
Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 115/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX

Technical requirements for the use of activated alumina for the removal of fluoride from natural mineral waters and spring waters

The following critical processing steps shall be implemented and monitored appropriately:

1. Before the activated alumina is used for the treatment of water it shall be subjected to an initialisation procedure which includes the use of acidic or alkaline chemicals to remove any residues and a backwash treatment to remove fine particles.
2. A regeneration procedure shall be applied at intervals ranging from one to four weeks depending on the water quality and throughput. It shall include the use of appropriate chemicals to remove the adsorbed ions in order to restore the adsorption capacity of the activated alumina, and to remove any possibly formed biofilms. This procedure shall be done in the following 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 water as the final step in order to ensure that the filter has no impact on the overall mineral content of the treated water.
3. The chemicals and reagents used for the initialisation and regeneration procedures shall comply with the relevant European standards⁽¹⁾ or applicable national standards relating to the purity of the chemical reagents used for treatment of water intended for human consumption.
4. The activated alumina shall comply with the European standard for leaching tests (EN 12902)⁽²⁾ to ensure that no residues are released into the water resulting in concentrations exceeding the limits set in Directive 2003/40/EC or in the absence of limits in that Directive, the limits set in Directive 98/83/EC or in applicable national legislation. The total amount of aluminium ions in the treated water as it results after the release of aluminium, the main component of activated alumina, shall not exceed 200microg/L, as established in Directive 98/83/EC. This amount shall be checked regularly in accordance with the Council Directive.
5. The processing steps shall be subject to good manufacturing practices and HACCP principles set out in Regulation (EC) No 852/2004 of the European Parliament and of the Council on food hygiene⁽³⁾.
6. The operator shall establish a monitoring programme in order to ensure the proper functioning of the processing steps in particular as regards the maintenance of the essential characteristics of the water and its fluoride content.

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- (1) European Standards developed by the European Committee for Standardisation (CEN).
- (2) European Standard EN 12902 (2004): Products used for treatment of water intended for human consumption. Inorganic supporting and filtering materials.
- (3) [OJ L 139, 30.4.2004, p. 1.](#)

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Changes and effects yet to be applied to :

- Annex point 4(b) Annex point 4(c) renumbered as Annex point 4(b) in earlier amending provision S.I. 2019/529, Sch. 1 by [S.I. 2020/1501 reg. 4\(5\)\(b\)](#)
- Annex point 4(c) Annex point 4(d) renumbered as Annex point 4(c) in earlier amending provision S.I. 2019/529, Sch. 1 by [S.I. 2020/1501 reg. 4\(5\)\(c\)](#)
- Annex point 4(b) omitted in earlier amending provision S.I. 2019/529, Sch. 1 by [S.I. 2020/1501 reg. 4\(5\)\(a\)](#)
- Annex words substituted by [S.I. 2019/529 reg. 4\(3\)](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature omitted by [S.I. 2019/529 reg. 4\(2\)](#)