

**2004 No. 656**

**FOOD, ENGLAND**

**The Natural Mineral Water, Spring Water and Bottled Drinking  
Water (Amendment) (England) Regulations 2004**

<i>Made</i>	- - - -	<i>8th March 2004</i>
<i>Laid before Parliament</i>		<i>15th March 2004</i>
<i>Coming into force</i>		
<i>Except for regulations 5, 8(2), 11(a) and 12(2)</i>		<i>5th April 2004</i>
<i>Regulations 5, 8(2), 11(a) and 12(2)</i>		<i>1st July 2004</i>

The Secretary of State, in exercise of the powers conferred on him by sections 16(1), 17(1), 26(1)(a) and (3), 31 and 48(1) of, and paragraph 1 of Schedule 1 to, the Food Safety Act 1990(a) and now vested in him(b) and having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation 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) and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

**Title, commencement and application**

1.—(1) These Regulations may be cited as the Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2004 and shall apply in relation to England only.

(2) Subject to paragraph (3) below these Regulations shall come into force on 5th April 2004.

(3) Regulations 5, 8(2), 11(a) and 12(2) shall come into force on 1st July 2004.

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(a) 1990 c. 16.

(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 paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999 (c. 28) and paragraphs 12 and 21 of that Schedule amend sections 17(1) and 48 of the 1990 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 those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (c. 46) as read with section 40(2) of the 1999 Act. Regulation 13(4) of S.I. 2000/656 expressly authorises the Secretary of State to amend or revoke existing Regulations made or having effect as if made by the Minister of Agriculture, Fisheries and Food (whether with others or not) under the Food Safety Act 1990.

(c) OJ No. L31, 1.2.2002, p.1.

## **Amendments to the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999**

2. The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999(a) shall be amended insofar as they apply to England in accordance with regulations 3 to 14.

3.—(1) In regulation 2 paragraph (1) after the definition of “the Agency” there shall be inserted the following definition —

“ “authorised ozone–enriched air oxidation technique” means —

- (a) a treatment with ozone–enriched air authorised and carried out in accordance with Schedule 5; or
- (b) in the case of water brought into England from other parts of the United Kingdom or from another EEA State a treatment which complies with Article 5 of Directive 2003/40 as implemented in that part of the United Kingdom or that EEA State.”.

(2) In regulation 2 paragraph (1) after the definition of “Directive 98/83” there shall be inserted —

“ “Directive 2003/40” means Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone–enriched air for the treatment of natural mineral waters and spring waters.”.

4. In regulation 7 paragraph (1) for sub–paragraph (a) there shall be substituted —

“(a) any treatment other than —

- (i) an authorised ozone–enriched air oxidation technique;
- (ii) a treatment referred to in sub–paragraph (a) or (d) of Article 4.1; or”

5. After regulation 7 there shall be inserted —

“7A.—(1) No person shall bottle any natural mineral water which, at the time of bottling, contains any substance listed in Schedule 6 at a level which exceeds the maximum limit specified in relation to that substance in that Schedule.

(2) No person shall sell any natural mineral water bottled in contravention of paragraph (1).

(3) The methods used for detection of the substances listed in Schedule 6 shall conform to the performance characteristics for analysis specified in Schedule 7.

(4) For the purposes of paragraphs (1) and (2) above, where —

- (a)
  - (i) the water concerned exceeds the maximum limits specified in Schedule 6,
  - (ii) the water concerned was bottled in another EEA State,
  - (iii) the EEA State concerned had not, at the time of bottling, implemented Article 2(1) of Directive 2003/40, and
  - (iv) the water was bottled prior to 1st January 2006 and at the date of bottling otherwise complied with Directives 80/777, 98/83 and the provisions of Directive 2003/40 which were in force in that EEA State; or
- (b)
  - (i) the water concerned exceeds the maximum limits specified in Schedule 6 relating to nickel and fluoride,
  - (ii) the water concerned was bottled in another EEA State,

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(a) S.I. 1999/1540, as amended by S.I. 2000/656 and S.I. 2003/666.

- (iii) the EEA State concerned had not, at the time of bottling, implemented Article 2(1) of Directive 2003/40 insofar as it relates to maximum limits for nickel and fluoride, and
- (iv) the water was bottled prior to 1st January 2008 and at the date of bottling otherwise complied with Directives 80/777, 98/83 and the provisions of Directive 2003/40 which were in force in that EEA State,

that water shall be deemed not to exceed the maximum limits specified in Schedule 6.”.

**6.** After regulation 9 there shall be inserted —

“**9A.** No person shall bottle any natural mineral water, or sell natural mineral water which is bottled, if it has been treated with ozone-enriched air unless that treatment is an authorised ozone-enriched air oxidation technique.”.

