EXPLANATORY MEMORANDUM TO

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015

This Explanatory Memorandum has been prepared by the Food Standards Agency (FSA) and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Member's Declaration

In my view the Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015. I am satisfied that the (monetised and non-monetised) benefits identified in the appraisal outweigh the costs.

Vaughan Gething
Deputy Minister for Health, one of the Welsh Ministers

4 November 2015

EXPLANATORY MEMORANDUM TO

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015

1. Description

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015 will consolidate all European and domestic requirements relating to Natural Mineral Water, Spring Water and Bottled Drinking Water into a single Statutory Instrument.

2. Matters of Special Interest to the Constitutional and Legislative Affairs Committee

None.

3. Legislative Background

The Regulations are made in exercise of the powers conferred on the Welsh Ministers by paragraph 1A of Schedule 2 to the European Communities Act 1972 ("the 1972 Act") and sections 6(4), 16(1), 17(1), 26(1), 31 and 48(1) of the Food Safety Act 1990 ("the 1990 Act").

The Welsh Ministers are designated for the purposes of section 2(2) of the 1972 Act in relation to measures relating to food (including drink) including the primary production of food and measures in relation to the veterinary and phytosanitary fields for the protection of public health. The relevant designation orders are the European Communities (Designation) (No. 2) Order 2005 and the European Communities (Designation) (No. 2) Order 2008. The 2005 Order conferred functions on the National Assembly for Wales. Those functions were transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006.

4. Purpose and Intended Effect of the Legislation

The objective of the Regulations is to

- 1. Consolidate existing Regulations
- 2. Introduce civil sanctions for most instances of non-compliance
- 3. Include new EU requirements for monitoring of radioactivity in water
- 4. Clarify permitted treatments for spring water in line with European requirements
- 5. No longer require the fortification of water with calcium up to a level of 60 mg/l in the case where it has been softened or desalinated

1) Consolidation of existing Regulations

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007 ("The 2007 Regulations") have been separately amended three times in 2009, 2010 and 2011, so a consolidation of these amendments into a single Statutory Instrument would be helpful to businesses, regulators and enforcers.

2) Introduction of civil sanctions for most instances of non-compliance

Food authorities in Wales are responsible for the enforcement of the proposed Regulations. Where it becomes necessary to take formal enforcement action for a contravention of a provision of the Regulations, enforcement officers will have the power to serve an improvement notice under section 10 of the Food Safety Act 1990 (as modified by the proposed Regulations). A food business operator who fails to comply with the requirements of the improvement notice will be guilty of a criminal offence and may be prosecuted for not complying with the notice.

Any person served with an improvement notice has the right of appeal. It is proposed that appeals continue to be referred to the Magistrates' Court as is currently the case in respect of comparable appeals under the Food Hygiene (Wales) Regulations 2006 and the Food Information (Wales) Regulations 2014. In relation to the equivalent Regulations in England led by Defra, Ministry of Justice advice is that appellants are referred to the General Regulatory Chamber of the First-Tier Tribunal (FTT) in England.

3) New EU requirements for monitoring of radioactivity in water

The Council of the European Union adopted a new Directive under the Euratom Treaty on 22 October 2013; Council Directive 2013/51/Euratom¹ laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (the "Directive").

The Directive sets out parametric values, and frequencies and performance characteristics for analytical methods for monitoring radioactive substances in water intended for human consumption. This includes water as defined in the scope of the Drinking Water Directive 98/83/EC for drinking, cooking, food preparation or other domestic purposes supplied from a distribution network, tanker or in bottles or containers. It also includes all water used in any food production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption.

Natural mineral waters are exempt from the requirements of the Directive.

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 $^{1 \}hspace{0.1cm} \underline{\text{http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0051\&from=EN}}\\$

4) Clarifying permitted treatments for spring water in line with European requirements

Directive 2009/54/EC² [recast] on the exploitation and marketing of natural mineral water (the "Natural Mineral Water Directive") states that natural mineral water and spring water must be free from pollution and pathogenic bacteria at source and that disinfection treatment must not be used at any stage in their production.

The Natural Mineral Water Directive has been transposed into national legislation. In Wales, the relevant legislation is the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007³ (the "2007 Regulations"). However, the implementing legislation in force in the UK, including in Wales, has been unintentionally under-implementing the Directive by permitting the use of disinfection treatments in the production of spring water, as opposed to natural mineral water. The under-implementation was due to the misinterpretation of a particular provision in the Directive which appeared to allow Member States to continue with national treatments for spring water, which for the UK, was the use of ultraviolet (UV) disinfection treatment.

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015 will ensure compliance with EU law.

