

## EXPLANATORY MEMORANDUM TO

### THE NATURAL MINERAL WATER, SPRING WATER AND BOTTLED DRINKING WATER (ENGLAND) (AMENDMENT) REGULATIONS 2018

2018 No. 352

#### 1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs (Defra) and is laid before Parliament by Command of Her Majesty

#### 2. Purpose of the instrument

- 2.1 These Regulations ('the 2018 Regulations') amend the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 (S.I. 2007/2785), as amended ('the 2007 Regulations'), which govern the exploitation, bottling and marketing of natural mineral water, spring water and other bottled drinking water.
- 2.2 The 2018 Regulations amend the 2007 Regulations by:
- a) including provisions in the 2007 Regulations that implement Directive 2013/51 EURATOM laying down requirements for the monitoring of radioactive substances in water intended for human consumption in so far as those requirements apply to bottled water;
  - b) including provisions in the 2007 Regulations that implement Commission Directive (EU) 2015/1787 amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption in so far as those requirements apply to bottled water;
  - c) removing an outdated requirement to ensure a calcium carbonate content of 60mg/l for any bottled spring water and bottled drinking water which has been softened or desalinated;
  - d) introducing a lighter touch enforcement regime in the 2007 Regulations moving from a purely criminal based approach to one based on improvement notices, with appeals against such notices going to the First-tier Tribunal. This approach includes a supporting criminal offence of a failure to comply with an improvement notice. This is in line with Government policy and uses a more proportionate approach on food enforcement by Defra for similar food composition and standards Regulations over the last few years.

#### 3. Matters of special interest to Parliament#

##### *Matters of special interest to the Joint Committee on Statutory Instruments*

- 3.1 None.

##### *Other matters of interest to the House of Commons*

- 3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

#### **4. Legislative Context**

- 4.1 EU legislation regulates the quality of water for human consumption. Some of that legislation has been in place since the 1980s. The legislation regulates public and private supplies of water as well as bottled water. These 2018 Regulations relate to bottled water.
- 4.2 Bottled water falls into three separate categories, natural mineral water, spring water and other bottled drinking water (often known as table water).
- 4.3 The main EU legislation regulating natural mineral water is Directive 2009/54/EC of the European Parliament and of the Council on the exploitation and marketing of natural mineral waters.
- 4.4 The main EU legislation regulating spring water is (a) Directive 2009/54/EC (which applied, initially, just to natural mineral water but was extended to apply to spring water in 1997), (b) Council Directive 98/83/EC on the quality of water for human consumption and (c) Directive 2013/51/Euratom laying down requirements for the protection of health of the general public with regard to radioactive substances in water intended for human consumption.
- 4.5 Directive 98/83/EC and Directive 2013/51/Euratom also apply to bottled drinking water but not Directive 2009/54/EC.
- 4.6 Directive 98/83/EC sets quality standards and provides for monitoring, including the setting of microbiological and chemical parameter levels. Further information is provided in paragraph 7.4 below.
- 4.7 Directive 2013/51/Euratom is concerned with radiological controls. It contains regulatory and monitoring requirements for radon and tritium and for checking the indicative dose (the level at which it is safe for humans to ingest radionuclides in water). Further information is provided in paragraph 7.3 below.
- 4.8 All EU legislation relating to bottled water, including Directives 89/83/EC, 2009/54/EC and 2013/51/Euratom, is implemented in England by way of The Natural Mineral Water, Spring Water and Bottled Water (England) Regulations 2007 (S.I. 2007/2785), which has been amended on a number of occasions,
- 4.9 The 2018 Regulations amend the 2007 Regulations to implement the provisions of Directive 2013/51/Euratom and the amendments made to Directive 98/83/EC by Commission Directive 2015/1787. The Department is intending to consolidate the 2007 Regulations when a suitable opportunity arises but it is not certain when this will be.
- 4.10 Implementation of the EU requirements provisions relating to the public and private supply of water are contained in separate enabling Regulations.

#### **5. Extent and Territorial Application**

- 5.1 The extent of the Regulations is England and Wales.
- 5.2 The territorial application of the Regulations is England only.
- 5.3 Scotland, Wales and Northern Ireland have introduced their own separate but parallel Regulations.

## **6. European Convention on Human Rights**

- 6.1 The Secretary of State Michael Gove has made the following statement regarding Human Rights: “In my view the provisions of The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) (Amendment) Regulations 2018 are compatible with the Convention rights”.

