2010 No. 433

FOOD, ENGLAND

The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) (Amendment) Regulations 2010

Made	23rd February 2010
Laid before Parliament	1st March 2010
Coming into force	9th April 2010

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1), 17, 26(1)(a) and (3), 31 and 48(1) of and paragraphs 1 and 4(b) of Schedule 1 to the Food Safety Act 1990(**a**) and now vested in him(**b**).

In accordance with section 48(4A) of that Act, he has taken into account relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**c**) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title and commencement

1. These Regulations may be cited as the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) (Amendment) Regulations 2010 and come into force on 9th April 2010.

⁽a) 1990 c. 16; section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999 Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting out Act 1994 (1994 c. 40), Schedule 6 to the 1999 Act and S.I. 2004/2990.

⁽b) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Functions of "the Ministers" so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act, and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c.46) as read with section 40(2) of the 1999 Act.

⁽c) OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L 188, 18.7.2009, p.14).

Amendment of the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007

2. The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007(**a**) are further amended in accordance with regulations 3 to 9.

3. In paragraph (1) of regulation 2 (interpretation)—

(a) immediately after the definition of "the Agency" there is inserted the following definition-

"authorised activated alumina treatment" means-

- (a) a treatment of natural mineral water and spring water with activated alumina in order to remove fluoride, that has been authorised in accordance with Schedule 1A; or
- (b) in the case of natural mineral water or spring water brought into England from another part of the United Kingdom or from another EEA state, a treatment which complies with Articles 1 to 3 of Regulation 115/2010;"; and
- (b) immediately after the definition of "prescribed concentration or value" there is inserted the following definition—

""Regulation 115/2010" means Commission Regulation (EU) No. 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters;(b)".

4. For paragraph (1) of regulation 6 (treatments and additions for natural mineral water) there is substituted the following paragraph—

"(1) No person shall subject natural mineral water in its state at source to—

- (a) any treatment other than—
 - (i) an authorised ozone-enriched air oxidation technique,
 - (ii) the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, whether or not preceded by oxygenation, in so far as the treatment does not alter the composition of the water as regards the essential constituents which give it its properties,
 - (iii) the total or partial elimination of free carbon dioxide by exclusively physical methods, or
 - (iv) an authorised activated alumina treatment; or
- (b) any addition other than the introduction or the re-introduction of carbon dioxide to produce effervescent natural mineral water.".

5. Immediately after paragraph (2) of regulation 10 (bottling of spring water and exploitation of spring water springs) there is inserted the following paragraph—

"(2A) No person shall cause any water which has been treated with activated alumina for removal of fluoride to be bottled in a bottle marked or labelled "spring water", unless that treatment is an authorised activated alumina treatment.".

6. For paragraph (3) of regulation 16 (enforcement) there are substituted the following paragraphs—

"(3) Each relevant authority shall, within its area, carry out periodic checks on any authorised activated alumina treatment in respect of which the authorisation was granted by it in accordance with Schedule 1A, to ensure that the requirements of that Schedule continue to be satisfied.

(4) Each food authority shall, within its area, execute and enforce these Regulations.

⁽a) S.I. 2007/2785, amended by S.I. 2009/1598.

⁽b) OJ No. L37, 10.2.2010, p.13.

(5) For the purposes of carrying out the function referred to in paragraph (4) in relation to bottled drinking water and spring water each food authority shall—