5) No longer requiring the fortification of water with calcium up to a level of 60 mg/l in the case where it has been softened or desalinated

The 2007 regulations contain a national provision which calls for the re-calcification up to 60 mg/l for any bottled water or spring water which had been softened or desalinated. While this was no longer required by EU regulations⁴, the UK retained the requirement for minimum hardness as a national provision in SI 1999 No. 1540⁵ and its replacement in relation to Wales, SI 2007 No. 3165 (W. 276) 6. This was done on health grounds, based on advice at the time from the Committee on Medical Aspects of Food Policy⁷, which claimed that calcium helped prevent coronary heart disease. The original EU requirement was therefore maintained as a national provision.

² http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0045:0058:EN:PDF

³ http://www.legislation.gov.uk/wsi/2007/3165/contents/made
4 Directive 80/778/EEC (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1980:229:0011:0029:EN:PDF)) first detailed the original requirement for a minimum level of calcium in a control of the control of th EC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:330:0032:0054:EN:PDF) did not retain the requirement, and thus many Member States' (MS) legislation no longer stipulated the minimum calcium level based on scientific evidence.

⁵ http://www.legislation.gov.uk/uksi/1999/1540/contents/made

⁶ http://www.legislation.gov.uk/wsi/2007/3165/contents/made

⁷ The Committee on Medial Aspects of Food Policy was disbanded in 2000 and advice in this area is now provided by the Scientific Committee on Nutrition.

More recent (2010) national scientific evidence produced by the Scientific Advisory Committee on Nutrition⁸ shows the national provision no longer has a scientific basis, as the validity of the original evidence is disputed.

5. Consultation

A public consultation exercise was carried out by the Food Standards Agency (FSA) between 1 June 2015 and 24 August 2015.

Responses were received from the following organisations:

- British Retail Consortium (BRC)
- British Soft Drinks Association (BSDA)
- Wales Food Safety Expert Panel (FSEP)
- Powys County Council
- Water Health Partnership for Wales (WHPW)
- The Government Chemist (GC)

A detailed summary of responses will be placed on the FSA website.

Summary of consultation responses

1) Consolidate existing Regulations

There was broad support and no objections to this measure.

2) Introduce civil sanctions for most instances of non-compliance

While there was broad support from other responders, the BRC has objected to this measure across all Regulations where it applies. It is clear policy to move, where appropriate, to civil sanctions, with a backstop offence of failing to comply with an Improvement Notice. This policy has been agreed by the Minister for Health and Social Services in response to **LF/MD/0592/13**. No new objection to this policy has been raised that applies specifically to these Regulations.

3) Include new EU requirements for monitoring of radioactivity in water

FSEP and Powys council have challenged assumptions regarding the costs associated with this measure and these challenges are taken into account in the impact assessment below. They have also queried whether the costs of the sampling should be borne by local authorities. The responsibility in the Directive is on the Competent Authority (and those with delegated authority from the Competent Authority) so currently there is no mechanism for passing those costs to industry.

⁸ http://www.sacn.gov.uk/pdfs/sacn_position_statement_hard_water_and_cardiovascular_disease.pdf

4) Clarify permitted treatments for spring water in line with European requirements

BRC has objected to this on the grounds that the FSA has not adequately reflected the secondary costs to businesses that use Spring Water as an ingredient. However, the BDSA suggest that "members that did use UV for this purpose [decontamination of spring water] have invested in changes to their manufacturing facilities during discussions on the consolidated regulations." In addition, BRC, which is well placed to supply evidence in this area, has not taken the opportunity provided by the 12-week public consultation exercise to provide any evidence to back up its assertion.

Use of spring water as an ingredient or processing aid is a commercial decision. It is not the place of regulators to be involved in the commercial decisions of food business operators. The remit of a regulator is to ensure compliance with Regulation. The food industry is one where the supply chain is constantly changing to reflect changes in price, availability and a great many other factors. To suggest that requiring compliance with this Regulation would be solely responsible for significant changes in the supply chains of large sectors of the industry is not a credible assertion, particularly without any supporting evidence.

The FSA has subsequently been in touch with a spring water producer operating in Wales that uses the spring water to produce a composite product (i.e. a product with Spring Water as an ingredient). Evidence supplied by this producer will be incorporated into the impact assessment as part of the Explanatory Memorandum.

5) No longer require the fortification of water with calcium up to a level of 60 mg/l in the case where it has been softened or desalinated

There was broad agreement and no objection to this measure.

Consultations in other administrations

Of the other UK administrations, only Northern Ireland carried out a consultation at the same time as Wales. FSA Northern Ireland received two responses. One from the BRC which mirrored the response to Wales and one from a local authority, principally concerned with the size of the market in Northern Ireland.