**7.** For regulation 10 paragraph (3) there shall be substituted —

“(3) Natural mineral water shall be bottled in a bottle marked or labelled with —

- (a) where it has undergone the treatment of total or partial elimination of free carbon dioxide by exclusively physical methods, the indication “fully de-carbonated” or “partially de-carbonated” as appropriate;
- (b) where it has undergone an authorised ozone-enriched air oxidation technique, the words “water subjected to an authorised ozone-enriched air oxidation technique”, which shall appear in proximity to the analytical composition of characteristic constituents;
- (c) where its fluoride concentration exceeds 1.5 mg/l —
  - (i) the words “contains more than 1.5 mg/l of fluoride not suitable for regular consumption by infants and children under 7 years of age”, which shall appear in proximity to the trade name and in clearly visible characters,
  - (ii) the actual fluoride content in relation to the physico-chemical composition, which shall be included within the mandatory information referred to in paragraph (4) below; and
- (d) the mandatory information referred to in paragraph (4) below.”.

**8.—(1)** In regulation 10(5)(b), after “has undergone any of the treatments referred to in paragraph (3)(a)” there shall be inserted the words “or (b)”.

(2) In regulation 10(5)(c) the word “or” shall be omitted, and at the end of sub-paragraph (d) there shall be added —

“or

- (e) does not bear the labelling indications set out in sub-paragraph (c) of paragraph (3) above where required by that sub-paragraph.”.

**9.** In regulation 11(1) at the end of sub-paragraph (d) the word “and” shall be omitted and at the end of sub-paragraph (e) the following shall be inserted —

“and

- (f) where the water has undergone an authorised ozone-enriched air oxidation technique, the bottle is marked or labelled with the words “water subjected to an authorised ozone-enriched air oxidation technique” which shall appear in proximity to the particulars in paragraph (3) of this regulation.”.

**10.** After regulation 11 there shall be inserted —

“**11A.** No person shall cause any water to be bottled in a bottle marked or labelled with the description spring water, or sell any bottled water which is described as spring water, if it has been treated with ozone-enriched air unless that treatment is an authorised ozone-enriched air oxidation technique.”.

**11.** In regulation 17 —

- (a) after the number “7,” there shall be inserted “7A(1) or (2),”;
- (b) after the number “9,” there shall be inserted “9A,”;
- (c) after “11(1), (2), (3) or (5),” there shall be inserted “11A,”.

**12.—**(1) In regulation 18, after paragraph (3) there shall be added the following —

“(4) In any proceedings for an offence for contravening regulation 9A, 10(3)(b), 11(1)(f) or 11A it shall be a defence for the accused to prove that —

- (a) the water in respect of which the offence is alleged to have been committed was bottled and marked or labelled before 1st July 2004; and
- (b) the matters constituting the alleged offence would not have constituted an offence under these Regulations as they stood immediately before the coming into force of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2004.”.

(2) In regulation 18, after the paragraph (4) inserted by paragraph (1) above there shall be added the following —

“(5) In any proceedings for an offence for contravening regulations 7A or 10(5)(e) it shall be a defence for the accused to prove that —

- (a) the water in respect of which the offence is alleged to have been committed was bottled and marked or labelled as the case may be, before 1st July 2004; and
- (b) the matters constituting the alleged offence would not have constituted an offence under these Regulations as they stood immediately before the coming into force of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2004.”.

**13.—**(1) In Schedule 1 Part I paragraph 2, sub-paragraph (c), for the words following “contains no substance” there shall be substituted the words —

“listed in Schedule 6 at a level which exceeds the maximum limit specified in relation to that substance in that Schedule.”.

(2) In Schedule 1 Part II paragraph 2, sub-paragraph (c), for the words following “contains no substance” there shall be substituted the words —

“listed in Schedule 6 at a level which exceeds the maximum limit specified in relation to that substance in that Schedule.”.

**14.** After Schedule 4 there shall be added Schedules 5, 6 and 7 contained in the Schedule to these Regulations.

### **Consequential amendments**

**15.—**(1) In Schedule 1 to the Food Safety (Sampling and Qualifications) Regulations 1990<sup>(a)</sup> (provisions to which those Regulations do not apply) the reference in the second column, opposite to the reference in the first column to the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999 shall be amended insofar as it applies to England so as to read “S.I. 1999/1540 as amended by S.I. 2000/656, S.I. 2003/666 and S.I. 2004/656”.

(2) In the Food Safety (General Food Hygiene) Regulations 1995<sup>(b)</sup> in paragraph (1) of regulation 2 (interpretation), in the definition of “water”, after the words “as amended by the Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2003” there shall be inserted the words “and the Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2004”.

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<sup>(a)</sup> S.I. 1990/2463.

<sup>(b)</sup> S.I. 1995/1763.

