

## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

**Commission Regulation (EU) No. 16/2012 amending Annex II to Regulation (EC) No. 853/2004 of the European Parliament and of the Council regarding the requirements concerning frozen food of animal origin intended for human consumption**

**File No:** SPARD/FSAS  
**Date:** February 2012  
**Stage:** Final  
**Source of intervention:** EU  
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## **1. Title of Proposal**

- 1.1 Commission Regulation (EU) No. 16/2012 amending Annex II to Regulation (EC) No. 853/2004 of the European Parliament and of the Council regarding the information requirements concerning frozen food of animal origin intended for human consumption.

## **2. Purpose and Intended Effect**

### Objectives

- 2.1 The objective of Regulation (EU) No. 16/2012 is to ensure that Food Business Operators (FBOs) that fall within the scope of Regulation (EC) No. 853/2004 keep and make available more detailed information regarding the dates of production and freezing of food of animal origin at each stage of production prior to it being labelled in accordance with Directive 2000/13/EC. The consequential improvement in record keeping will improve transparency for FBO's throughout the foodchain, assist enforcement officers in identifying fraudulent activity and thereby improve consumer confidence and protect business against reputational damage.

### Background

- 2.2 Regulation (EC) No. 853/2004 lays down rules on the hygiene of food of animal origin for FBOs. FBOs are required to comply with the requirements set out in Annex II. However, experience gained since the date of application of 853/2004 has exposed certain difficulties regarding the storage of food of animal origin. If the date of initial freezing of such food was indicated, FBOs would be better able to judge the suitability of the food for human consumption.
- 2.3 Directive 2000/13/EC concerns the labelling of foodstuffs to be delivered as such to the final consumer and certain aspects relating to presentation and advertising. However, that Directive does not apply to prior stages of food production.
- 2.4 Regulation (EU) No. 16/2012 shall amend Annex II of 853/2004 in order to include requirements applicable to frozen food of animal origin. This will improve and enhance record keeping so that FBOs are better equipped to judge the suitability of food of animal origin for human consumption through all stages of its production. This will also assist enforcement officers in determining that FBOs are following the correct procedures.
- 2.5 The Regulation will come into force on 1 July 2012.
- 2.6 The Commission proposal followed the Eurofreeze food incident in 2005/2006 when Port Health Enforcement Officers became suspicious of consignments of chicken destined for a cold store in Northern Ireland. Further investigations led to the discovery of food fraud in the cold storage sector. The Commission launched an EU-wide survey of cold stores which in turn revealed further issues that suggested a lack of traceability within the cold storage sector. The purpose of this Regulation is to address some of the issues and gaps in the food hygiene legislation revealed by the EU survey. It may also serve to help minimise the potential for food fraud activities

within this industry sector and thereby improve consumer confidence and protect industry against reputational damage.

- 2.7 Freezing food of animal origin has been a common industry practice for many years and many companies already have good internal traceability and stock control systems as part of their HACCP (hazard analysis critical control point) procedures. Any difficulties meeting the requirements of this proposal are more likely to be for smaller FBOs, including some meat cutting plants and catering butchers whose operating procedures might be less well developed.
- 2.8 The UK initially opposed the proposal as it was considered that the original proposals were disproportionate and that the traceability requirements contained in Regulation (EC) No. 178/2002 may be sufficient and that more rigorous enforcement of the existing legislation would help to address the issues covered by the proposal. During negotiations, the UK suggested a number of amendments to the early drafts of the proposal, such as establishing the requirement to only require the initial date of freezing and the subsequent date of processing, instead of the suggested requirement for FBOs to provide the date of production at each stage. A number of these suggestions were adopted which meant that the UK was able to support the proposal.

