

EXECUTIVE NOTE

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Regulations 2007 SSI/2007/435

1. The above 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 (Scotland) Regulations 2003 (SSI 2003 No. 139) and the Natural Mineral Water, Spring Water and Bottled Drinking Water Amendment (Scotland) Regulations 2004 (SSI 2004 No 132). The instrument is subject to negative resolution procedure.

Policy Objective

2. This Statutory Instrument in Scotland consolidates revokes and re-enacts with changes the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999 (as amended) and implements all existing European legislation relating to natural mineral water, spring water and bottled drinking water.

The principal changes of the consolidation are;

- it is specifically provided that the Regulations do not apply to packaged ice portions for use in cooling food;
- the requirements in the Regulations relating to marking and labelling of natural mineral water and spring water are extended to advertising of such water; and
- provision is made for retained parts of samples obtained by authorised officers of food authorities for the purpose of analysis to be submitted for analysis to the Government Chemist in specified circumstances.

Legislative Background

3. 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.

Policy Background

4. 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.
5. 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 (Scotland) 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.

Consultation

6. In 2006, FSA Scotland consulted with over 250 stakeholders across Scotland from industry, enforcement and consumer groups as well as sector specific organisations. The Food Standards Agency received eight responses (one no comment). All responses were broadly supportive of the consolidation and agreed that it would make the legislation easier to understand and enforce.
7. Of the responses received three were from UK wide trade associations of which duplicate responses were sent to FSA in London. FSA Scotland also received comments from a Scottish trade association and from two Scottish Local Authorities. Comments were made by other Scottish stakeholders; public water supplier, public health organisation, university lecturer and natural mineral water producer. During the redrafting of the Regulations and Guidance, stakeholders' comments have been taken into consideration.

Other Administrations

8. Similar Regulations will apply in England, Wales and Northern Ireland.

Impact

9. The Food Standards Agency Scotland fully consulted all stakeholders on the proposed regulations. The consolidation is expected to yield a benefit to industry, enforcement authorities and consumers.

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Food Standards Agency Scotland
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Annex 2

www.food.gov.uk



FULL REGULATORY IMPACT ASSESSMENT

1. Title of proposal

These regulations are to be known as The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Regulations 2007.

2. Purpose and intended effect of measure

Objective

2.1 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 2003/139 and SI 2004/132). 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.

2.2 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.

3. Background

3.1 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.

3.2 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 bottling and sale of the particular product.

3.3 The Regulations require that spring water and bottled drinking water, which has been softened or desalinated, must meet a minimum level for water hardness. Council Directive 80/778/EEC (now revoked) set a minimum concentration for softened or desalinated water intended for human consumption of 60mg/L of calcium (Ca) or equivalent. 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 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

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

3.4 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 technological difficulties make it hard 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.

3.5 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.

The Regulations being proposed will be in place by the 31 October 2007

Other Administrations

3.6 The Regulations relate to Scotland only. Separate, parallel legislation will be made in England, Wales and Northern Ireland.

Rationale for Government Intervention

3.7 The consolidation is intended to make the Regulations clearer and more user-friendly. This will 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 consumers have an accurate basis on which to choose a product.

4 Consultation

4.1 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 Technical Barrier to Trade (TBT) notification was also distributed via 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.

Within Government

4.2 The Scottish Government and DG Rural Affairs and Environment and Scottish Water were also contacted on these proposed Regulations during May 2006. In their response Scottish Water was content with our proposed Regulations, no comments were made from the other Government Departments.

Result of public consultation in Scotland

4.3 In Scotland, the Agency held a public consultation in May 2006, on the draft of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Regulations 2007 and the associated Regulatory Guidance. This included consultation with the Scottish Federation of Small Businesses.

4.4 This consultation included over 250 stakeholders across Scotland from industry, enforcement and consumer groups as well as sector specific organisations. FSA Scotland received eight responses (one no comment). Of the responses received three were from UK wide trade associations of which duplicate responses were sent to FSA in London. FSA Scotland also received comments from a Scottish trade association and from two Scottish Local Authorities. Comments were made by other Scottish stakeholders; public water supplier, public health organisation, university lecturer and natural mineral water producer.

4.5 All eight responses were broadly supportive of the consolidation and agreed that it would make the legislation easier to understand and enforce. During the redrafting of the Regulations and Guidance, stakeholders' comments have been taken into consideration. The responses to the Scottish consultation have been summarised and are available at:

<http://www.food.gov.uk/consultations/consultscot/2006/naturalmineralwater2006s>

5 Options

There are two options:

Option 1 - Do nothing i.e no consolidation

Option 2 - Consolidation of existing Regulations

Option 1- Take no action

5.1 Under this option, if no intervention was made, enforcement bodies and stakeholders

would need to continue to refer to the three Scottish Statutory Instruments and ensure that they

have used the appropriate Regulations (as amended in relation to Scotland) with the current

requirement to cross refer to the parent EC legislation frequently.

