

EXPLANATORY MEMORANDUM TO
THE NATURAL MINERAL WATER, SPRING WATER AND BOTTLED DRINKING
WATER (ENGLAND) REGULATIONS 2007

2007 No. 2785

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Description

This Statutory Instrument consolidates the existing requirements of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999 (SI 1999 No 1540) as amended by the Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2003 (SI 2003 No. 666) and the Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2004 (SI 2004 No 656).

The existing Statutory Instruments implement all existing European legislation relating to natural mineral water, spring water and bottled drinking water and, by virtue of the consolidation, so will the 2007 Regulations.

3. Matters of special interest to the Joint Committee on Statutory Instruments

None

4. Legislative Background

The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999 and subsequent amendments (in 2003 and 2004) transpose the requirements of European Directives 80/777/EEC as amended by 96/70/EC; 98/83/EC and 2003/40/EC. The Regulations lay down requirements for the exploitation, bottling, labelling or other marking and sale of natural mineral water, spring water and bottled drinking water. Limits are set for certain chemical and microbiological parameters in the water to ensure the quality and safety of bottled water.

The 1999 Regulations require to be read with the instruments amending them and also substantial cross reference to the parent Directives. The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 consolidate these existing requirements and substantially reduce the need for cross reference to EC legislation. The new Regulations have been drafted under the Agency's Simplification Plan.

The Ministerial powers under which the Regulations are made are Sections 16(1), 17(1), 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.

5. Extent

This instrument applies to England. Separate but parallel legislation is being drawn up in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

In the UK the bottled water industry is worth £1,680 million per annum (market retail value). This industry is currently governed by the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999 (as amended).

UK trade associations and enforcement authorities have previously cited difficulties in interpreting the complex requirements when spread across three Statutory Instruments. The need to cross-refer to EC Directives further complicates the reading of the Regulations. The proposal to consolidate and simplify the existing requirements was supported by enforcement authorities and trade associations. This piece of legislation is incorporated in the Agency's simplification plan.

A 12-week public consultation of over 250 interested parties was carried out on the draft consolidated Regulations, accompanying draft regulatory guidance and partial Regulatory Impact Assessment (RIA). The consultation concluded on 12 August 2006.

Thirty six responses (of which four responded with 'no comment' on the consolidation) were received to the public consultation in England. Although five respondents welcomed the consolidated Regulations, the majority (i.e. 19) registered objections to the proposed redrafting of Paragraph 1(d), Part 1 of Schedule 8 (Requirements for spring water and drinking water including prescribed concentrations or values of parameters), i.e. the so-called minimum hardness provision.

The current 1999 Regulations require that the hardness of spring water and bottled drinking water which has been softened or desalinated is not below a minimum concentration of 60 milligrams of calcium (ion) per litre, so tacitly permitting minerals to be added back to the treated water to meet this requirement. However, the proposed revised provision in the draft Regulations effectively prohibited the addition of minerals by requiring that the treated water must not have its hardness reduced below the minimum value. The changed wording was proposed to better reflect the available UK scientific advice at that time, to ensure that health benefits associated with hard water were not removed by excessive softening/desalination.

Present-day industry practice has been developed on the basis of the existing requirement, which originates from Council Directive 80/778/EEC (relating to the quality of water intended for human consumption, now revoked). The FSA received an overwhelming response from industry stating that such a prohibition would be impractical and the

current market place would be adversely affected, meaning further process requirements would be placed on bottled water producers. In view of the responses to the public consultation and technical notification, the FSA has accepted that allowing remineralisation is likely to confer similar benefits to limiting the degree of softening, while being a proportionate response to the problem and not imposing a de facto prohibition on certain treatment methods currently in use. By retaining the existing wording (as in SI 1999/1540 as amended) more flexibility in achieving the minimum hardness is permitted, but where beneficial minerals are removed by processing, their reinstatement is ensured.

