

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

Commission Regulation establishing the conditions for using activated alumina for the removal of fluoride from natural mineral waters and spring waters

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to [Council Directive 80/777/EEC]¹, of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters, as last amended by Directive 96/70/EC of the European Parliament and of the Council², and in particular Articles [4(1)(c) and 11(1)] thereof,

Whereas:

- (1) Article 4 (1) (c) of Directive 80/777/EEC (as amended) provides for the separation of naturally present undesirable constituents from natural mineral waters, using a treatment which does not alter the composition of the water as regards the essential constituents. Such treatment must be subject to an assessment by the European Food Safety Authority and to the adoption of the condition of use by the Standing Committee on the Food Chain and Animal Health.
- (2) Commission Directive 2003/40/EC³ has set up as from 1 January 2008 a maximum limit of 5 mg/l for fluoride in natural mineral waters and a statement on the label of natural mineral waters which fluoride level is above 1.5 mg/l;
- (3) Natural mineral waters with a fluoride content exceeding the maximum limit above mentioned could only be marketed after having undergone a treatment in order to remove fluoride selectively;
- (4) The European Food Safety Authority has issued on 27 September 2006 a favourable opinion on the fluoride removal treatment on activated alumina;

¹ OJ L [...], [...], p. [...]. [Name of act] as [last]amended by [Name and number of act] (OJ L [...], [...], p. [...]).

² OJ L [...], [...], p. [...]. [Name of act] as [last]amended by [Name and number of act] (OJ L [...], [...], p. [...]).

³ Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labeling requirements for the constituents of natural mineral waters and the condition for using ozone-enriched air for the treatment of natural mineral waters and spring waters.

- (5) The fluoride removal treatment on activated alumina shall not modify the composition in terms of characteristic constituents within the meaning of Article 7 (2) (a) of Directive 80/777/EEC or have a disinfectant action within the meaning of Article 4 (3) or generate the formation of treatment residues which may have a harmful effect on public health;
- (6) The fluoride removal treatment shall not add impurities or residues to the treated natural mineral water at concentration which may pose a risk for public health;
- (7) in view of a higher quality of the water, Member States should be allowed to maintain or adopt detailed rules for the maximum permitted release of impurities or residues from the media filter;
- (8) Pursuant to Article 7 (2) (c) of Directive 80/777/EEC, natural mineral waters which have been treated for fluoride removal must bear a reference on the label giving customers sufficient information about the treatment carried out;
- (9) In accordance with the provisions of Article 9 (4) (a) indent 4 of Directive 80/777/EEC, the provisions concerning the treatments provided for in its Article 4, and in particular the fluoride removal treatment on activated alumina, are applicable to spring waters;
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The use of activated alumina media for removal of fluoride from natural mineral waters and spring waters shall be allowed in accordance with the present Regulation.

Article 2

Natural mineral waters whose fluoride content exceed the maximum limit for fluoride which is laid down in Annex I of Commission Directive 2003/40/EC shall only be marketed after having undergone a fluoride removal treatment on activated alumina. Such treatment may also be applied on a voluntary basis to natural mineral waters with a fluoride content above 1.5 mg/l.

Article 3

1. Natural mineral waters which are treated with activated alumina for must comply with all following conditions:

- (a) the physico-chemical composition of the natural mineral waters in terms of essential constituents shall not be modified by the treatment;

(b) they shall not contain residues, impurities and aluminium at concentrations which do not comply with the provisions laid down in point 4 for of the Annex to the present Regulation.

With a view to applying higher quality standards to natural mineral waters produced on their territory, Members States may adopt more detailed rules concerning the maximum increase of residues or impurities released from the media.

2. The technical requirements which are laid down in the Annex apply to the treatment.

Article 4

The application of the treatment on activated alumina for fluoride removal to natural mineral waters must be notified in advance to the competent authorities who shall verify that:

- (a) the use of such treatment is justified with respect to the composition of the water in terms of fluoride concentration;
- (b) the operator takes all measures necessary to guarantee that the treatment is effective and safe, that it complies with the requirements laid down in the Annex,
- (c) the treatment is subject to specific official controls.

Article 5

With their notification as referred to in Article 4, the operators shall communicate to the competent authorities appropriate information, documentation and analytical results on the activated alumina treatment which, in particular, give evidence of its compliance with the provisions of Article 3.

Article [6]

The labeling of natural mineral waters which have been treated on activated alumina for fluoride removal shall bear, in proximity to the analytical composition of characteristic constituents, the words " water subjected to an authorized adsorption technique".

Article [7]

The provisions of Articles 3, 4, 5 and 6 of this Regulation shall apply to spring waters.

Article [8]

This Regulation shall enter into force on the [20th] day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

For the Commission
[...]
Member of the Commission

ANNEX

1. The activated alumina media used for the treatment of natural mineral waters shall comply with the European standards 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).
2. The activated alumina media is subject to an initialisation procedure before producing the treated natural mineral water which includes the 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 to remove the adsorbed ions and to restore the adsorption capacity of the activated alumina.
3. The chemicals and reagents used for initialisation, regeneration and disinfection of the activated alumina media shall comply with the European or national applicable standards for drinking water treatment.
4. The release of impurities or residues from the activated alumina media into the natural mineral water or spring water shall be as low as technically feasible according the best practices and shall not pose a risk to public health. The process shall not release more than 60 µg/l of aluminium in addition to the concentration before treatment.
5. The process shall be subject to good manufacturing practices and HACCP principles in accordance with provisions of Regulation (EC) 852/2004 on food hygiene. The operator shall apply appropriate controls in order to ensure the proper functioning of the different processing steps (initialization, production, regeneration), in particular as regards to the maintenance of the essential characteristics of the water and to its fluoride content.