

14 DECEMBER 2007

**GUIDELINES ON THE CONDITIONS FOR USING
ACTIVATED ALUMINA FOR THE REMOVAL
OF
FLUORIDE FROM NATURAL MINERAL WATERS AND
SPRING WATERS**

1. INTRODUCTION

Commission Directive 2003/40/EC sets up a maximum limit¹ (ML) of 5 mg/l for the fluoride concentration in natural mineral waters (NMW); that provision comes into application on 1 January 2008. From this date, NMW which do not comply with this requirement can no longer be marketed unless they have undergone a treatment for fluoride removal in accordance with Article 4 of Directive 80/777/EEC.

Pursuant to Article 4.1.c) of Council Directive 80/777/EEC, such treatment has to:

- comply with conditions of use to be determined after consultation of the European Food Safety Authority (EFSA);
- be notified to the competent Member State authorities and be submitted to a specific control of these authorities.

The fluoride removal on activated alumina was evaluated by EFSA which issued on 27 September 2006 a favourable opinion on the use of that treatment in NMW and spring waters.

It was not possible to determine on a regulatory basis the conditions for the use of the treatment mentioned above before the date from which the maximum limit of fluoride shall be complied with.

Pending adoption by way of regulatory instrument that should be done as soon as possible, the purpose of the present guidelines is to provide the operators concerned as well as the Member State control authorities with the conditions of use of the treatment. These guidelines have been agreed with the Standing Committee on the Food Chain and Animal Health at its meeting of 14 December 2007.

It has to be noted that no other treatment for NMW de-fluoridation has been assessed and validated by the EFSA. Therefore, the treatment on activated alumina is the only usable treatment in that purpose for both natural mineral waters and spring waters.

2. CONDITIONS OF USE OF THE TREATMENT

2.1. General requirements.

- Natural mineral waters whose fluoride content exceeds the maximum limit for fluoride of 5 mg/l (respectively 1.5 mg/l for spring waters) laid down in Annex I of Directive 2003/40/EC cannot be marketed unless they have been treated with a selective fluoride removal treatment. Such treatment may also be applied to natural mineral waters with a fluoride content which do not exceed that limit but is higher than 1.5 mg/l.

¹ A maximum limit of 1.5 mg/l for fluoride in spring waters is already in application according to Annex I, part B of Council Directive 98/83/EC on the quality of water intended for human consumption.

- It is recalled that Article 4 (1) c) of Directive 80/777/EEC states that such treatment can not modify the physico-chemical composition of the water in terms of essential constituents.
- Article 4 (1) c) also requests the use of the treatment on activated alumina to natural mineral waters to be notified in advance to the competent authorities and to be subject to a specific control from these authorities.

Therefore, with a view to enabling these authorities to perform the control, operators should be requested, where they notify the use of a treatment, to communicate to these authorities appropriate information, documentation and analytical results on the activated alumina treatment which in particular give evidence of its compliance with the general and technical requirements applicable to it. The control should ensure in particular that:

- The use of such treatment is justified with respect to the composition of the water in terms of fluoride concentration;
- The operator takes all measures necessary to guarantee that the treatment is effective and safe, that it complies with the general and technical requirements applicable to this treatment.

It should be noted that the pieces of information above mentioned are not intended to perform a case by case assessment of the safety of these treatments- which has been done by EFSA- but to have a prior check by the competent authorities.

2.2. Technical specifications.

The fluoride removal treatment should also comply with the following specific requirements:

- The activated alumina media used for the treatment of natural mineral waters complies with the European standard on granular activated alumina (EN 13753) or other applicable Member State standards for drinking water treatment and with the European standard for leaching tests (EN 12902).
- The activated alumina media is subject to an initialisation procedure before producing the treated natural mineral water which includes an initial regeneration cycle of the activated alumina to remove leachable impurities and a backwash treatment to remove fine particles. A regeneration process is applied in due time to remove the adsorbed ions and to restore the adsorption capacity of the activated alumina.
- The chemicals and reagents used for initialisation, regeneration and disinfection of the activated alumina media comply with the European or national applicable standards for drinking water treatment.
- The release of impurities or residues from the activated alumina media into the natural mineral water or spring water is as low as technically feasible according the best practices and does not pose a risk to public health. The process does not release more than 60 µg/l of aluminium in addition to the concentration before treatment.

- The process is subject to good manufacturing practices and HACCP principles in accordance with provisions of Regulation (EC) 853/2004 on food hygiene. The operator applies appropriate controls in order to ensure the proper functioning of the different processing steps (initialisation, production, regeneration), in particular as regards to the maintenance of the essential characteristics of the water and to its fluoride content.

3. LABELLING REQUIREMENTS.

Article 7 (2) c) of Directive 80/777/EEC requests that, with a view to informing consumers, the use of a treatment mentioned in Article 4 (1) c) shall be indicated on the label of the water concerned.

To that effect, the following statement is proposed so as to assist operators in complying with the labelling requirement mentioned above:

" water subjected to an authorised adsorption technique "

However, in accordance with Article 7 (2) a) of Directive 80/777/EEC, in absence of Community legislation, Member States may adopt national provisions, in accordance with the rules of the Treaty, requesting the indication of the treatment on the labelling of the products concerned. Therefore, Member States would be allowed to request specific labelling information in so far as this would not be likely to create unjustified trade barriers.