Signed by authority of the Secretary of State for Health

8th March 2004

*Melanie Johnson*  
Parliamentary Under Secretary of State,  
Department of Health

## SCHEDULE

Regulation 14

### SCHEDULES 5, 6 AND 7 TO BE ADDED TO THE NATURAL MINERAL WATER, SPRING WATER AND BOTTLED DRINKING WATER REGULATIONS 1999

## SCHEDULE 5

Regulation 2

### CONDITIONS FOR TREATMENT OF NATURAL MINERAL WATERS AND SPRING WATERS WITH OZONE-ENRICHED AIR

1. Treatment of natural mineral waters and spring waters with ozone-enriched air shall only be carried out if —

- (a) it is for the purpose of separating compounds of iron, manganese, sulphur and arsenic from water in which they occur naturally at source;
- (b) prior to treatment the water satisfies regulation 8 of these regulations;
- (c) the treatment does not have a disinfectant action.

2. Treatment of natural mineral waters and spring waters with ozone-enriched air shall not —

- (a) modify the physico-chemical composition of the water in terms of its characteristic constituents;
- (b) leave residues in the water which could pose a risk to public health, or, in the case of the substances listed below, above the levels specified:

<i>Treatment residue</i>	<i>Maximum limit (<math>\mu\text{g/l}</math>)</i>
Dissolved ozone	50
Bromate	3
Bromoforms	1

3. A person seeking to have a process of treatment with ozone-enriched air authorised shall —

- (a) make application 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 14;
- (c) provide such information in support of the application as is requested by the relevant authority.

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

- (a) the treatment process is justified by the composition of the water at source;
- (b) the person carrying out the treatment is taking all necessary measures to ensure that the treatment is effective and safe;
- (c) the treatment process otherwise complies with paragraphs 1 and 2 of this Schedule.

**5.**

- (a) Where the relevant authority decides to authorise a treatment process pursuant to paragraph 4 above, it shall inform the operator of the treatment process in writing, and state the date on which the authorisation for commercial use of the process begins.
- (b) Where the relevant authority refuses to authorise a treatment process pursuant to paragraph 4 above, it shall inform the operator of the treatment process in writing, stating its reasons.

**6.** Where a treatment process has been authorised pursuant to paragraph 4 above, the person carrying out the treatment process must continue to allow periodic examination of the treatment process by the relevant authority by the methods in paragraph 3(b) and (c), for the purpose of assessing whether the conditions in paragraph 4(a) and (b) continue to be satisfied.

**7.** If the relevant authority is satisfied that the conditions in paragraph 4 above are no longer fulfilled, it may withdraw its authorisation of a treatment process by giving the person operating that process a written notice stating the grounds for withdrawal.

**8.**

- (a) Where the relevant authority decides either not to grant or to withdraw authorisation of a treatment process under paragraph 5(b) or paragraph 7 above, the person who wishes to carry out the treatment process may apply to the Agency for a review of that decision.
- (b) Upon receiving the application for review the Agency shall make such inquiry into the matter as may seem to the Agency to be appropriate, and having considered the results of that enquiry and any relevant facts elicited by it, shall either confirm the decision or direct the relevant authority to grant or restore, as appropriate, authorisation of the treatment process in operation. In the case of such a direction the relevant authority shall thereupon comply with the said direction.

## SCHEDULE 6

Regulation 7A

### MAXIMUM LIMITS FOR CONSTITUENTS OF NATURAL MINERAL WATERS

<i>Constituents</i>	<i>Maximum limits (mg/l)</i>
Antimony	0.0050
Arsenic	0.010 (as total)
Barium	1.0
Cadmium	0.003
Chromium	0.050
Copper	1.0
Cyanide	0.070
Fluoride	5.0
Lead	0.010
Manganese	0.50
Mercury	0.0010
Nickel	0.020
Nitrate	50
Nitrite	0.1
Selenium	0.010

**Notes:**

1. The constituents described above refer to constituents naturally present in the water at source and not to substances present as the result of contamination.

## SCHEDULE 7

Regulation 7A

### PERFORMANCE CHARACTERISTICS FOR ANALYSING THE CONSTITUENTS IN SCHEDULE 6

<i>Constituent</i>	<i>Accuracy of parametric value in %</i>	<i>Precision of parametric value</i>	<i>Detection limit of parametric value in %</i>
Antimony	25	25	25
Arsenic	10	10	10
Barium	25	25	25
Cadmium	10	10	10
Chromium	10	10	10
Copper	10	10	10
Cyanide	10	10	10
Fluoride	10	10	10
Lead	10	10	10
Manganese	10	10	10
Mercury	20	10	20
Nickel	10	10	10
Nitrate	10	10	10
Nitrite	10	10	10
Selenium	10	10	10

**Notes:**

1. The method of analysis used to measure the concentration of the constituents in Schedule 6 shall be able to measure at least concentrations equal to the parametric value with the specified accuracy, precision and detection limits.