#### Rationale for Government Intervention

- 2.9 Food of animal origin can pose a risk to human health if it is not produced, manufactured, handled or stored hygienically and at the correct temperature. In general, consumers are not always in a position to know whether this is the case and it is difficult for FBOs to credibly inform the public to what extent food safety risks have been minimised. The measures which the Commission have proposed will provide better information about the production and freezing of food with the aim to improve food safety throughout the frozen food chain. There is hence a benefit from government intervention, both in terms of enabling authorities to better monitor that food hygiene regulations have been adhered to throughout the food chain, and in terms of allowing authorities to enforce those requirements in cases where the regulations have not been upheld.
- 2.10 This is in accordance with the Scottish Government's national performance framework target to increase economic sustainable growth in Scotland and that we live longer and healthier lives.

#### Devolution

- 2.11 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

### **3. Consultation**

#### Public Consultation

- 3.1 The Agency conducted a full public consultation in Scotland in February 2009 seeking views from stakeholders to shape the UK negotiating line. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

3.2 Further views were sought from stakeholders before the proposal was agreed and adopted. Regulation (EU) No. 16/2012 was then published in the Official Journal of the European Union on 12 January 2012.

#### Within Government

3.3 Scottish Government officials from the Rural Directorate and Food & Drink Industry Division were consulted as part of the above-mentioned public consultation as were all 32 Scottish Local Authorities and COSLA (Convention of Scottish Local Authorities). No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

#### With Business

3.4 Industry bodies, such as the Scottish Association of Meat Wholesalers, Scottish Federation of Meat Traders, Scottish Salmon Producers Organisation, Seafood Scotland and the Chilled Food Association have been consulted during the Commission negotiations and kept informed of Hygiene Working Group discussions on the proposal for FBOs to provide more detailed information regarding the dates of production and freezing of food.

3.5 A shortened consultation to seek stakeholders' views on the impact of the Regulation was issued in February 2012 with one comment received, fully supporting the Regulation. No further comments were provided, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

### **4. Options**

4.1 The options considered were:

Option 1 – Do nothing. In this instance, doing nothing would mean that the UK would not be able to enforce this directly applicable Regulation. Member States, including the UK, have voted to accept the proposal. If the UK did not legislate to enforce the Regulation, the Commission could open infraction procedures against the UK as we would not be meeting our Treaty obligation to ensure compliance with an EU Regulation.

Option 2 – Provide for enforcement of the amended EU hygiene legislation to enforce this directly applicable Regulation and provide for its execution and enforcement in Scots law.

### **Sectors and groups affected**

#### Industry

4.2 All food businesses that are approved under Regulation (EC) No. 853/2004 and that undertake food production, handling and storage, including cold stores, will need to ensure that proper records are kept to be able to access information on the date of production and freezing of food of animal origin. This cumulative data should be passed from producer to producer with the product of animal origin. The types of

businesses likely to be affected by the proposal are set out below in table 1 using Standard Industrial Classification (SIC) codes taken from the Office for National Statistics (ONS) Inter Departmental Business Register (IDBR).

Table 1 – Type of businesses affected by Standard Industrial Classification Code

SIC Code	Business Type
10.11	Processing and preserving of meat
10.12	Processing and preserving of poultry meat
10.13	Production of meat and poultry meat products
10.20	Processing and preserving of fish, crustaceans and molluscs,
10.51	Operation of dairies and cheese making
10.52	Manufacture of ice cream
46.32	Wholesale of meat and meat products
46.33	Wholesale of dairy products, eggs and edible oils and fats,
46.38	Wholesale of other foods including fish, crustaceans and molluscs

Source: The Inter Departmental Business Register 2011 (IDBR) – accessible via the Office of National Statistics (ONS). <http://www.statistics.gov.uk/idbr/idbr.asp>

Table 2 – Number of affected businesses by country and firm size

Country/ Firm Size	Micro	Small	Medium	Large	Total
<b>Scotland</b>	<b>731</b>	<b>112</b>	<b>14</b>	<b>3</b>	<b>860</b>
England	5,114	787	96	23	6,020
Wales	263	41	5	1	310
NI	310	48	6	1	365
UK	6,418	987	120	29	7,555

Source: [IDBR, 2011 \(ONS\)](#)

**Notes:**

1. Totals may not sum due to rounding
2. Figures are the sum of premises listed under SIC codes as per table 1.
3. Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

## **Local Authorities**

4.3 Local Authorities (LAs) will need to familiarise themselves with the new legislation as they will be responsible for enforcement. Familiarisation should take no more than one hour. Formal training would not be required.

