law.

The Biomedicines Convention, focussing upon human rights and upon the involuntary application of medication has been opened for signature by the Council of Europe in Oviedo in 1997. However, the convention has not been ratified at this stage by the European Community, and for the time being it has no legal effects in the Community. Moreover, it is noted that according to the information available to the Commission, none of the EU members States which add fluoride to drinking water[1] is a party to the Convention.

Conclusion

Taking into account that there is no evidence of an infringement of EU law in this case, the Commission can take no legal action.

Furthermore, the Commission has no plans to undertake a further toxicological review nor an impact assessment on the use of fluorosilicic acid as a source of fluoride in drinking water, as available scientific evidence shows there is no risk hazard related to applying fluorosilicic acid at the drinking water plant.

4. (REV) Commission reply, received on 21 October 2008.

The petitioners express concern about the fluoridation of drinking water through the addition of hexafluorosilicic acid (H_2SiF_6). Key concerns voiced are the intrinsic properties of this substance and, in particular, infringements of the Drinking Water Directive, the Medicinal Products Directive and the European Convention on Human Rights and Biomedicines. The Commission produced a communication on the petitions in November 2007. An additional document submitted to the 26th May 2008 meeting of the Petitions Committee by the petitioner, as well as interventions during that meeting, served to reiterate the concerns voiced and the alleged infringements of the Drinking Water Directive[2], the Hazardous Waste Directive[3] and the Medicinal Products Directive[4].

The Commission's comments on the additional document and the interventions at the meeting of the Petition Committee of 26th May 2008

Drinking Water Directive 98/83/EC

Scientific advice in the Drinking Water Guidelines of the World Health Organisation (WHO) has established a guideline value of 1.5 mg fluoride per litre. The Drinking Water Directive established a legally binding maximum concentration value for drinking water of 1.5 mg

[1] Ireland and the UK.
2 Directive 98/83/EC, OJ *** of 5.12.1998, as amended
3 Directive 91/689/EEC, OJ L377 OF31.12.1991, as amended
4 Directive 2001/83/EC, OJ L311 of 28.11.2001, as amended

fluoride per litre. Both the WHO Guidelines (chapter 1.1.) and the directive (recital 13) base the values on lifetime consumption. With this in mind, the addition of hexafluorosilicic acid (fluorosilicic acid) is not considered an infringement of the directive, if the maximum permissible concentration value of 1.5 mg fluoride per litre set in the directive is not exceeded.

Hazardous Waste Directive 91/689/EEC and related waste issues

From the point of view of waste legislation the questions posed in the petition are:

a) If the material in question is hazardous waste as defined in Directive 91/689/EEC (Hazardous Waste Directive).

b) If this is the case, why would it be possible to use it for drinking water treatment?

Ad a) Under EU waste legislation, a material is defined as any substance or object which the holder discards or intends or is required to discard, and which fulfils the criteria of annex 1 of Directive 2006/12/EC[1] (the Waste Framework Directive) and Decision 2000/532/EC[2] (the European Waste List). However, both these sources are indicative, the definition of waste essentially turns on the notion of 'discard', and leaves, therefore, the obligation for the competent authorities to decide on a case by case basis. The European Court of Justice has stressed this on several occasions: whether a material is a waste or not depends on the specific, factual circumstances and the decision must be taken on a case by case basis. The Communication from the Commission to the Council and the European Parliament on the Interpretative Communication on waste and by-products COM(2007)59 final, contains useful guidelines which are based on the jurisprudence of the European Court of Justice and these address the issues of by-products in relevant industry sectors, on when by-products should or should not be considered as waste in order to clarify the legal situation for economic operators and competent authorities.

As key basis for the assessment of a material being 'waste' is its intentional production, i.e. whether the chosen production process for the main product (in this case fertilisers) intentionally delivers a certain by-product. A further element of assessment set out in the guidelines concerns market for the material, i.e. its economic value, and whether the material in question would be subject to standard waste treatment operations.

Ad b) The EU legislation on waste does not, per se, prevent the use of any substances which fulfil the criteria for waste (including hazardous waste) for purposes deemed useful on conditions that such use will not endanger human health or harm the environment. As a result, even if the material in question was to be regarded as hazardous waste, its use for water treatment is possible, provided that all necessary conditions concerning the usefulness of the process, safety, etc. are met and notwithstanding adherence to safe handling, permitting, labelling etc.
Medicinal Products Directive 2001/83/EC

[1] OJ L 114, 27.4.2006, p. 9-21.
[2] As last amended by Council Decision 2001/573/EC, OJ L 203 28.7.2001 p. 18.

