

**Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)
on a request related to**

the safety in use of the activated alumina treatment for the removal of fluoride from natural mineral waters

Question N° EFSA-Q-2005-069

Adopted on 27 September 2006

SUMMARY

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) has been asked to evaluate the food safety aspects related to the removal of fluoride from natural mineral waters (NMWs) by filtration through a bed of activated alumina.

NMWs at source may contain levels of fluoride higher than the maximum concentration limits established for the constituents of natural mineral waters by the Commission Directive 2003/40/EEC. Removal of the fluoride is only allowed by an authorised process.

Information concerning the source and treatment of activated alumina and the filtration process conditions was provided and showed that critical steps of the proposed process are the following:

- Testing of activated alumina filter according to the European standard applicable for leaching tests (EN 12902) [6] to ensure that no impurities are leached to the water in quantities that result in concentrations exceeding the limits set in Commission Directive 2003/40/EC on the constituents of natural mineral waters, or in the absence of relevant limits in that Directive, the restrictions set in Council Directive 98/83/EC on the quality of water intended for human consumption or in national applicable legislation.
- Initialisation procedure with alkaline or acidic chemicals to remove any impurities and fine particles before the use of the filter.
- Regeneration procedure with appropriate chemicals to renew the capacity of the filter resulting at the same time in the removal of any possibly formed biofilm.

From the information provided it was shown that under optimised process conditions the release of impurities due to the use of the activated alumina, if it occurs at all, is always lower than the relevant limits set in the Directives mentioned above. In addition, due to the regular regeneration process of the activated alumina according to Good Manufacturing Practice (GMP) and the principles of Hazard Analysis and Critical Control Points (HACCP), there is no additional risk of microbial contamination.

It was also demonstrated that fluoride can be removed effectively from NMWs by filtration through a bed of activated alumina. To maintain compliance with the limits set in Directive 2003/40/EC the fluoride content of the treated water needs to be monitored due to the reducing absorption capacity of the activated alumina during the cycle of use and regeneration.

The Panel concluded that the removal of fluoride from NMWs by filtration through activated alumina can be safely applied provided the critical steps as described above are implemented and monitored appropriately.

KEY WORDS

Fluoride removal, activated alumina, natural mineral waters.

BACKGROUND

Council Directive 80/777/EEC¹ lays down the provisions applicable to the exploitation and marketing of natural mineral waters (NMWs). NMWs are characterised by their constant chemical composition, of so-called “essential constituents” which are supposed to have a beneficial effect on the human organism. NMWs sources have to be continuously kept free from any environmental contamination (microbiological and chemical contaminants) because of their underground origin and the required measures of protection of the sources. Therefore, treatments for the removal of a microbiological or chemical contamination are not allowed by the E.U. NMW legislation. However, for technological and food safety purposes a limited number of treatments may be used e.g. removal of unstable elements (iron, sulphur and manganese compounds) by precipitation, filtration or treatment with ozone-enriched air without changing the composition of the NMWs as regards the essential constituents. Such treatments should be notified to and controlled by competent authorities.

NMWs may also contain so-called “undesirable constituents” which, though naturally present may have undesirable effects on public health. NMWs shall be “suitable” for human consumption at source, but do not have to comply with the maximum limits for constituents and residues applicable to drinking waters.

In 2003, the Commission adopted Commission Directive 2003/40/EC² which established an exhaustive list of undesirable constituents and related maximum limits. In the case of fluoride, Directive 2003/40/EC states both a maximum limit of 5 mg/l (applicable from 1st January 2008) and a labelling requirement (applicable from 1st July 2004): “contains more

¹ Council Directive of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters.

² Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone enriched air for the treatment of natural mineral waters and spring waters.

than 1.5 mg/l of fluoride: not suitable for regular consumption by infants and children under 7 years of age” The maximum limit will be re-examined on the basis of the EFSA opinion³

Where maximum limits for undesirable constituents in NMWs are exceeded, operators shall put in place a treatment approved by the Commission to remove them totally or partially. Article 4 of Directive 80/777/EEC lays down the mandatory requirements applicable to each removal treatment that operators can put in place:

- It complies with the conditions of use which have been adopted by the Commission (so-called “EU approval”), following EFSA consultation (Article 4.1b and 4.1c);
- It does not alter the composition of the water as regards the “essential constituents” (Article 4.1);
- It may not be subject of any addition other than the introduction or re-introduction of carbon dioxide (Article 4.2)
- It does not lead to any disinfection action (Article 4.3)

After the assessment of the fluoride removal treatment, the Commission will set the conditions of use of the treatment according to the provisions of Article 4.1(c) of Directive 80/777/EEC.