- (a) subject to paragraph (6), carry out regular monitoring of the quality of any such water to check whether—
 - (i) it satisfies the requirements of Directive 98/83,
 - (ii) it contains a concentration or value for any parameter in excess of its prescribed concentration or value,
 - (iii) it contains a concentration or value for a property, element, substance or organism set out in Schedule 9 (as read with the Notes to that Schedule) in excess of the concentration or value specified in relation to the property, element, substance or organism concerned in that Schedule as measured by the unit of measurement so specified,
 - (iv) in the case where, in accordance with sub-paragraph (iii), a food authority determines that the water concerned contains a concentration or value for *Clostridium perfringens* (including spores) in excess of the concentration or value specified in relation to it in Schedule 9 (as read with Note 2 to that Schedule), there is any potential danger to human health arising from the presence in the water of pathogenic micro-organisms, and
 - (v) in the case where disinfection forms part of the preparation or distribution of the water concerned, the disinfection treatment applied is efficient and any contamination from disinfection by-products is kept as low as is possible without compromising the disinfection;
- (b) in order to comply with sub-paragraph (a)—
 - (i) carry out regular check monitoring in relation to the parameters, properties, elements, substances and organisms set out in Schedule 10, as read with the Notes to that Schedule, and
 - (ii) carry out audit monitoring in relation to any parameter and the properties, elements, substances and organisms set out in Schedule 9, as read with the Notes to that Schedule;
- (c) for the purposes of sub-paragraph (b), carry out sampling and analysis in accordance with the relevant minimum frequencies set out in Schedule 11; and
- (d) carry out additional monitoring in relation to any property, element, substance or organism which is neither a parameter nor a property, element, substance or organism set out in Schedule 9 if the food authority has reason to suspect that it may be present in the water concerned in an amount or number which constitutes a potential danger to human health.

(6) The checks and monitoring referred to in paragraph (5)(a), (b) and (d) shall be carried out using samples representative of the quality of the water concerned consumed throughout the year in which the samples are taken."

7. For regulation 20 (offences and penalties) there is substituted the following regulation—

"Offences and penalties

20.—(1) A person is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale if that person —

- (a) contravenes regulation 5, 6(1), 7(1), (3) or (4), 8, 9, 10, 11, 12, 13, 14, 15 or 22(3);
- (b) fails to comply with any provision of Regulation 115/2010 specified in paragraph (2); or
- (c) carries out an authorised activated alumina treatment that has a disinfectant action.
- (2) The provisions are—

- (a) Article 1.2 (requirement that authorised activated alumina treatments be performed in accordance with the technical requirements set out in the Annex);
- (b) the first sentence of Article 2 (requirement that the release of residues into natural mineral water or spring water as a result of any authorised activated alumina treatment be as low as technically feasible according to the best practices and not pose a risk to public health);
- (c) the second sentence of Article 2 (requirement that, to ensure compliance with the first sentence of Article 2, operators implement and monitor the critical processing steps set out in the Annex);
- (d) Article 3.1 (requirement that the application of an authorised activated alumina treatment be notified to the competent authorities at least three months prior to use); and
- (e) Article 4 as read with the second paragraph of Article 5 (requirement that, subject to a transitional provision, the label on natural mineral water or spring water subjected to any authorised activated alumina treatment include specified information in proximity to the statement of the analytical composition).".

8. Immediately after Schedule 1 (conditions for treatment of natural mineral water and spring water with ozone-enriched air) there is inserted the Schedule set out in Schedule 1 to these Regulations.

9. Immediately after Schedule 8 (labelling indications for natural mineral water and criteria for use) there are added the Schedules set out in Schedule 2 to these Regulations.

Signed by authority of the Secretary of State for Health

23rd February 2010

Gillian Merron Minister of State, Department of Health

SCHEDULE INSERTED IMMEDIATELY AFTER SCHEDULE 1 TO THE NATURAL MINERAL WATER, SPRING WATER AND BOTTLED DRINKING WATER (ENGLAND) REGULATIONS 2007

"SCHEDULE 1A Regulations 2(1) and 16(3)

CONDITIONS FOR TREATMENT OF NATURAL MINERAL WATER AND SPRING WATER WITH ACTIVATED ALUMINA TO REMOVE FLUORIDE

1. A person seeking to have authorised a treatment of natural mineral water and spring water with activated alumina in order to remove fluoride shall—

- (a) apply in writing to the relevant authority within whose area the water is extracted;
- (b) permit representatives of that authority to examine the proposed method of treatment and place of treatment and take samples for analysis in accordance with regulation 17; and
- (c) provide such information in support of the application as is requested by the relevant authority.