Under the Medicinal Products Directive a product is to be considered as a medicinal product if it is:-
(a) a substance or combination of substances presented as having properties for treating or preventing disease in human beings (medicinal product by presentation), or;
(b) a 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 (medicinal product by function);

A product is deemed to be presented for treating or preventing disease within the meaning of Directive 2001/83/EC, not only when it is expressly indicated or recommended as such. Account must also be taken of the attitude of an averagely well-informed consumer, when he/she gains the impression that the product in question should have such an effect. Regard should be paid to the product's form and the manner in which it is packaged, and to the information provided to the consumer. These criteria demonstrate that drinking water from the tap cannot be regarded as a medicinal product by presentation. Furthermore, drinking water as referred in the petition cannot be considered as a medicinal product by function. Where fluorosilicates are added to drinking water in low concentrations, similar to the natural concentrations, the water does not lose its main purpose, namely of being nutritional. The way such drinking water is used and the low risks inherent in such water confirm this classification. Thus, drinking water to which fluorosilicates have been added in concentrations similar to natural concentrations are neither from the presentational nor from the functional viewpoint a medicinal product within the scope of the Medicinal Products Directive.

Overall exposure to fluoride from a range of sources

The WHO outlines in its Drinking Water Guidelines that exposure to fluoride depends on a range of factors: "In most circumstances, food seems to be the primary source of fluoride intake, with lesser contributions from drinking-water and from toothpaste. In areas with relatively high concentrations, particularly in groundwater, drinking-water is increasingly important as a source of fluoride. Intakes in areas where high fluoride coal is used indoors may also be significant."

In order to update the assessment of potential risk associated to exposure of the public to fluoride, the Commission will request the Scientific Committee on Health and the Environment to deliver an opinion for an updated assessment of potential risks associated to exposure of the public to the intake of fluoride.

Conclusions

1. The Commission has scrutinised the practice of adding hexafluorosilicic acid to drinking water whilst adhering to the maximum permissible fluoride concentration values under the Drinking Water Directive. It confirms that it does not see any evidence of infringements of the Drinking Water Directive, the Dangerous Waste Directive and the Medicinal Products Directive.

2. In order to update scientific knowledge for any policy re-evaluation, the Commission will

request the Scientific Committee on Health and the Environment to deliver an opinion for an updated assessment of potential risks associated to exposure of the public to the intake of fluoride.

5. (REV II) Commission reply, received on 2 September 2010

Petitions 210/2007 and 211/2007

As previously indicated, the Commission had decided to request the Scientific Committee on Health and Environmental Risks (SCHER) to deliver an opinion for an updated assessment of potential risks associated to exposure of the public to the intake of fluoride.

Following this request, the Scientific Committee on Health and Environmental Risks (SCHER) has now adopted its preliminary opinion. In line with Commission Decision 2008/721/EC[1], this preliminary opinion is now subject to a public consultation.

The preliminary opinion is publicly available via the server of the Commission: http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scher_cons_05_en.htm

The final opinion of the Scientific Committee on Health and Environmental Risks (SCHER) is expected before the end of 2010.

6. (REV III) Commission reply, received on 29 March 2011

Petitions 210/2007 and 211/2007

The Scientific Committee on Health and Environmental Risks (SCHER)
- adopted its preliminary opinion on 18 May 2010:-

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scher_cons_05_en.htm;

- submitted this preliminary opinion to a public consultation[2] with deadline 22 September 2010;
- has not yet adopted its final opinion in a Plenary Session of the Committee.

7. Commission reply (REV IV), received on 18 July 2011.

[1] Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC, OJ L241 of 10.9.2008.
[2] Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC, OJ L241 of 10.9.2008.

Petitions 210/2007 and 211/2007

As a final follow-up to previous correspondence on this petition and following approval of the preliminary opinion and public consultation, the final opinion of the Scientific Committee, SCHER, adopted at its last meeting in May 2011 is now available. The opinion document and accompanying documents can be accessed at the following website :

http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/index_en.htm#id3, and go to "Risk Assessment".