The minimum hardness provision is a national provision and a technical notification (Directive 98/34/EC) was submitted by England (and devolved administrations) to the European Commission. In response, to feedback from Member States and the Commission, the UK submitted detailed information on intra-community trade and informed the Community of its intention to allow remineralisation of softened or desalinated water so as to meet the minimum requirement.

8. Impact

A Regulatory Impact Assessment (RIA) has been prepared for this statutory instrument and is attached to this memorandum at Annex 1.

The consolidation is expected to yield a benefit to Industry, enforcement authorities and consumers.

9. Contact

Dr Nigel Harrison at the Food Standards Agency (Tel: 020 7276 8177) or E-mail: nigel.harrison@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

FINAL REGULATORY IMPACT ASSESSMENT

TITLE OF PROPOSAL

The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007

PURPOSE & INTENDED EFFECT OF THE REGULATIONS

- 1.1 Since the publication of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (SI 1999/1540), two amendments have come into force (SI 2003/666 and SI 2004/656). The consolidation of these three Statutory Instruments is intended to clarify the detailed legislative requirements and so reduce burdens on the bottled water producers and enforcement authorities.
- 1.2 The consolidation is intended to make the Regulations clearer and more user-friendly. This would reduce the risk of the Regulations being misinterpreted and ensure consistent application of chemical, microbiological and labelling requirements thus enhancing the consumer safety elements of the legislation and ensuring that consumers have an accurate basis on which to choose a product.
- 1.3 The 1999 Regulations (as amended) contain a number of cross-references to the Directives that they implement¹. By increasing the instances in which text from the parent European legislation is transposed into the 2007 Regulations, it is intended that the need to cross-refer with the Directives will be reduced.
- 1.4 The Regulations are applicable to the three types of bottled drinking water: natural mineral water, spring water and bottled drinking water. The regulatory requirements vary between each type. The Regulations have been restructured and the language simplified for clarity and to aid interpretation. Parts 2, 3 and 4 of the Regulations deal separately with each type of bottled drinking water, and within each part, the separate stages of manufacture and sale of the particular product.

¹ Council Directive 80/777/EEC OJ No L 229, 30.8.1980, p. 1
Directive 96/70/EC of the European Parliament and of the Council OJ No L 229, 23.11.96, p. 26
Council Directive 98/83/EC OJ No L 330, 5.12.98, p. 32
Commission Directive 2003/40/EC OJ No L 126, 22.5.2003, p. 34

- 1.5 The Regulations require that spring water and bottled drinking water which has been softened or desalinated must meet a minimum level of water hardness. Council Directive 80/778/EEC (now revoked) set a minimum concentration for softened or desalinated water intended for human consumption of 60 mg/L of calcium (Ca) or equivalent cations. In 1994 the Committee on Medical Aspects of Food Policy (COMA)² advised that it remained prudent not to undertake softening of drinking water supplies and as such the minimum hardness requirement remained in UK law by way of Statutory Instrument No. 1999/1540. The requirement has been retained in the 2007 Regulations for the purposes of public health.
- 1.6 These Regulations do not apply to packaged ice portions (ice cubes) intended for use in cooling food and drink (as laid down in Exemptions (2)). There is an emerging and fast growing industry in making ice cubes for sale in bags to the public made from spring water or purified water. It is understood that there are considerable practical difficulties for the producers to comply with the minimum hardness provision when manufacturing ice as opposed to water. The Agency's position is that bags of small-portioned ice cubes are not intended to be regulated by these Regulations, though freezing water in a bottle/container to later be defrosted and drunk would be. The new exemption will put any confusion on the applicability of the regulations to portions of ice intended for cooling food beyond doubt.
- 1.7 The Regulations reduce the lower limit for pH in spring water and bottled drinking water (i.e. from pH 6.5 to pH 4.5) in line with the requirements of Council Directive 98/83/EC on the quality of water intended for human consumption.
- 1.8 The Regulations provide for retained parts of samples, obtained by authorised officers of food authorities, be submitted for secondary analysis to the Government Chemist in specified circumstances.