2. The relevant authority shall assess the application and any information in its possession and shall authorise the treatment if it is satisfied that—

- (a) Articles 1 to 3 of Regulation 115/2010 are complied with in relation to the treatment; and
- (b) the treatment does not have a disinfectant action.

3. Where the relevant authority decides to authorise a treatment pursuant to paragraph 2, it shall inform the applicant in writing and state the date from which the authorisation for commercial use of the treatment has effect.

4. Where the relevant authority refuses to authorise a treatment pursuant to paragraph 2, it shall inform the applicant in writing, stating its reasons.

5. Where a treatment has been authorised pursuant to paragraph 2, the person carrying out the treatment must, for the purpose of enabling the relevant authority to assess whether the conditions in paragraph 2 continue to be satisfied—

- (a) permit representatives of the authority to examine the method of treatment and place of treatment and take samples for analysis in accordance with regulation 17; and
- (b) provide such information related to the treatment as is requested by the authority.

6. If the relevant authority is satisfied that the conditions specified in paragraph 2 are no longer fulfilled, it may withdraw authorisation of a treatment by giving the person carrying out the treatment a written notice stating the grounds for withdrawal.

7. Where the relevant authority has informed an applicant under paragraph 4 of its refusal to authorise a treatment under paragraph 2 or withdraws authorisation of a treatment under

paragraph 6, the person who wishes to carry out the treatment may apply to the Agency for a review of that decision.

8. Upon receiving the application for review, the Agency shall —

- (a) make such enquiry into the matter as may seem to the Agency to be appropriate; and
- (b) having considered the results of that enquiry and any relevant facts elicited by it, either confirm the decision or direct the relevant authority to grant or restore, as appropriate, authorisation of the treatment in respect of which the application was made.
- 9. In the case of such a direction, the relevant authority shall comply with the direction."

Regulation 9

SCHEDULES ADDED IMMEDIATELY AFTER SCHEDULE 8 TO THE NATURAL MINERAL WATER, SPRING WATER AND BOTTLED DRINKING WATER (ENGLAND) REGULATIONS 2007

"SCHEDULE 9 Regulation 16(5)(a)(iii), (b)(ii) and (d)

PROPERTIES, ELEMENTS, SUBSTANCES AND ORGANISMS, NOT BEING PARAMETERS, WHOSE CONCENTRATION OR VALUE IN BOTTLED DRINKING WATER AND SPRING WATER MUST BE DETERMINED BY AUDIT MONITORING

Property, element, substance or organism	Concentration or value	Unit	Notes
Ammonium	200	μg/l	
Chloride	250	mg/l	Note 1
Clostridum perfringens (including spores)	0	number/ 100 ml	Note 2
Conductivity	2500	μ S cm ⁻¹ at 20°C	Note 1
Iron	200	μg/1	
Oxidisability	5,0	mg/1O2	Note 3
Coliform bacteria	0	Number/250 ml	
Total organic carbon (TOC)	No abnormal change		Note 4
Note 1: The water s	should not be aggressive.		

Note 2: This parameter need not be measured unless the water originates from or is influenced by surface water.

Note 3: This parameter need not be measured if the parameter TOC is analysed.

Note 4: This parameter need not be applied for supplies less than 10000 m^3 per day.