8. Commission reply (REV V), received on 30 August 2012.

Considering:

- The petitioner's (210/2007) e-mail message from 2 March 2012, including the correspondence with the Irish Health Minister on the issue of water fluoridation;
- The letter from the National Pure Water Association Ltd, dated 26 March 2012, supporting petition 210/2007 and including their *statement* in relation to the practice of fluoridation in drinking water.
- The study "*Human Toxicity, Environmental Impact and Legal Implications of Water Fluoridation. Public Health Risks from Dietary Overexposure to Fluoride Compounds*"

The Commission would like to add the following information:

To recall, the EU has not regulated specifically the practice of fluoridation of drinking water for health purposes. It is, therefore, the competence of the Member States to take the necessary steps for risk management of this practice. Given that only three Member States (including Ireland), or parts thereof, continue with this practice, it is also not an area where the Commission would envisage harmonised EU action in the future because it would not be justified on the basis of the principles of subsidiarity and proportionality. In other words, it is more efficient that Member States act in certain areas, provided that they comply with EU legislation.

It is the Commission's opinion, that the current practice of fluoridation of drinking water in Ireland does not breach the provisions set out in the Drinking Water Directive (98/83/EC) because the concentrations are below the limit value for fluoride even after its addition for dental health purposes.

Nevertheless, because of the many scientific questions that have been raised, the Commission asked the Scientific Committee on Health and Environmental Risk (SCHER) to assess some of the specific aspects in this area, specifically referring to the hazard profile, health effects, and human exposure to fluoride and fluoridating agents in drinking water. The SCHER published its opinion on 16 May 2011.

(See: http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_122.pdf).

At around the same time, the World Health Organization (WHO) updated its Drinking Water Guidelines. Further to a review of the latest scientific evidence, the WHO maintained its recommended guideline value of 1.5 mg/l for fluoride in drinking water.

In summary, neither the WHO nor the SCHER concluded that an amendment of the limit value for fluoride in the Drinking Water Directive was necessary because of new scientific evidence. Both recognise, however, that there are specific aspects like the protection of vulnerable groups, such as children, that may be exposed to higher levels of fluorides if no appropriate risk management is in place. As mentioned above, it is up to the national authorities to take the necessary risk management steps.

Therefore, the Commission informed the competent authorities of the Member States at the latest meeting of the Regulatory Committee for the implementation of the Drinking Water Directive on 30 April 2012, about the SCHER opinion and the WHO guidelines, and asked them to consider them when implementing the directive at national level.

The Commission has also conducted a preliminary review of the report on the "*Human Toxicity, Environmental Impact and Legal Implications of Water Fluoridation. Public Health Risks from Dietary Overexposure to Fluoride Compounds*". The report raised many issues and addresses many legislative areas under the competence of different Commission services. However, the Commission is of the opinion that the report does not change the conclusions that are outlined above as far as the Drinking Water Directive is concerned. Nevertheless, we recognise that the scientific debate in this area, as in many other areas, is on-going and is producing new, relevant evidence which needs to be monitored carefully. The Commission will call on the WHO to pay particular attention to the latest scientific evidence when reviewing their guidelines for drinking water again, including those in the above-mentioned report and the issues raised in the statement by the *National Pure Water Association Ltd*.

As for the other legislative areas potentially concerned, the Commission has come to the conclusion that there is no significant new information in the report and that, based on the report, no obvious breach of any other EU legislation could be identified at this stage.

In particular, the Commission highlights that the fluoridation of drinking water cannot be in breach of Regulation (EC) No 178/2002, the EU General Food Law. As it complies with the Drinking Water Directive, it shall be deemed to be safe in so far as the aspects covered by these specific EU provisions are concerned, as stated by Article 14(7) of Regulation (EC) N°178/2002.

In the same way, it cannot be in breach of the EU legislation on medicinal products and cosmetic products since the definitions of these products (provided respectively in Article 1 of Directive 2001/83/EC and Article 1 of Directive 76/768/EEC) do not cover drinking water.

Regulation (EC) N° 1924/2006 on nutrition and health claims made on foods sets rules for the use of voluntary statements in commercial communications whether, in the labelling, presentation or advertising of foods. It is, therefore, not relevant in the context of mandatory fluoridation of drinking water.

Regarding the alleged breach of the Charter of Fundamental Rights of the European Union, it

has to be recalled that under the Treaties on which the European Union is based[1], the European Commission has no general powers to intervene with the Member States in the area of fundamental rights. The Charter of Fundamental Rights of the European Union does not apply to every situation of an alleged violation of fundamental rights. According to its Article 51(1), the Charter applies to Member States only when they are implementing European Union law. The practice of fluoridation of drinking water does not stem from the implementation of the Drinking Water Directive or any other EU law. Therefore it appears that the Charter is not applicable in this case.

As regards the application of Article 5 of the Council of Europe's Convention on Human Rights and Biomedicine, the Commission is not empowered to control the compliance of Member States' legislation with this Convention.

[1] Treaty on European Union and Treaty on the functioning of the European Union