CONSULTATION

Regarding the consolidation of existing regulations

² COMA- established in 1963 to provide expert advice to the UK Department of Health and other UK Government Departments on medical and scientific aspects of nutrition in relation to policy

- 1.9 The UK Food Standards Agency has undertaken a public consultation on the draft Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (England) 2007. The partial Regulatory Impact Assessment was distributed as part of the 12-week public consultation. Approximately 250 interested parties including: other government departments, industry representatives, enforcement authorities, consumer groups, health professionals (via professional associations), and NGOs were invited to submit comments on the draft Regulations, as well as the partial regulatory impact assessment and draft regulatory guidance.
- 1.10 Governmental departments included in the consultation were the Department of Health, the Department of Environment, Food and Rural Affairs (DEFRA), the Office of Fair Trading and Small Business Services. Food Standards Agency Scotland, Wales and Northern Ireland have been involved in a continuous cycle of consultation and feedback in drafting equivalent legislation for devolved administrations.
- 1.11 The draft Regulations were notified to the European Commission in order to fulfil UK obligations under Directive 98/34/EC, in relation to the notification of technical standards. A World Trade Organization (WTO) Technical Barrier to Trade (TBT) notification was also distributed via the Department for Business, Enterprise and Regulatory Reform (formerly the Department of Trade and Industry) allowing WTO members to comment on the minimum hardness provision. This provision is mandatory for all softened or desalinated bottled water sold in the UK.

OPTIONS

1.12 Option 1 – No action (no consolidation)

- 1.12.1 If no intervention is made, enforcement bodies and stakeholders would need to continue to refer to the three Statutory Instruments and ensure that they have used the appropriate Regulations (as amended in relation to England) with the current requirement to cross refer to the parent EC legislation frequently.

1.13 Option 2 – Consolidation of existing regulations

- 1.13.1 Consolidation of the existing requirements would provide enforcement bodies and stakeholders with a single Statutory Instrument against which compliance with the law

can be measured. The language used within the 2007 Regulations is more accessible and the requirements more clearly defined and separated between different types of water. There will be less scope for differing interpretation of the Regulations. Inclusion of the exemption of ice used for cooling and the provisions for secondary analysis by the Government Chemist further clarifies the scope and procedural steps of the regulations.

1.13.2 The Food Standards Agency routinely receives requests for information regarding the Regulations from local authorities, industry and consumers (averaging about 30 a month). Private companies produce unofficial consolidated Regulations at their customers' request. This indicates a demand for these consolidating Regulations. Furthermore, the complexity of the existing Regulations is recognised by virtue of this piece of legislation's inclusion in the Agency's Simplification Plan.

COSTS & BENEFITS

1.14 Sector groups affected

1.14.1 The Regulations apply to producers and bottlers of natural mineral waters, spring waters and bottled drinking waters. Charities and the voluntary sector that are involved in the production or sale of bottled water will be subject to the same requirements as other sectors of the industry.

1.14.2 In 2006, bottled water accounted for 15.9% of the total UK soft drinks market and had a retail value of £1,680 million. Sales of bottled water reached 2,275 million litres, 68% of which was attributed to natural mineral water sales, 19% for spring water and 13% for other bottled drinking water.

1.14.3 In the absence of more detailed data for 2006, further analysis of the bottled water sector has been undertaken using data from 2005. In 2005 sales of bottled water were estimated at 2,170 million litres and the water cooler sector accounted for 20% of these sales (the remainder being packaged water).

1.14.4 In 2005 the leading three brands (all packaged water) accounted for 18.1%, 11.5% and 9.1% of the UK bottled water market. The leading cooler water brand accounted for 5.7% of the market.