Option 2 – Implement consolidated Regulation

5.2 Consolidation of the existing requirements would provide enforcement bodies and

stakeholders with a single Scottish 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.

6. Costs and benefits

Sectors groups affected

6.1 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. The FSA does not consider that the new legislation has any impact on race equality and on sustainability.

Scottish Bottled Water Market

6.2 During this consultation, FSA Scotland requested specific figures on the consumption of natural mineral water and spring/bottled water in Scotland received recent market research data from Highland Spring some of which is summarised below.

6.3 The bottled water market in Scotland is worth an estimated £169 million. In 2006 the take home bottled water market in Scotland was worth an estimated £44.5 million which is equivalent to 10% of the total UK take home market.³

6.4 Scottish brands account for 35% of volume sales of branded water in Scotland, with one leading Scottish brand accounting for 16.7% of the volume market share. The other three leading brands of bottled water in Scotland are French and account for 16.3%, 9.4% and 4.7% of the Scottish market. Own label sales account for 42% of Scottish take home volume sales.⁴ The proportion of Scottish adults drinking bottled water was approximately 54% in April 2006. The propensity to purchase still bottled water is highest among those aged 35-44 years, which is equivalent to 519,000 adults drinking bottled water. The consumption of bottled water declines with age to 37.6% among the over –65s.⁵

UK Bottled Water Market

6.5 The Mintel and Zenith 2007 reports have provided FSA with general market information on the bottled water which is based on UK figures, some of which is summarised below.

6.6 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.

6.7 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

³ & ⁴ AC Nielsen 22 April 2006

⁵ TGI at BMRB Q1 2006

million litres and the water cooler sector accounted for 20% of these sales (the remainder being packaged water).

6.8 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.

6.9 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%).

6.10 Retail sales accounted for 1,509.7 million litres whereas 660.3 million litres was consumed away from home (i.e. horeca⁶; 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%).

6.11 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.

7. Benefits

7.1 In addition, the 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.

Consumers

7.2 The consumer will benefit from better enforcement, and additionally, the maintenance of the requirement for a minimum level of water hardness, which epidemiological studies show

⁶ "Horeca" meaning hotels, restaurants and catering

produces positive health effects. This could therefore improve consumer welfare, though by what amount is not calculable at this time.

Producers

9.5 To further understand the benefits of the Regulation for Scottish producers, the Agency contacted Managing Directors from two large and three small Scottish bottled water companies. When asked how long they spent understanding legislation (in average days), the smaller companies said that it was an integral part of their job and they could not quantify time spent doing this. They all mentioned the importance of support from Local Authorities and some mentioned help received from local enterprise groups. The two larger Scottish bottled water producers explained that they relied on their own quality/technical managers and on their consultants to deal with changes in legislation.

9.6 Producers of bottled drinking water will benefit from the Regulations, as they will provide them with an unambiguous set of regulatory requirements that are clearly defined with respect to the type of bottled water, e.g. the clearer distinction for maximum parameters for the three different types of water.

9.7 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.

Local Authorities

9.8 Local Authorities will benefit from having a single consolidated Scottish Statutory Instrument to use for enforcement. It will provide a means for more effective and uniform enforcement by Local Authorities. COSLA was consulted but made no comments on this occasion. One Scottish local authority commented that the consolidated regulations would make the legislation easier to understand and should lead to more uniformity in enforcement.

10. Costs

Option - 1 Take no action

10.1 If no consolidation was made, enforcement bodies and stakeholders would need to continue to refer to the three Scottish Statutory Instruments and ensure that they have used the

appropriate Regulations (as amended in relation to Scotland) with the current requirement to cross refer to the parent EC legislation frequently.

Option - 2 Implement consolidated Regulation

10.2 The following costs to stakeholders' across the UK was identified during the consultation held in May 2006.

Natural Mineral Water producers

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

10.4 The mandatory requirements for natural mineral water, spring water and bottled water producers across the UK are unchanged in the consolidated version and therefore no additional policy or administrative costs are envisaged.

Spring water and bottled drinking water producers

10.5 The Agency initially proposed to clarify the wording of the minimum hardness provision as it was not the intention of the Regulation to allow the removal and subsequent replacement of calcium to the prescribed level (60 mg Ca/l). The Agency specifically asked for comments on the proposed re-wording and for estimates of any associated costs and benefits.