## **7. Policy background**

### *What is being done and why*

- 7.1 The 2007 Regulations are being amended to implement EU Directives 2013/51/Euratom and 2015/1787 in order to comply with the UK’s EU obligations and provide the benefits that the implementation of those provisions bring,
- 7.2 The underlying objectives of these Directives is to protect human health and ensure good quality of water. The Directives take into account the World Health Organisation (WHO) approach to risk assessment in relation to the monitoring of bottled spring water and bottled drinking water.
- 7.3 The Regulations implement Directive 2013/51/Euratom which contains monitoring requirements for radon and tritium and for checking the indicative dose of bottled spring water and bottled drinking water. Natural Mineral Water is exempt from these requirements. Monitoring by local authorities is only required if an assessment by the relevant local authority determines that the radioactive limits laid down in the instrument are likely to be exceeded. The Regulations include exemptions from monitoring on a five-yearly basis if it can be established that the levels of radon or tritium and the level of the indicative dose will remain below those specified limits over that five year period.
- 7.4 The Regulations implement Commission Directive (EU) 2015/1787 which amends the monitoring and method of analysis provisions in Council Directive 98/83/EC for bottled spring water and bottled drinking water. It takes into account updated World Health Organisation (WHO) approaches to risk assessment in relation to the monitoring of water for human consumption.. The purpose of the provisions in Directive 98/83/EC is to provide for microbiological and chemical parameters in the water, as well as other parameters that indicate the quality of the water (indicative parameters), to be monitored in an appropriate way and to specify the methods of analysis that should be used in connection with such monitoring, taking into account scientific and technical progress. The amendments made by Directive (EU) 2015/1787 bring EU water requirements for bottled spring water and bottled drinking water up-to-date with international requirements relating to methods of analysis. It also makes changes to the monitoring frequencies with the aim of ensuring a level of monitoring and intervention by enforcement authorities that is proportionate, while ensuring a high degree of consumer safety. This it brings such waters into step with general food law requirements for food making it simpler for enforcers and food businesses.
- 7.5 As part of the Red Tape Challenge in 2015, it was decided that a national requirement contained in the 2007 Regulations relating to the hardness of water (which was allowed but not required by Directive 98/83/EC) could be deregulated. The provision imposed a minimum calcium carbonate content of 60mg/l for any bottled drinking water which has been softened or desalinated. The Regulations remove this requirement from the 2007 Regulations,

- 7.6 In line with Government policy on the use of appropriate enforcement mechanisms, the Regulations replace provisions in the 2007 Regulations that made it a criminal offence to contravene a substantive requirement in the Regulations with a regime based on the service of improvement notices. Under the amended 2007 Regulations a failure to comply with an improvement notice will (by the application of certain provisions in *The Food Safety Act 1990*) be a criminal offence. Businesses will be able to appeal against an improvement notice to the First-tier Tribunal (FTT). Criminal offences relating to the obstruction of officers will continue to apply.
- 7.7 The shift to using civil sanctions is part of a wider approach to avoiding the proliferation of unnecessary criminal offences and ensuring more effective and proportionate regulation.

## **8. Consultation outcome**

- 8.1 The policy areas covered and changes within the 2018 Amending Regulations have been the subject of two public consultations in 2015 and 2017/18.

### **Consultation October 2015**

- 8.2 A four week written public consultation relating to the implementation of Directive 2013/51/Euratom was held from 2 - 30 October 2015. Comments were also previously sought in 2015 on the proposed new enforcement regime, the implementation of the Euratom provisions on radionuclide monitoring and the removal of the provision imposing a minimum calcium carbonate content of 60mg/l for any bottled drinking water which has been softened or desalinated.
- 8.3 The consultations followed extensive informal engagement by the Department with interested parties and stakeholders on a number of issues. The 2015 consultation in England generated four formal responses; two from Local Authorities, one from a consultancy firm and one from a UK-wide trade association.
- 8.4 All the respondents were supportive of proposals to simplify the regulations by removing the hardness requirement relating to bottled drinking water and introducing an improvement notice-based enforcement regime. There was some concern over the different route of appeals for food hygiene notices and improvement notices (the route of appeal for a food hygiene notice is via the magistrates' courts, whereas appeals against improvement notices will be made to the First-tier Tribunal). The concern was that this could lead to confusion for businesses and extra costs for local authorities dealing with both types of appeal.
- 8.5 One Local Authority respondent was concerned about the potential for conflict to arise between the bottled drinking water regulatory requirements and the private water supply regulatory requirements.
- 8.6 The responses were supportive of the suggested proposals for monitoring radiation in bottled spring water and bottled drinking water which provides for initial assessments to be done to determine which radionuclides need to be monitored and allows for screening to be carried out to determine whether radionuclides in bottled spring water and bottled drinking water are likely to exceed the level at which the ingestion of such radionuclides is regarded as safe (known as the indicative dose). Where such assessments and screening indicate that there is no reason for concern, five year exemptions from the need for local authority monitoring apply. Respondents all agreed that monitoring should be based on identified risk and agreed that the minimum frequencies proposed for monitoring (where such monitoring is needed)

were appropriate. The majority of respondents would have preferred permanent exemptions to be granted rather than exemptions for five year periods. This five-year time-frame will be reviewed again in England in 2023. In the meantime, it mirrors the approach taken in similar Regulations in Scotland, Wales and Northern Ireland.