- 1.14.5 A total of 587.5 million litres of bottled water (inc. natural mineral water, spring water and bottled drinking water) was imported into the UK in 2005, which equated to 25.4% of the total market share. Imports from Member States accounted for 97% of this volume, with the majority imported from France (90%), Ireland (3.2%) and Italy (3.0%).
- 1.14.6 Retail sales accounted for 1,509.7 million litres whereas 660.3 million litres was consumed away from home (i.e. horeca³; pubs and clubs, offices). Distribution figures for 2005 show that supermarkets accounted for the majority of sales (49.9%), followed by offices (19.7%), independents (18.3%), horeca etc. (9.8%) and door-to-door sales (1.4%).
- 1.14.7 The latest figures show that the UK population consumed (on average) 37.6 litres per person in 2006. A study carried out between October 2004 and September 2005 showed that the proportion of adults (aged 15 and above) who consumed bottled water was estimated at 55%. Those which consumed bottled water more than once a week account for 28%. The data showed that consumption of bottled water reduces with age; 64% of 15-24 year olds drink bottled water compared to 37% in the 65+ range.

1.15 Benefits

Producers

- 1.15.1 Producers of bottled drinking water will benefit from the Regulations, as they will provide an unambiguous set of regulatory requirements that are clearly defined with respect to the type of bottled water, i.e. a clearer distinction for maximum parameters for the three different types of water.
- 1.15.2 Based on previous work for simplification of this Regulation, a technical or regulatory affairs manager from any of the 64 UK bottled water producers spends around 2-3 days on average working with local authorities discussing legislation. Also many companies will employ consultants to aid their work with legislation. It has been proposed that benefits will be enjoyed through cost savings occurring from less pressure on the time of managers and consultants. It has been estimated that £79,500 every year would be saved by the bottled water industry through this legislation.

³ "Horeca" meaning hotels, restaurants and catering

1.15.3 Producers of spring water and bottled drinking water will be permitted to have lower levels of pH which are appropriate for bottled waters and are aligned to the requirements of Directive 98/83/EC. There are no health implications for changing this limit.

Local Authorities

1.15.4 Local Authorities will benefit from having a single consolidated statutory instrument to use for enforcement. It will provide a means for more effective and uniform enforcement by Local Authorities. Local authority responses to the consultation cited that the consolidated regulations would be “more efficient” and praised the general structure of the draft Regulations. In particular one respondent noted that the inclusion of text from the EC Directives would aid work and meetings undertaken away from the office.

Consumers

1.15.5 The consumer will benefit from more effective enforcement, and additionally, the maintenance of the requirement for a minimum level of water hardness which, epidemiological studies show, produces positive health effects. This could therefore improve consumer health, though by what amount is not calculable at this time.

1.16 Costs

The following estimates of implementation and policy costs are estimated using the available information and that provided during the consultation process.

1.16.1 Natural mineral water producers

The mandatory requirements for natural mineral water are unchanged in the consolidated version and therefore no additional policy or administrative costs are envisaged.

1.16.2 Spring water and bottled drinking water producers

The minimum hardness requirement for bottled water originates from Directive 80/778/EEC relating to the quality of water intended for human consumption. The requirement is currently in the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999. Under previous and existing regulations the level of water hardness for spring waters and bottled drinking waters that have been softened or desalinated *must not be below* a prescribed minimum (measured as 60 milligrams of calcium ion per litre).

The originally proposed redrafted provision required that softened or desalinated water *must not be reduced below* the existing limit for water hardness. This was based on advice provided in 2003 by a Department of Health official who advised that because the properties of water hardness that provide the benefits to cardiac health are not known, the aim should be to retain rather than re-introduce minerals. The intention of this advice was to take a precautionary approach by preventing the supply of water, being excessively artificially softened, whether or not it is then treated to "re-harden" it. This advice was felt to be more in keeping with the COMA opinion (Para 2.5). In consolidating the existing regulations, the Agency proposed to clarify the wording of the minimum hardness provision to better reflect this original advice.