## **Consumers**

4.4 Consumers will not necessarily be aware of any changes to food safety systems as traceability requirements are already included in Regulation (EC) No 178/2002. However, by keeping records of the date of production FBOs will be better able to judge the suitability of food for human consumption, which could improve the safety of food offered for sale, by providing additional information about the date of kill and the date of freezing.

## Costs and benefits

### COSTS

#### Option 1

4.5 Doing nothing would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. This would leave the UK Government open to monetary sanctions by the European Commission. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.

#### Option 2

##### *Industry*

##### *Familiarisation Costs*

4.6 There will be a one-off familiarisation cost incurred by FBOs affected by this proposal. We have assumed that it will take one FBO one hour to read and disseminate the enhanced requirements to key staff. The cumulative information relating to the date of slaughter and the date of freezing will need to accompany the product to the next stage of production with the traceability information which is already required under Article 18 of Regulation (EC) No 178/2002. We assume that many FBOs will already be keeping the information required by this proposal. The proposal does not specify a form in which the records must be kept, so it is up to the individual FBO to decide how this information is recorded. This means that, as long as the relevant information is readily available on request, the system for keeping this information should not be overly complex.

4.7 Familiarisation costs are calculated using the UK Standard Cost Model (SCM)<sup>2</sup> and ONS Annual Survey of Hours and Earnings (ASHE, 2011)<sup>3</sup>. We assume that it will take 30 minutes per business to read and familiarise themselves with the new arrangements and a further 30 minutes disseminating to key staff<sup>4</sup>. This means a total of one hour for familiarising. There are currently 860 food businesses operating in Scotland, which will have to adhere to this Regulation. Table 2 above displays the number of businesses affected in the UK broken down by country and firm size.

4.8 The total familiarisation cost is quantified by multiplying the hourly wage rate of a 'manager in distribution, storage and retail' of £15.68<sup>5</sup> by the total number of businesses affected in the UK, resulting in a familiarisation cost to Scottish

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

<sup>2</sup> Standard Cost Model Manual can be accessed here: <http://www.bis.gov.uk/files/file44503.pdf>

<sup>3</sup> ONS ASHE can be accessed via: <http://www.statistics.gov.uk/statbase/Product.asp?vlnk=1951>.

<sup>4</sup> While we recognise that dissemination of information will result in an opportunity cost in terms of time of key staff members we anticipate that this will be minimal and the assumed cost of the additional hour will cover these opportunity costs.

<sup>5</sup> Wage rate obtained from The Annual Survey of Household Earnings, 2011) (See: <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of 'managers in distribution, storage and retail' (£12.06 + 30% to cover overheads = £15.68).

businesses of £13,483 – assuming that one manager per firm will be required to familiarise themselves with the Regulation. Table 3 displays the familiarisation cost to industry broken down by location and firm size.

Table 3 – Industry familiarisation cost by country and firm size (2011)

Location/ Firm Size	Micro	Small	Medium	Large	Total
<b>Scotland</b>	<b>£11,455</b>	<b>£1,762</b>	<b>£215</b>	<b>£52</b>	<b>£13,483</b>
England	£80,184	£12,331	£1,502	£365	£94,382
Wales	£4,129	£635	£77	£19	£4,860
NI	£4,862	£748	£91	£22	£5,722
UK	£100,629	£15,476	£1,885	£458	£118,447

Note: Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 decimal points and when grossed may result in a rounding error  
Calculations by FSA, based on ASHE 2011 and IDBR 2011

