

EN

EN

EN

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]<sup>1</sup>, 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 Council<sup>2</sup>, and in particular Articles [4(1)(c) and 11(1)] thereof,

Whereas:

- (1) [Commission Directive 2003/40/EC has set up a maximum limit of 5 mg/l for fluoride in natural mineral waters which enter into force from 1 January 2008 and a labelling requirement<sup>3</sup> applicable to all natural mineral waters which fluoride level is above 1.5 mg/l]
- (2) Natural mineral waters whose fluoride content exceeds the maximum limit for fluoride shall be subjected to a separation treatment for public health purposes. Other natural mineral waters which fluoride content exceeds 1.5 mg/l may also apply this treatment on a voluntary basis.
- (3) 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.
- (4) Article 4 (1) (c) lays down that any treatment under its scope is subject to an assessment by the European Food Safety Authority and to the adoption of the conditions of use by the Standing Committee on the Food Chain and Animal Health.

---

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

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

<sup>3</sup> "contains more than 1.5 mg/l of fluoride: not suitable for regular consumption by infants and children under 7 years of age"

- (5) The European Food Safety Authority has issued a favourable opinion<sup>4</sup> on the fluoride removal treatment on activated alumina which provides for given results. It does not provide for processing parameters due to the need to adapt the treatment to the composition of each natural mineral water.
- (6) Moreover, 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.
- (7) The fluoride removal treatment shall not add impurities or residues to the treated natural mineral water at concentrations which are above the applicable food safety limits.
- (8) Member States may have adopted additional provisions about the maximum quantity of impurities or residues which could be added by the water process and which should apply to this treatment.
- (9) Pursuant to Article 7 (2) (C) of the above Directive, 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.
- (10) In accordance with the provisions of Article 9 (4) (a) four indent 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;
- (11) The measures provided for in this Regulation are in accordance with the opinion of the [Scientific] Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

### *Article 1*

The treatment of natural mineral waters on activated alumina for fluoride removal 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) the natural mineral water before treatment must comply with the microbiological criteria laid down in Article 5 (1) and (2) of Directive 80/777/EEC;
- (c) it shall not lead to the formation of residues or impurities with a concentration exceeding the maximum limits laid down in the Annex, point 3 or which could pose a risk to public

---

<sup>4</sup> Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food of 27 September 2006 on a request related to the safety in use of the activated alumina treatment for the removal of fluoride from natural mineral waters.

health. Additional national provisions related to the release of residues or impurities from the treatment on activated alumina may apply.

(d) the technical requirements which are laid down in the Annex are met.

#### *Article 2*

The application of the natural mineral water treatment on activated alumina for fluoride removal must be notified in advance to the competent Authorities which shall ensure that:

(a) the use of such treatment is justified with respect to the composition of the water in terms of fluoride composition;

(b) the operator takes all measures necessary to guarantee that the treatment is effective, safe and that it complies with the requirements laid down in the Annex.

(c) the treatment is subject to specific official controls.

#### *Article 3*

In application to the notification procedure laid down in Article 2, the operators shall communicate to the competent Authorities appropriate information and documentation on the activated alumina treatment which, in particular, give evidence of its compliance with the provisions of Article 1.

#### *Article [4]*

The labelling 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 authorised adsorption technique".

#### *Article [5]*

The provisions of Article 1 (b), (c), (d), Articles 2, 3 and 4 of this Regulation shall apply to spring waters.

#### *Article [6]*

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 or national applicable standards for drinking water treatment and in particular 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 chemical treatment of the activated alumina to remove leachable impurities and a backwash treatment to remove fine particles. A regeneration process is applied to remove the adsorbed ions.
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 activated alumina media shall not release impurities or residues into the natural mineral water in concentrations which, in addition to concentrations in the water before treatment, would exceed the limits set in Annex I of Commission Directive 2003/40/EC, the limit for Polycyclic Aromatic Hydrocarbons (PAH) set in Annex I, part B of Directive 98/83/EC and the limit for aluminium set in Annex I, part C of Directive 98/83/EC.
5. The process shall be subject to good manufacturing practices and HACCP principles.