The Agency specifically asked for comments on the proposed re-wording and for estimates of any associated costs and benefits. UK industry representatives informed the Agency that available treatment methods (e.g. reverse osmosis) cannot remove minerals to a predetermined level. Respondents raised concerns that the proposed text would incur a high cost to industry, particularly the bottled water cooler sector (20% of UK market). The Agency has been informed that de/remineralisation is extensively used in the bottled water cooler sector and that current practices have been built around existing statutory requirements. Industry representatives have estimated that 62% of UK bottled water cooler producers will be affected by the retention of the redraft and that this may result in a potential loss of 3000 jobs due to plant closures. One respondent quoted a cost to them of £1 million pounds (i.e. 12.5% of annual turnover).

The scientific basis for the redrafted provision has also been challenged by industry. Recently, UK bodies and international expert committees have further scrutinised the available epidemiological evidence regarding health benefits associated with hard water and its principal components, i.e. calcium and magnesium ions.^{4,5} In April 2006, an international symposium examined the roles of both calcium and magnesium in drinking water, in terms of health benefits. The intention of the symposium was to present a wide range of perspectives regarding the question of the value of providing drinking water with

⁴ Nutrients in Drinking Water, Water, Sanitation and Health Protection and the Human Environment, World Health Organisation, Geneva, 2004: http://www.who.int/water_sanitation_health/dwg/nutrientsindw.pdf

⁵ Catling, L., Abubakar, I., Lake, I., Swift, L. and Hunter, P. (University of East Anglia and Drinking Water Inspectorate), 2005, Review of evidence for relationship between incidence of cardiovascular disease and water hardness, Final Report for DWI/70/2/176: <http://www.dwi.gov.uk/research/Water%20hardness%20final%20report1.pdf>

a small amount of magnesium and/or calcium. A number of health aspects were considered, including (but not exclusively) osteoporosis, hypertension, stroke and insulin resistance. Epidemiological studies of water hardness and cardiovascular disease were also considered. Although this report did not support a relationship between water hardness (calcium) and cardiovascular disease, it did strongly recommend that further well designed epidemiological studies should be undertaken to elucidate the health implications of waterborne calcium and magnesium. We understand that the findings of the symposium are not conclusive and will be subject to further review (by a World Health Organisation (WHO) Expert Committee and Guideline activities) before WHO decides what further actions are to be taken.

In view of these on-going assessments we consider that it is precautionary to retain a minimum hardness provision for treated bottled water to avoid removal of any potential health benefit. It is considered that allowing the continued practice of remineralisation is likely to confer similar benefits to limiting the degree of softening, which the industry has advised would pose a major technological problem. This approach is a proportionate response to the problem whilst not prohibiting certain treatment methods commonly in use.

The Agency has received only one response welcoming the proposed redrafted provision, which was from a Local Authority.

Given the information provided, the existing (in force) minimum hardness provision has been retained in the 2007 Regulations, thus maintaining the status quo (i.e. remineralisation of treated water is permitted). As such no additional costs are anticipated for spring water and bottled drinking water producers currently using softening and desalination techniques.

1.17 Local Authorities

The consolidation of existing requirements will not in itself incur any additional costs to local authorities or require any long term resources as there are no new requirements.

6 SMALL FIRM IMPACT TEST

- 6.1 The bottled water industry is dominated by six major brands that share 69% of the market (top 5 companies claiming 50% of the market alone). To assess the potential impact of the

consolidated Regulations on small businesses the Agency contacted five micro-enterprises (i.e. businesses with fewer than ten full-time employees). The companies selected represent a range of business types that are affected by the UK bottled water Regulations and include producers of bottled water, a broker of water products and a marketing firm. The distribution of business for these companies ranged from being local to national.

- 6.2 Given enough time, none of the small businesses had particular difficulty in understanding the current Regulations; however three had employed private consultants and all had extensively utilised their local authorities as a source of advice. The time invested by a small firm in understanding the Regulations was fairly burdensome, with one business estimating that they had spent six weeks working with the Regulations. All five small businesses enthusiastically expressed their support for the consolidation stating that it would reduce the burden on them by making the interpretation of the Regulations easier and less time consuming.
- 6.3 Although the minimum hardness criterion did not pose a problem for any of the five businesses consulted, a consultation response indicated otherwise. The text of the minimum hardness provision has now been reverted to that which has been in force since 1999. Therefore no additional costs to small businesses are expected as a result of continuing the status quo.