TERMS OF REFERENCE

In accordance with Article 29 (1) (a) of the Regulation (EC) no 178/2002 of the European Parliament and of the Council, the European Commission requests the European Food Safety Authority to examine the food safety aspects of the use of the activated alumina treatment for the removal of fluoride from natural mineral waters.

ASSESSMENT

To remove fluoride, the water is filtered through a bed of granulated activated alumina. The emphasis in this opinion is placed on the food safety aspects, in respect to the release of substances from the activated alumina and microbiological contamination of the NMW from the use of the filter. A report [5] was provided by the *ad hoc* working group⁴ on the technological assessment of natural mineral water treatments on the basis of dossiers [1-4] forwarded to the Commission by the industry, national food safety agencies and

³ Opinion of the scientific panel on contaminants in the food chain on a request of the Commission related to concentration limits for boron and fluoride in natural mineral waters adopted on 22 June 2005.

⁴ The Ad Hoc Working group on the technological assessment of natural mineral water treatment has been set up by the European Commission and agreed by the Member States at the Standing Committee on the Food Chain and Animal Health on 23 June 2005

specialised laboratories in water treatment. This information [1-5] was evaluated and is summarised below.

The Panel noted that filtration through a bed of activated alumina is legally used for many years in the production of drinking water in various Member States.

Activated Alumina

Activated alumina is a filter media made by treating aluminum ore (bauxite) so that it becomes porous and highly adsorptive. It consists mainly of Al_2O_3 . The production process includes calcination at 500°C, which at the same time removes all organic substances. Besides the main components some trace elements may be present and the composition of the activated alumina may vary depending on the source of bauxite. To ensure that no impurities are released to the water during the treatment, the media used shall be tested according to the standard applicable for leaching tests (EN 12902) [6].

In any case the release of impurities during the treatment from the activated alumina into the NMW shall not result in concentrations exceeding the limits set in Commission Directive 2003/40/EC [7] or in the absence of limits in that Directive the restrictions set in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption [8] or in national applicable legislation.

Activated alumina is capable of removing a variety of substances including excessive fluoride, arsenic and selenium. The fluoride removal process is based on adsorption on the surface of the activated alumina. Before using the calcinated activated alumina for NMW treatment, an initialisation process is applied. During this process any impurities are removed from the media or decreased to a level that leaching of trace elements does not occur. Leaching of the main component, aluminium, depends on the pH and composition of the treated water. Besides the initialisation procedure, the activated alumina requires a periodic cleaning with an appropriate regenerating agent in order to remove absorbed substances and to restore the absorption capacity (see section 3.2).

Initialisation and regeneration procedures

Once a filter has been loaded with virgin activated alumina, the medium is backwashed to remove the fine particles generated by the handling of the material and subsequently chemically treated to activate the adsorption sites and to remove the impurities. The modalities of this treatment are similar to those for regeneration.

The regeneration of activated alumina filters is done in three stages:

- Treatment with sodium hydroxide to remove fluoride ions and replace them with hydroxide ions;
- Treatment with an acid to remove residual sodium hydroxide and activate the medium;
- Rinsing with drinking or demineralised water and conditioning with the natural mineral water so that the filter has no impact on the overall mineral content of the treated water.

The regeneration and in particular the first stage is also important from a microbiological point of view. During this stage, the pH of the water is ≥ 13 . At this high pH, the solution is bactericidal. Biofilms are destroyed, and then removed through subsequent rinsing.

Humic and fulvic acids are also eliminated, thus preventing these compounds from building up over time.

Regeneration is carried out at intervals ranging from one to four weeks depending on water quality and throughput.

The reagents used for initialisation and regeneration have to comply with the relevant European standards relating to the purity of the chemical reagents used for drinking water treatment.

Fluoride and trace elements removal

It was demonstrated that fluoride can be removed effectively from natural mineral water by filtration through a bed of activated alumina using optimised conditions. To maintain the fluoride content of the treated water in compliance with the limits set in Directive 2003/40/EC, the fluoride content of the treated water needs to be monitored due to the reducing absorption capacity of the activated alumina during the cycle of use and regeneration.

When applying the fluoride removal treatment with activated alumina, the operating conditions may also lead to the co-removal of other undesirable constituents which are present in very low quantities (trace elements).

Release of substances by the use of activated alumina

Data on the actual content of many anions and cations in various types of NMW were provided. An increase of the concentration after the treatment was found in some cases for aluminium (from 18 up to 86 microg/l, bromide (160 -> 280 microg/l) and boron (66 -> 550 microg/l). However, in most types of water these changes were not observed at all and the observed variations of composition before and after treatment were low.