10.6 Industry representatives across the UK have informed the Agency through the consultation process, 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 predominantly 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. over 12% of annual turnover).

10.7 Aside from the economic impact on the bottled water cooler industry in particular, environmental impact was also of concern if bottling plants were to be moved to areas that avoid the need to meet the hardness criteria.

10.8 The Agency has also been challenged by Industry on the scientific basis for the need to redraft the provision. The original advice from COMA was on the basis that the benefits could not

be attributed to an exact property of water hardness. During the drafting of the 1999 Regulations, the Department of Health 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. After the consultation both 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.^{7,8} 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 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.

10.9 The Agency understands that the findings of the symposium are not conclusive and will be subject to further review (by a WHO Expert Committee and Guideline activities) before WHO decides on what further actions are to be taken. In view of these on-going assessments the Agency considers that it remains prudent to retain a minimum hardness provision for treated bottled water so as not to remove any potential health benefit which seems to be indicated. It is considered that remineralisation is likely to confer similar benefits to limiting the degree of softening, while being a proportionate response to the problem and not prohibiting certain treatment methods commonly in use.

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

Local Authorities

⁷ 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

⁸ 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>

10.11 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.

11 Small/Micro Firms Impact Test In Scotland

11.1 In Scotland, the Agency has identified over 20 bottled water producers. A few of the larger groups such as Greencore and Highland Spring exploit several springs, producing natural minerals waters, spring waters, bottled drinking waters and flavoured waters as well as products for own label and customer brands. According to the Mintel 2007 market research report, Highland Spring is the leading UK producer of natural mineral water and a key player in the sparkling bottled water sector.

11.2 Many of the Scottish bottled water producers tend to vary from medium to small sized companies producing more niche bottled waters. There seems to be fewer smaller sized family owned companies such as Sangs (Deveron Valley), Speyside Glenlivet and Deeside Natural Mineral Waters (Royal Deeside). Also approximately nine of the Scottish natural mineral sources are currently not being exploited but which remain registered as authorised recognised natural mineral waters.

11.3 To assess the potential impact of the consolidated Regulations on small businesses FSA Scotland contacted three small Scottish bottled water companies (with 10-20 full time employees). The companies indicated that they did not experience particular difficulty in understanding the current Regulations. However, they do spend a considerable amount of time reading the Regulations and they liaise extensively with their Local Authority for advice. They all expressed their support for consolidation stating that it would reduce the burden on them by making the interpretation of the Regulations easier and less time consuming. Therefore it is considered that the impact of the consolidated Regulations on small firms will be insignificant.

Across the UK

11.4 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 UK-wide. 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.

11.5 Although the minimum hardness criterion did not pose a problem for any of the five businesses consulted, a consultation response indicated otherwise. The Country Land and Business Association expressed concern over the number of companies contacted. 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.

12 “Test Run” of business forms

There are no forms associated with this piece of legislation.

13 Competition assessment

13.1 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 the product has.

13.2 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. 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.

13.3 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).

13.4 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. We have seen 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. With the rumour of a relaunch of Dasani by Coca-Cola, introduction by PepsiCo of Aquafina and the possibility of other brands, we can expect a dynamic change year to year of the UK Bottled Water Market with more choice on the shelves threatening the dominance of companies like Danone and Nestle (together their interests account for 35% of the UK bottled water market).

14 Sustainable Development

14.1 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 and labelling of water that is suitable for the preparation of infant formulae or follow-on-formulae. 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.

15. Enforcement and Sanctions and Monitoring

15.1 Enforcement of the Scottish Regulations will continue to be the responsibility of Local Authority Environmental Health Departments. Officials will maintain regular contact with COSLA and relevant trade associations to monitor compliance with, and enforcement of, these Regulations.

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

16 Implementation and Delivery Plan

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

16.2 Regulatory Guidance 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.

17. Post-implementation review

17.1 FSA Scotland will continue to consult with Local Authorities industry and other stakeholders to evaluate the effectiveness of and experience with the Regulations and guidance notes. If the Regulations are subsequently amended as a consequence of Community legislation, then the guidance will be updated accordingly.

17.2 In accordance with the Scottish Government's, Improving Regulation in Scotland Unit (IRIS) guidelines, this RIA will be reviewed, as appropriate, in order to establish that it is "fit for purpose" therefore not adding any additional burdens to businesses. In line with Scottish Government's guidance, FSA Scotland will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed within 10 years.

18 Summary and Recommendation

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

18.2 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.

19 Declaration and publication

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

Signed by the responsible Minister

Date

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