## Local Authorities

### Familiarisation Costs

- 4.9 There will be a one-off familiarisation cost incurred by local authorities as a result of this Regulation (Regulation (EU) No. 16/2012) which will amend Regulation (EC) No 853/2004. No formal training would be required. We assume that one official in each Local Authority (LA) and one official in each Port Health Authority (PHA) – of which there are none in Scotland - will be required to familiarise themselves with the Regulation. We further assume that it will take half an hour per official to read the amendments, and a further half hour to disseminate the information to other authorised officers in the organisation. This means a total of one hour for familiarisation.
- 4.10 Familiarisation costs are quantified by multiplying the time it will take an official to familiarise themselves with the Regulation by their respective hourly wage rate and the number of enforcement authorities affected.
- 4.11 We assume that one official per LA will be required to familiarise themselves with the Regulation and new enforcement provisions. In order to account for wage differences across local authorities<sup>6</sup>; we use a range of wage rates. As the lower bound value we use the median hourly wage rate of an Environmental Health Officer (£20.45<sup>7</sup>) and as the upper bound value we use the median hourly wage rate of a Trading Standards Officer (£21.01<sup>8</sup>). Taking the midpoint we obtain a central/ best estimate of £20.74<sup>9</sup>.
- 4.12 There are 32 local authorities in Scotland with responsibility for the enforcement of food hygiene legislation who will need to familiarise themselves with this proposal. The total one off familiarisation cost for local authorities in Scotland is £664 (central

<sup>6</sup> Note that TSOs or EHOs may be responsible for enforcing this legislation depending on resource in each local authority

<sup>7</sup> Wage rates obtain from the Annual Survey of Household Earnings (ASHE), 2011, All Employees, Median hourly wage rate of “Environmental Health Officers” <http://www.ons.gov.uk/ons/rel/ashe/annual-survey-of-hours-and-earnings/2010-results/index.html>. This includes an overhead of 30% (15.74\*1.3=20.46).

<sup>8</sup> Wage rates obtain from the Annual Survey of Household Earnings (ASHE), 2011, All Employees, Median hourly wage of “Inspectors of factories, utilities and trading standards” <http://www.ons.gov.uk/ons/rel/ashe/annual-survey-of-hours-and-earnings/2010-results/index.html>. This includes an overhead of 30% (16.16\*1.3=21.01).

<sup>9</sup> Calculated as the average wage rate across EHO and TSO [(20.46+21.01)/2]

estimate)<sup>10</sup>. Table 4 displays the number of LAs (and PHAs) per country with familiarisation cost.

Table 4 – Enforcement familiarisation cost by country (central estimate)

Location	No. of LAs	No. of PHAs	Total No. of Enforcement Authorities	Familiarisation Cost (Lower Bound Estimate)	Familiarisation Cost (Upper Bound Estimate)	Familiarisation Cost (Central Estimate)
<b>Scotland</b>	<b>32</b>	<b>0</b>	<b>32</b>	<b>£655</b>	<b>£672</b>	<b>£664</b>
England	354	39	393	£8,042	£8,256	£8,149
Wales	22	1	23	£471	£483	£477
NI	26	0	26	£532	£546	£539
UK	434	40	474	£9,699	£9,958	£9,828

Note 1: Reported costs include an uplift of 30% to account for overheads.

This means that the wage rates reported in the text are approximate to 2 decimal points and when grossed may result in a rounding error.

## FSA

4.13 Any costs to the FSA would be considered as in line with business as usual.

## BENEFITS

### Option 1

4.14 There is no benefit associated with the Do Nothing option; it is the baseline against which benefits identified in option 2 will be compared.

### Option 2

#### *Consumers*

4.15 The new requirements aim to enhance the food safety systems already in place and help to safeguard the food chain and therefore the consumer. Consumers will not necessarily be aware of any changes to food safety systems as traceability requirements are already included in Regulation (EC) No. 178/2002. However, by keeping records of the date of production FBOs will be better able to judge the suitability of food for human consumption, which could improve the safety of food offered for sale, by providing additional information about the date of kill and the date of freezing.

#### *Industry*

4.16 These measures will help FBOs to be able to better judge the suitability of the food they produce for human consumption and should help to enhance consumer confidence that the correct procedures are being followed.