2. Regardless of the sensitivity of the method of analysis, the result must be expressed to the same number of decimal places as the maximum limit set out in Schedule 6 for the particular constituent being analysed.

3. Accuracy is the systematic error and represents the difference between the average value of a large number of repeated measurements and the exact value.

4. Precision represents the random error and is expressed in general as the standard deviation (within a batch and between batches) of a sample of results from the average.

5. Acceptable precision is equal to twice the relative standard deviation.

6. The detection limit is either —

- (a) three times the relative standard deviation within a batch of a natural sample containing a low concentration of the constituent; or
- (b) five times the relative standard deviation within a batch of a virgin sample.

7. The method used to detect cyanide must be such that it is possible to determine total cyanide in all its forms.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations, which apply to England only, implement Commission Directive 2003/40 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters. They amend the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999.

The Regulations —

- (a) prescribe a definition of authorised ozone-enriched air oxidation technique (*regulation 3 and the Schedule*);
- (b) allow, for the first time, treatment of natural mineral waters with an authorised ozone-enriched air oxidation technique (*regulation 4*);
- (c) set maximum limits for certain naturally-occurring substances in natural mineral water and standards for methods used to detect these substances (*regulation 5 and the Schedule*);
- (d) provide for a defence for products produced in other EEA States which do not yet conform to the limits, where the EEA State concerned has not yet implemented those limits and the deadline for implementation has not yet passed (*regulation 5*);
- (e) prohibit the treatment of natural mineral water with unauthorised ozone-enriched air oxidation techniques (*regulation 6*);
- (f) provide for an appropriate form of labelling indication on natural mineral water where it has undergone an authorised treatment with ozone-enriched air or where it contains a high level of fluoride (*regulation 7*);
- (g) prohibit the sale of natural mineral water without the applicable labelling indications (which will become an offence by virtue of the operation of regulation 17 of the principal Regulations the penalty for which is specified by regulation 17 of the principal Regulations as being a fine not exceeding level 5 on the standard scale) (*regulation 8*);
- (h) provide for an appropriate labelling indication where a spring water has undergone an authorised ozone-enriched air oxidation technique and prohibit its sale without that labelling indication (which will become an offence by virtue of the operation of regulation 11(5) of the principal Regulations, the penalty for which is specified by regulation 17 of the principal Regulations as being a fine not exceeding level 5 on the standard scale) (*regulation 9*);
- (i) prohibit bottling or sale of water described as spring water if treated with an unauthorised ozone-enriched air oxidation treatment (*regulation 10*);
- (j) create offences in relation to the prohibitions mentioned in paragraphs (c), (e) and (i) above (subject to penalties provided for in the principal Regulations as being a fine not exceeding level 5 on the standard scale) (*regulation 11*);
- (k) introduce a transitional defence to allow the use of stock products bottled and labelled before 1st July 2004, where the product would otherwise be legal under existing law (*regulation 12*);
- (l) provide that the maximum limits in the new Schedule 6 to be added to the principal Regulations shall be the relevant limits for recognition of a natural mineral water, replacing the limits in Schedule 3 to the principal Regulations for this purpose (*regulation 13*);
- (m) insert a new Schedule 5 into the principal Regulations, which sets down —
  - (i) conditions to be satisfied before an ozone-enriched air oxidation technique can be authorised;
  - (ii) a process for obtaining a written authorisation for a treatment from a district council or London Borough;

- (iii) a requirement to allow officers of the relevant authority to conduct periodic examinations of the process in order to check that the treatment continues to be necessary and is effective and safe;
- (iv) the ability of an authority to withdraw authorisation by means of a written notice if conditions are not observed;
- (v) a mechanism for applying to the Food Standards Agency for review of an authority's decision not to grant or to withdraw authorisation (*regulation 14, Schedule*);
- (n) insert a new Schedule 6 into the principal Regulations, setting down maximum limits for certain naturally-occurring substances in natural mineral water (*regulation 14, Schedule*);
- (o) insert a new Schedule 7 containing standards for scientific methods used to detect the substances specified in Schedule 6 (*regulation 14, Schedule*);
- (p) make consequential amendments to the Food Safety (Sampling and Qualification) Regulations 1990 and the Food Safety (General Food Hygiene) Regulations 1995 to bring up to date references to the principal Regulations (*regulation 15*).

A full Regulatory Impact Assessment has been prepared and placed in the Library of each House of Parliament, together with a Transposition Note setting out how the main elements of the European legislation referred to above are transposed in these Regulations. Copies may be obtained from the Food Labelling and Standards Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.

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