Scotland and England have latterly launched consultations on significantly different regulations, but the responses to these consultations are not available at the time of preparing this Explanatory Memorandum.

Regulatory position in other administrations.

The table below shows which measures the UK administrations will be bringing in as part of the first Regulations in 2015/16.

Measure	Wales	Northern Ireland	Scotland	England	
Consolidate existing Regulations	November 2015	November 2015	(amending Regulations in 2016)	2015 (or early 2016)	
Introduce civil sanctions for most instances of non-compliance	November 2015	November 2015	Unknown	2015 (or early 2016)	
Include new EU requirements for monitoring of radioactivity in water	November 2015	November 2015	November 2015	2015 (or early 2016)	
Clarify permitted treatments for spring water in line with EU Directive 2009/54/EC	November 2015	November 2015	No indication of date of Regulations required to comply with EU Directive 2009/54/EC	No indication of date of Regulations required to comply with EU Directive 2009/54/EC	
No longer require the fortification of water with calcium up to a level of 60 mg/l in the case where it has been softened or desalinated	November 2015	November 2015	(amending Regulations in 2016)	2015 (or early 2016)	

It is not currently known if Regulations in England and Scotland will be made to address the requirements of Directive 2009/54/EC regarding the use of disinfection treatment in the production of spring water. However, producers in England and Scotland that continue to subject spring water to disinfection treatment will be prohibited from placing that product on the market in Wales (and Northern Ireland). Spring water produced according to the Regulations in Wales (and Northern Ireland)

can still be place on the market in England and Scotland, and by conforming with all EU Regulations, will be compliant with the requirements of the European market. Therefore, Welsh producers will not be disadvantaged in their access to the market in any territory by the Regulations in Wales.

6. Regulatory Impact Assessment

Options

Option 1: Do nothing: leave the regulatory framework as it is.

Option 2: Transpose the Euratom Directive and enforce compliance with EU Directive 2009/54/EC. Consolidate Regulations and remove minimum hardness requirement.

Option 2 is the preferred option.

Costs and Benefits

The costs and benefits associated with the Regulations have been appraised over a ten-year period 2015-16 to 2024-25. Historic prices used in the original consultation impact assessment have been uprated to 2015 prices using the GDP deflators. The HM Treasury central discount rate of 3.5% has been used throughout.

Option 1

Costs to Government:

By not transposing the Euratom Directive and not properly enforcing Directive 2009/54/EC the UK will be risking infraction by the EU. Fines for infraction are significant and ongoing.

Benefits

There are no incremental benefits associated with Option 1. This is the baseline which all other options are appraise against.

Option 2

This section details the costs and benefits of:

- 1) Consolidation of existing Regulations
- 2) Introduction of civil sanctions for most instances of non-compliance
- 3) New EU requirements for monitoring of radioactivity in water
- 4) Clarification of permitted treatments for spring water in line with European requirement
- 5) No longer requiring the fortification of water with calcium up to a level of 60 mg/l in the case where it has been softened or desalinated

1) Consolidation of existing regulations

Industry and Enforcement

Costs Apart from familiarisation costs (see page 13 below), there are no additional costs associated with this measure.

Benefits

There may be benefits to enforcement bodies and businesses in terms of simplification as a result of the consolidations. After the change, any new entrants into the sector would only need to familiarise themselves with one statutory instruments as opposed to the four at present. It is difficult to estimate how many new businesses will enter the sector over the next ten years (which is the expected lifespan of the policy). Also the FSA does not record the number of new entrant officers and therefore it is not possible to separate new entrants out from the data on numbers of food law enforcement officers. We are therefore unable to monetise the benefits at this time for the reduced familiarisation.

2) Introduction of civil sanctions for most instances of non-compliance

Industry and Enforcement

Costs

There are no additional costs associated with this measure. Civil sanctions have already been introduced for a number of Regulations and enforcement authorities will therefore already be familiar with this measure

Benefits

There is a benefit to industry and Government in terms of moving from the current criminal sanctions regime to the new civil sanctions regime by way of compliance notice. This would be followed up by a criminal offence in those cases where a compliance notice is not complied with. It is anticipated that the gains will originate from time saved to businesses and Government officials in resolving issues rapidly. There is presumed to be a reduction in costs which will materialise as only the most serious offences would need to be escalated to a magistrate court, the vast majority being resolved through the issuing of improvement notices.