## 5. Scottish Firms Impact Test

5.1 We assume that this Regulation has the potential to have more of an impact on a large number of micro, small and medium-sized businesses than on larger businesses depending on the systems which they already have in place. However,

<sup>10</sup> £20.74 (familiarisation cost (best estimate) per LA) \* 474 (total LA's and PHA's) = £9,828



under existing legislation, record keeping is required for traceability purposes, so to be in compliance with current legislation all businesses should already have systems in place. The requirements contained in this proposal merely enhance those requirements in needing to also retain information on the date of slaughter and the date of freezing. We are unable either to apply an exemption for micro businesses or to apply the requirements to a lesser degree, as the risk to human health if food safety measures are not applied correctly does not depend on the size of the business. Food safety measures must be risk-based therefore these measures need to be applied to all businesses whatever the size.

- 5.2 Given the nature of these regulations (i.e. principally a matter of expanding requirements already in place with no significant policy change) no face to face visits have taken place with industry. However, key stakeholders have been kept fully informed of negotiations that have taken place between the FSA and the European Commission. The purpose of this consultation is to seek views on the Agency's assessment of the impact this Regulation will cause to stakeholders from 1 July 2012, when the Regulation will be applied.

### Competition Assessment

- 5.3 Using the Office of Fair Trading (OFT) competition assessment Framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition as all food businesses that require approval under Regulation (EC) No. 853/2004 and that handle frozen food of animal origin will need to comply with the requirements. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

### Test Run of Business Forms

- 5.4 There will be no new forms as a result of the Regulation. Although the requirements in Regulation (EU) No. 16/2012 are being put forward by the Commission as extra requirements for businesses, the requirement to keep records are already in place in Regulation (EC) No. 178/2002. To assist FBOs, specific information about the type of information required is provided in the EC Guidance on Regulation (EC) No. 178/2002.

## **6. Legal Aid Impact Test**

- 6.1 The proposed amendments to the Regulations do not introduce new criminal sanctions or civil penalties; therefore, there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

## **7. Enforcement, Sanctions, and Monitoring**

- 7.1 The FSA must remain responsible for enforcement of official controls. Powers will be drawn down from the SSI which will provide national Regulations for the execution and enforcement by local authorities in Scotland of the new EU Regulation. As well as enforcement measures, the proposed Regulations will link

the new EU Regulation to provisions relating to sampling and analysis, powers of entry, etc.

- 7.2 The effectiveness and impact of the Regulation will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys, and general enquiries from the public.
- 7.3 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

## 8. Implementation and Delivery Plan

- 8.1 Regulation (EU) No. 16/2012 entered into force in the UK from 1 February 2012 (i.e. 20 days after being published in the EU Official Journal on 12 January 2012). It shall apply from 1 July 2012.
- 8.2 The publication of the Food Hygiene (Scotland) Amendment Regulations 2012, providing for the enforcement in Scotland of Regulation (EU) 16/2012, will be communicated to stakeholders by email, letter and via the Agency's website.

### Post-Implementation Review

- 8.3 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in January 2017 (i.e. 5 years from the direct application of Regulation (EU) No. 16/2012 in the UK).
- 8.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## 9. Summary and Recommendation

- 9.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EU) 16/2012.
- 9.2 Taking this option allows the Government to fulfil its obligations to implement EU law.
- 9.3 Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.
- 9.4 Summary Costs and Benefits Table