COMPETITION ASSESSMENT

- 6.4 In light of the available information, the market will be defined as that for all unflavoured bottled water. Any substitution is more likely to be demand side than supply side, because of the tight controls on origin for the product.
- 6.5 The level of competition is already quite high with much use being made of product differentiation to attract different types of consumer. Danone Waters (UK & Ireland) Ltd accumulated 392 million litres sales in 2005 (18% of the UK bottled water market) with its Evian and Volvic brands doing particularly well. UK's Highland Spring comes in second with 249 million litres (11.5% of the market). Growth has been steadily positive for these brands with an increasing market over the past 5 years.
- 6.6 A competition filter test was performed and it indicated that this policy would not have a significant impact on competition (subject to the assumption that the cost of ensuring the

calcium content of water does not substantially impact on small firms, which may be predisposed to producing spring and bottled drinking waters).

- 6.7 This policy may prove to lower existing barriers to entry, which themselves are reducing as demand increases and extraction processes become more efficient. It is not likely this policy will have a detrimental effect on competition; indeed it may further promote it. There has been a steady increase in the bottled water market of the UK and Zenith International envisages a continual increase in this market by at least 7% per year especially with greater education of the health benefits of water over soft drinks and the elimination of soft drinks and vending machines from schools within the UK.

SUSTAINABLE DEVELOPMENT

- 6.8 Many aspects have already been considered, such as the benefit to industry through time saved; the cost to the public sector through the need to reassess producers' practices, and potential benefits to consumers through the retention of the health provision. Bottled water consumption peaks with consumers aged 15-24, so any consumer impact (positive or negative) will be borne most by this group. There is no evidence to suggest particular ethnic or social groups will be affected disproportionately by what is, in effect, an impact that is marginal to start with.

ENFORCEMENT, SANCTIONS & MONITORING

- 6.9 Trading Standards Officers and Environmental Health Officers will enforce the Regulations. Officials will maintain regular contact with LACORS and relevant trade associations to monitor compliance with, and enforcement of, these Regulations.
- 6.10 Enforcement of the England Regulations will be the responsibility of Local Authority Trading Standards and Environmental Health Departments. This remains unchanged from the existing enforcement arrangements.
- 6.11 Each Port Health Authority shall enforce and execute these Regulations in its district in relation to imported food. This remains unchanged from the existing enforcement arrangements.

6.12 The penalty on conviction for an offence under these Regulations is a fine not exceeding level 5 on the standard scale (currently £5,000).

IMPLEMENTATION & DELIVERY PLAN

6.13 The Statutory Instrument will be laid before Parliament with a coming into force date of 31 October 2007.

6.14 Guidance on compliance with the Regulations has been produced and has been subject to a 12 week public consultation. In light of responses to the consultation, the Guidance has been amended to produce a final document which will be published on the Agency's website. Interested parties will be informed of the coming into force date and revised Guidance. Training will be offered to Enforcement Authorities by way of workshops.

POST IMPLEMENTATION REVIEW

Feedback from industry and enforcement authorities is anticipated via routine correspondence. Any difficulties with the Regulations or Guidance notes will be reviewed as necessary on a case-by-case basis. If the Regulations are subsequently amended as a consequence of Community legislation, then the Guidance will be updated accordingly.

SUMMARY & RECOMMENDATION

6.15 Two options have been identified, which are 1) to take no action or 2) to consolidate existing requirements.

6.16 Option 2 is preferred as it will provide industry and enforcement authorities with a single Statutory Instrument which is easier to comprehend than existing legislation. By virtue of this consumers will benefit from more equitable and effective application of the Regulations and facilitation of compliance from stakeholders will enhance consumer safety elements of the legislation. Further financial benefits are foreseen for industry with an estimated saving of £79,500 per annum.

DECLARATION

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed *Dawn Primarolo*

Date *19th September 2007*

Dawn Primarolo MP
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