3) New EU requirements for monitoring of radioactivity in water

Industry

Costs

Apart from familiarisation costs (see page x below), there are no additional costs associated with this measure. As testing is to be carried out by local authority enforcement officers, there is not expected to be any additional costs to industry from this measure.

Enforcement

Costs

According to responses to the public consultation, the estimated cost of taking a sample for Radon contamination is approximately £250. It is expected that one sample per spring will enable an exemption from further sampling to be granted for five years, so the total cost per spring over the 10 year policy cycle is £500 for each producer of spring water.

A survey of all local authorities in Wales carried out separately from the public consultation identified six spring water producers in Wales. Therefore the cost of radon testing can be put at £3,000 over the period 2015-16 to 2024-25.

Consumers

Benefits

No monetised benefits are identified for this measure. This policy has been introduced by the European Commission to protect consumers from radon contamination from potable water sources, in line with expert scientific advice. The health risks from inhalation of radon have long been known. The risks associated with ingestion have not been as extensively documented because most of the radon in water will escape before it is ingested. The level where action is required in a domestic dwelling is 200 Bq/l air. The level where remedial action is required for water is 1000 Bq/l. The latter figure is higher to account for radon loss before ingestion. Nonetheless, if radon is ingested in significant levels, it can damage the lining of the stomach.

There is therefore, some benefit to consumer health from the new safeguards that will be put in place in terms of the assessment of risk of the presence of radon. However the risk to consumer health is currently very low. We do not have the evidence available on the exact impact on consumer health and how much consumers would value this benefit and it is disproportionately costly to try and gather this information.

4) Clarification of permitted treatments for spring water in line with European requirement

Industry

Costs

Decommissioning of UV equipment

Industry estimates for complying with the requirements of the Regulations were received from a producer that draws spring water for use (on the same site) in a composite "flavoured water" product. Options identified and their estimated costs for decommissioning the UV unit as up to £27,000. This contrasts with figures provided by the British Soft Drinks Association (BSDA) that suggest the associated cost for removal of UV equipment includes a one off cost of between £3,000 and £5,000 per business (2013 prices). Indeed, the BSDA, in response to the public consultation has suggested that its members "have invested in changes to their manufacturing facilities during discussions on the consolidated regulations" and so this cost is likely in most cases to have already been incurred.

One of the six identified businesses producing spring water in Wales has advised that it has a UV unit that can be isolated in-situ by the operation of a bypass valve at zero cost so that their production line can be used for either spring water or bottled drinking water production.

Allowing for the estimate of £27,000 for one business, zero for another, and using the BSDA median estimate of £4,100 (2015 prices) for the other four identified businesses, a total of £43,400 is identified as the one off cost to industry of decommissioning UV units. A zero salvage value for sale of this equipment is assumed.

"Write off" costs

The lifespan of a UV unit is not known, nor is the age of any UV unit being used in Wales. At least one producer has suggested that the UV unit will continue to be used for bottled drinking water production, while another has suggested that the unit may be moved elsewhere in its production process where its use will be compliant with the Regulations. As there is no evidence to suggest costs for "write-off" of any existing UV unit, this cost will not be included in this impact assessment.

Additional microbial sampling

In terms of microbiological testing for assurance once a UV unit is decommissioned, BSDA has advised that additional microbiological testing would be necessary for a defined amount of time (estimated at three months). Depending on the water source, industry could test for a longer period of time such as six months upon changing manufacturing methods such as removal of a UV installation. However industry has advised that it is unlikely that additional testing would go beyond three months.

BSDA has advised that this additional testing is likely to be a one off cost for each business per month of around £500 (2013 prices). Using a best estimate of a three month period of additional testing for six businesses, this equates to a one off cost of £9,200 (2015 prices). If a business wishes to continue testing beyond this point, it will be a commercial decision, rather than a cost associated with these Regulations.

There will be additional remedial costs incurred by a business **if** the microbiological testing identifies an issue. These costs are likely to vary on a case by case basis and as such it is not possible to quantify them in this RIA.

Benefits

We have been advised by a supplier of UV equipment that electricity consumption may vary according to the rate of the water flow being treated and that realistically most sites will have a small UV system. Electricity costs for a small UV system are estimated to be approximately £300 per annum. Large UV systems are assumed to have electricity costs of £4,000 per annum (2013 prices). For the purposes of this RIA, we adopt a mid-point estimate of £2,200 per annum for each business (2015 prices). For the six businesses, this is equivalent to a central estimate of £124,300 over the period 2015-16 to 2024-25.