Leaching of aluminium from the activated alumina depends on the pH of the NMW and the alumina manufacturing process [5]. In some cases levels between 100 and 200 microg/l were reported. However, based on data provided [5] by optimising the pH conditions and selection of the appropriate medium the aluminium release resulting from the process would normally not exceed 40-60 µg/l.

Microbiological risks

Although NMW sources must be protected from microbiological contamination, they may contain bacteria naturally present at the source. Activated alumina, being a porous medium may be colonised with bacteria, with the formation of a biofilm. Periodical regeneration of the activated alumina at a pH of ≥ 13 is bactericidal and biofilms are destroyed and removed upon rinsing. Therefore it is concluded that with correct control of the process there is no additional risk of microbiological contamination.

Monitoring and control

The release of aluminium and other contaminants originating from the fluoride removal process should comply with the requirements of Directive 2003/40/EC [7] and in the absence of requirements, with Council Directive 98/83/EC [8] and/or national applicable requirements and shall be checked regularly in accordance with the Council Directive. The fluoride content should be monitored frequently, preferably by on line measurements.

A process subject to GMP principles and a HACCP system should be implemented as required by the Regulation (EC) n° 852/2004.

DISCUSSION AND CONCLUSIONS

It was demonstrated that the treatment of NMW with activated alumina is suitable for the intended purpose. Under optimized conditions the release of cations or anions from the medium during treatment is negligible and will not pose a risk to human health. The total amount of aluminium ions in the NMW as it results after the release of aluminium from activated alumina should not exceed 200 microg/l, as established for drinking water [8].

The Panel notes that Joint FAO/WHO Experts Committee on Food Additives (JECFA, 2006) has recently adopted a new PTWI of 1 mg/kg bw (FAO/WHO, 2006). If it is assumed that aluminium might be present in treated NMW up to 200 microg/l and 2 l of NMW are consumed daily, then aluminium intake from NMW would contribute at most up to 5% of the PTWI.

Due to the regular regeneration process of the activated alumina no microbiological contamination from the use of the filter is likely to occur.

Therefore it is concluded that the fluoride removal from NMW by means of filtration through activated alumina does not pose a risk to human health.

To ensure the above conclusions the following should be fulfilled:

- The activated alumina should not release any significant amount of impurities. In any case the leaching of impurities and aluminium from the activated alumina into the NMW will not result in concentrations exceeding the limits set in Commission Directive 2003/40/EC [7], or in the absence of limits in that Directive, the restrictions set in Council Directive 98/83/EC [8] or in national applicable legislation.
- Activated alumina is subject to an initialisation procedure before producing the treated NMW. The initialisation procedure includes the chemical treatment of the activated alumina to remove leachable impurities and a backwash treatment to remove fine particles.
- Regeneration, using appropriate chemical treatment, is performed to remove the absorbed fluoride ions and to re-activate the active sites of the medium. In addition any biofilm possibly formed is also removed during this treatment.
- The activated alumina used for treatment of NMWs has to comply with the standard applicable for leaching tests (EN 12902).
- The process should be subject to GMP and HACCP principles.

LIMITATION IN THE SCOPE OF THIS EVALUATION

This evaluation and opinion is based on an assessment of the treatment of NMWs for the removal of fluoride from these waters. It does not take into account any other treatment of NMWs.

DOCUMENTS PROVIDED TO EFSA

1. Application for permission to defluoridate natural mineral waters forwarded by the Belgian Federation of the Water and Soft drink Industry (FIEB).
2. "Reduction of Fluoride from natural mineral waters" forwarded by the German mineral water industry (V.D.M.).
3. "Etude des procédés de traitement pour éliminer le fluor applicables aux eaux minérales naturelles et aux eaux de source" forwarded by the French mineral water industry.
4. "Fluorid-reduktion bei Naturlichen Mineralwassern" forwarded by the German mineral water industry (V.D.M.).
5. Report of the Commission ad hoc working group⁵ on the technological assessment of natural mineral water treatments on the evaluation of treatment by aluminium oxide for the removal of fluoride from natural mineral waters and spring waters, dated 30-03-2006:
http://ec.europa.eu/food/food/labellingnutrition/water/index_en.htm
6. European Standard EN 12902 of November 2004: Products used for treatment of water intended for human consumption. Inorganic supporting and filtering materials.
7. Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters.
8. Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, OJ L 330, 5.12.1998, p. 32.

REFERENCES

JECFA (2006), the Joint FAO/WHO Expert Committee on Food Additives, sixty-seventh meeting, 20-29 Rome 2006, summary and conclusions:
<http://www.who.int/ipcs/food/jecfa/summaries/summary67.pdf>

⁵ The Ad Hoc Working group on the technological assessment of natural mineral water treatment has been set up by the European Commission and agreed by the Member States at the Standing Committee on the Food Chain and Animal Health on 23 June 2005.

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