Regulation 16(5)(b) (i)

PARAMETERS , PROPERTIES, ELEMENTS, SUBSTANCES AND ORGANISMS IN RELATION TO WHICH CHECK MONITORING MUST BE CARRIED OUT

Aluminium (Note 1) Ammonium Colour Conductivity *Clostridium perfringens* (including spores) (Note 2) *Escherichia coli (E. Coli)* Hydrogen ion concentration Iron (Note 1) Nitrite (Note 3) Odour *Pseudomonas aeruginosa* Taste Colony count 22°C and 37°C Coliform bacteria Turbidity

- Note 1: Necessary only when used as flocculant
- Note 2: Necessary only if the water originates from or is influenced by surface water
- Note 3: Necessary only when chloramination is used as a disinfectant

MINIMUM FREQUENCIES FOR SAMPLING AND ANALYSIS OF SPRING WATER AND BOTTLED DRINKING WATER

Minimum frequency of sampling and analysis for water put into bottles or containers intended for sale

containers intended for sale			
Volume of water produced for offering for sale in bottles or containers each day (1) m^3	Check monitoring number of samples per year	Audit monitoring number of samples per year	
≤10	1	1	
> 10 ≤ 60	12	1	
> 60	1 for each 5 m ³ and part thereof of the total volume	1 for each 100 m ³ and part thereof of the total volume	
(¹) The volumes are calcu	lated as averages taken o	ver a calendar year."	

EXPLANATORY NOTE

(This note is not part of the Order)

1. These Regulations amend the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 (S.I. 2007/2785, as already amended).

2. These Regulations—

- (a) provide for the execution and enforcement in relation to England of Commission Regulation (EU) No. 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters (OJ No. L 37, 10.2.2010, p.13); and
- (b) implement, in relation to England, Article 7.1 to 3 and 6 of Council Directive 98/83/EC relating to the quality of water intended for human consumption (OJ No. L330, 3.11.98, p.32).

3. These Regulations amend the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 by—

- (a) inserting definitions of "authorised activated alumina treatment" and "Regulation 115/2010" into paragraph (1) of regulation 2 (interpretation) (*regulation 3*);
- (b) substituting a revised version of paragraph (1) of regulation 6 (treatment and additions for natural mineral water) in order to add authorised activated alumina treatments to the list of treatments to which natural mineral water in its state at source may lawfully be subjected (*regulation 4*);
- (c) adding a paragraph to regulation 10 (bottling of spring water and exploitation of spring water springs) prohibiting the bottling of water which has been treated with activated alumina for removal of fluoride in a bottle marked or labelled "spring water" unless the treatment is an authorised activated alumina treatment (*regulation 5*);
- (d) substituting for paragraph (3) of regulation 16 (enforcement) new paragraphs (3) to (6), which—
 - (i) require relevant authorities to carry out periodic checks on authorised activated alumina treatments which they have authorised in accordance with new Schedule 1A, to ensure that the requirements of that Schedule continue to be satisfied,
 - (ii) require food authorities to carry out regular monitoring of the quality of bottled drinking water and spring water to check specified matters,
 - (iii) in order to comply with that requirement, require food authorities to-
 - (aa) carry out regular check monitoring in relation to the parameters, properties, elements, substances and organisms set out in new Schedule 10, and
 - (bb) carry out audit monitoring in relation to any parameter and the properties, elements, substances and organisms set out in new Schedule 9,
 - (iv) for the purposes of that requirement, require food authorities to carry out sampling and analysis in accordance with the relevant minimum frequencies set out in new Schedule 11,
 - (v) require food authorities to carry out additional monitoring in relation to any property, element, substance or organism which is neither a parameter nor a property, element, substance or organism set out in new Schedule 9 if they have reason to suspect that it may be present in the water concerned in an amount or number which constitutes a potential danger to human health, and
 - (vi) require the checks and monitoring referred to in divisions (ii) to (v) of this subparagraph to be carried out using samples representative of the quality of the water concerned consumed throughout the year in which the samples are taken (*regulation 6*);

- (e) substituting a revised regulation 20 (offences and penalties) in order to make it an offence to fail to comply with specified provisions of Commission Regulation (EU) No. 115/2010 or to carry out an authorised activated alumina treatment that has a disinfectant action (*regulation 7*); and
- (f) insert new Schedules 1A, 9, 10 and 11 (regulations 8 and 9).

4. A full impact assessment has not been produced for this instrument as no impact on the public or voluntary sectors is foreseen.

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