The BSDA has indicated that incremental cost savings for not using UV would be for new lamps, safe disposal of spent lamps and preventative maintenance plans. This is estimated at between £300 and £3,000 per annum, depending on the size of the business (2013 prices). For the RIA, we have used a mid-point of the range at £1,690 per business (2015 prices). For the six businesses, this is equivalent to a central estimate of £95,100 over the period 2015-16 to 2024-25..

Since the Regulations will be introduced in November 2015, it is assumed that only part of the annual benefits identified above will accrue in 2015-16.

Enforcement

Costs

As familiarisation costs with the entirety of the Regulations is taken into account elsewhere, and verification of industry compliance with the Regulations is likely to take place within the normal intervention programme of the local authority, no additional costs are expected in respect of this aspect of the Regulations.

Consumers

Benefits

Rectifying the market failure is of ultimate benefit to the UK consumer who will be better informed about the category of bottled water product they choose to purchase, regardless of which EU MS it was produced in. We currently do not have data on how much consumers actually value this increased information therefore it has not been possible to monetise this benefit to consumers. Gathering this data would be a costly exercise which would not be an appropriate or proportionate use of resources,

given that the under-implementation of EU law must be addressed regardless of the market failure and only a minority of consumers use such information in their purchasing decision making processes. However it should be noted that the consumers who use bottled water information in their purchasing decisions will have increased information and will benefit from Policy Option 2. Therefore this impact assessment underestimates the net benefit of Policy Option 2.

5) No longer requiring the fortification of water with calcium up to a level of 60 mg/l in the case where it has been softened or desalinated

Industry

Costs

No businesses that are affected by this measure have been identified. Therefore there are no monetised costs for industry and enforcement.

Benefits

No businesses that are affected by this measure have been identified. Therefore there are no monetised benefits to this measure.

Familiarisation

There is a one-off familiarisation cost associated with the proposed package of Regulations:

Costs to Industry:

Affected businesses will need to become familiar with the new regulations. It is estimated that it would take two full time production manager/director in the manufacturing industry per business 6 hours in total to learn about these Regulations and disseminate information to key staff (4.5 hours for learning and 1.5 hours for dissemination). The median hourly pay rate for full time production managers/directors is around £26.12 (ASHE Provisional 2014 Estimates in 2014 prices, with a 30% overhead uplift in accordance with the UK standard cost model). Assuming 15 affected bottled water firms (including those producing spring water and natural mineral water, the total one-off learning and dissemination cost to businesses in Wales is approximately £2,350.

Costs to enforcement:

Local authority trading standard officers will also need to become familiar with the new regulation. Estimates from local authority responses to the public consultation suggest that it would take one trading standards officer one day (7.5 hours) to read

the regulations and disseminate information to key staff, as well as carry out additional work required by the Regulations. The median hourly pay rate for a trading standards officer is around £19.37 (ASHE Provisional 2014 Estimates in 2014 prices, with a 30% overhead uplift in accordance with the UK standard cost model). There are 22 local authorities in Wales. The total one-off familiarisation cost to enforcement bodies in Wales is approximately £3,200.

Costs to Consumers

It is quite possible that any costs borne by the industry from any of these Regulations could be passed onto consumers by higher prices for bottled water products. We currently do not have information on whether this would happen so this impact assessment assumes no pass-through to consumers.

Benefits to Government

By making the regulations Welsh Government is protected from contribution to any infraction fines incurred by the UK if other administrations do not meet the requirements of EU Directives

Summary

Table 1 presents a summary of the monetised costs and benefits associated with introducing these Regulations. The total monetised net impact to society is estimated to be £126,100 over 10 years (in present value terms). However, this does not include the unquantified benefits (identified in the preceding text) nor a share of the potential infraction fines if these Regulations are not introduced.

Table 1: Summary of costs and benefits (£)

	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23	2023-24	2024-25
COSTS										
Local Authorities										
Learning and Dissemination	3,200									
Radon sampling	1,500					1,500				
Total cost to Local authorities	4,700	-	-	-	-	1,500	-	-	-	-
Industry										
Learning and Dissemination	2,350									
Removal of UV Equipment	43,400									
Additional microbial sampling	9,200									
Total cost to industry	54,950	-	-	-	-	-	-	-	-	-
Total cost	59,650	_	_	_	-	1,500	-	_	_	_
Present Value	60,900									
BENEFITS										
Industry										
Electricity cost savings	5,500	13,200	13,200	13,200	13,200	13,200	13,200	13,200	13,200	13,200
UV lamp cost savings	4,200	10,100	10,100	10,100	10,100	10,100	10,100	10,100	10,100	10,100
Total benefit	9,700	23,300	23,300	23,300	23,300	23,300	23,300	23,300	23,300	23,300
Present Value	187,000									
Net Present Value	126,100									