- 8.7 A summary of the responses to the consultation was published and placed on the Government website [here](#).

### **Consultation December 2017-January 2018**

- 8.8 A five week public consultation through Citizen Space ran between 14 December 2017 and 18 January 2018, relating to the implementation of Commission Directive (EU) 2015/1787. Respondents were asked to what extent they agreed or disagreed with the implementation, and were asked for additional comments.
- 8.9 The consultation in England generated 10 formal responses: two from trade associations; 3 from local authorities, one from industry and four from individuals. There were no petition, campaign or otherwise duplicated responses. The low level of response was possibly due to the very technical nature of the changes to monitoring arrangements and the updating of associated methods of analysis.
- 8.10 The responses by business trade associations were supportive of the proposed implementation. They were satisfied that there are sufficient safeguards in place for spring and bottled waters in general food safety and HACCP requirements (Hazard Analysis Critical Control Point as established by EC 852/2004 Article 5).
- 8.11 The response from local authorities was mixed. The reasons for agreeing included that they believed there are already sufficient safeguards for spring and bottled waters. There was no supporting information on why one local authority disagreed with the implementation.
- 8.12 Individual respondents raised concerns about the level of scrutiny over Food Business Operator (FBO) responsibilities, particularly around sampling frequency given resource constraints for local authorities. There were also concerns around the level of impact assessment conducted around the effect of the implementation on industry. The changes are in line with WHO recommendations on the risk assessment for bottled waters and moves away from a complicated number and volume based monitoring system to a more proportionate risk based hazard analysis and critical control point (HACCP) approach in line with other food products.
- 8.13 A summary of the responses to the consultation will be published and placed on the Government website GOV.UK

## **9. Guidance**

- 9.1 New [guidance](#) relating to the regulation of bottled water was issued by the FSA Wales and Northern Ireland on 27 October 2017. This guidance explains the requirements imposed by the Euratom Directive and the changes made by 2015/1787 as well as containing more general provisions relating to the regulation of all three types of bottled water. Although the guidance relates to legislation apply in Northern Ireland and Wales, much of its content is also relevant to the 2018 English Regulations.
- 9.2 It is envisaged that updated guidance relating to the English Regulations will be prepared in time. In the meantime, food business operators will be encouraged to make use of the guidance mentioned in paragraph 9.1.

## **10. Impact**

- 10.1 A full impact assessment was not undertaken in relation to the provisions in the Regulations relating to the implementation of Directive 2013/51/Euratom, the removal of the hardness requirement and the change in the enforcement regime due to their limited impact and de-regulatory nature.
- 10.2 The proposed regulatory changes in October 2015 were approved as low cost by the Regulatory Policy Committee. 'Regulatory Triage Assessments' (RTAs) were undertaken in 2014 and these assessments show that the total quantifiable net benefit is estimated to be around £0.15m (best estimate), with £0.12m as the minimum estimate and £0.17m as the maximum estimate, in net present value terms over the 10 year appraisal period from 2016-2025 for removal of gold-plating. No impact on charities or voluntary bodies was anticipated.
- 10.3 The impact of radiological monitoring requirements in Directive 2013/51/Euratom is estimated at a net cost to businesses of - £0.01 m with an Equivalent Net Annual Cost to Business estimated at - £691.00.
- 10.4 A Regulatory Triage Assessment validating the cost benefit analysis for the deregulation of the minimum water hardness requirement was undertaken.
- 10.5 In terms of the changes provided for in 2015/1787/EU, again a full impact assessment has not been undertaken as the changes were considered to be deregulatory and below the £5m threshold.
- 10.6 A Regulatory Triage Assessment was undertaken in 2017 and these assessments show that the total quantifiable net cost to businesses is estimated to be neutral. No impact on charities or voluntary bodies is anticipated.
- 10.7 Following changes to the process, the Regulatory Policy Committee did not scrutinise the RTA produced for the 2017 consultation. This is because the low cost Regulatory Triage Assessment threshold of £5m applied. There has been departmental self-certification instead.

## **11. Regulating small business**

- 11.1 This instrument applies to all businesses involved in the production of bottled drinking water, including a number of small businesses. The rules provide minimum composition and labelling requirements that are of benefit to the consumer and must be applied to all those operating in the sector
- 11.2 Significant efforts were taken to identify and contact as many small businesses as possible in England prior to both formal consultations.

## **12. Monitoring & review**

- 12.1 This instrument does not include a review clause (requiring the legislation to be reviewed after five years from the date of coming into force) in light of the latest Department of Business, Energy and Industrial Strategy guidance. (Statutory Guidance under s.31 of the Small Business, Enterprise and Employment Act 2015)

## **13. Contact**

- 13.1 Miguel A Arranz at the Department for Environment, Food and Rural Affairs (Tel: 020 84 15 29 28 or email: [miguel.arranz@defra.gsi.gov.uk](mailto:miguel.arranz@defra.gsi.gov.uk)) can answer any queries regarding the instrument.