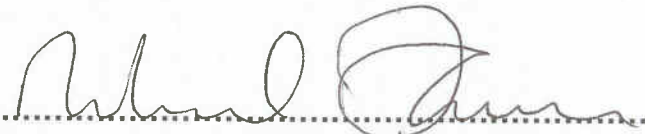
<b>Option</b>	<b>Total Benefit per annum: -Economic, environmental, social</b>	<b>Total Cost per annum: -Economic, environmental, social</b>
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		<b>- Policy and Administrative</b>
<b>1. Do Nothing</b>	No benefits have been identified.	<p>Risk of infraction proceedings for failure to implement (EC) 1020/2008, (EC) 1022/2008 &amp; (EC) 1023/2008. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>11</sup> or some €250 million (£211 million) per year.</p> <p>Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.</p>
<b>2. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</b>	<p>Allows the Government to meet its commitment to fulfil its EU obligations.</p> <p>Consumers will not necessarily be aware of any changes to food safety systems as traceability requirements are already included in Regulation (EC) No. 178/2002. However, by keeping records of the date of production FBOs will be better able to judge the suitability of food for human consumption, which could improve the safety of food offered for sale, by providing additional information about the date of kill and the date of freezing. These measures will help FBOs to be able to better judge the suitability of the food they produce for human consumption and should help to enhance consumer confidence that the correct procedures are being followed.</p>	<p>There will be a one-off familiarisation cost incurred by local authorities. There are 32 local authorities in Scotland with responsibility for the enforcement of food hygiene legislation, who will need to familiarise themselves with this proposal. The total one off familiarisation cost for local authorities in Scotland totals £664 (central estimate).</p>

<sup>11</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

**10. Declaration and publication**

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature.....  
Ministers Title ..... Minister for Public Health  
Date..... 29/2/12

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## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

**Commission Regulation (EU) No. 1276/2011 amending Annex III to Regulation (EC) No. 853/2004 of the European Parliament and of the Council regards the treatment to kill viable parasites in fishery products for human consumption**

**BRIA No:** SPARD/FSAS  
**Date:** February 2012  
**Stage:** Final  
**Source of intervention:** EU  
**Type of measure:** Other  
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# **BUSINESS AND REGULATORY IMPACT ASSESSMENT**

## **1. TITLE**

- 1.1 Commission Regulation (EU) No. 1276/2011 amending Annex III to Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards the treatment to kill viable parasites in fishery products for human consumption

## **2. PURPOSE AND INTENDED EFFECT**

- 2.1 The Commission Regulation will update the existing requirements in Regulation (EC) No. 853/2004 concerning parasites in fishery products and introduces a specific freezing exemption for farmed fishery products reared under specified controlled conditions. This will reduce burdens on the UK fish farming industry and address a long standing issue for the Scottish farmed salmon sector by ensuring that freezing controls are kept to the minimum necessary to provide adequate public health protection.

### **Rationale for Government intervention**

- 2.2 EU food hygiene legislation introduced in January 2006 required that fishery products intended to be consumed raw or almost raw, and certain cold smoked and marinated/salted fishery products, must undergo a freezing treatment to kill any parasites that may pose a risk to consumers, unless there is sufficient epidemiological evidence to demonstrate there that there is no health hazard with regard to parasites. To be efficient, these controls need to be risk-based, flexible, and proportionate, with all the costs of compliance fully justified by the benefits.
- 2.3 Recent scientific evidence generated by the Food Standards Agency in Scotland<sup>1</sup> and confirmed by a European Food Safety Authority (EFSA) opinion<sup>2</sup>, as well as practical experience, suggests that the risks to human health from parasites in farmed fish are minimal and there is no longer a clear public health case for continuing to require the freezing of farmed fishery products intended to be consumed raw or almost raw. Government intervention is therefore needed to update EU legislation to allow food business operators to adapt the freezing controls applicable to farmed fishery products to reflect the risks and available evidence and ensure that the UK is fully compliant with EU law.

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<sup>1</sup> Petrie, A, et al. A Survey of Anisakis and Pseudoterranova in Scottish fisheries and the efficacy of current detection methods: Food Standards Agency in Scotland, Study S14008, 2007

<sup>2</sup> <http://www.efsa.europa.eu/en/scdocs/doc/1543.pdf>

- 2.4 Intervention to update EU legislation is also in accordance with the Scottish Government's national performance framework and will contribute to Scotland's growth and productivity targets by reducing the regulatory burden on affected Scottish businesses. This will help to make Scotland an attractive place for doing business in Europe and contribute to realising our full economic potential.

### Objectives

- 2.5 The main change contained in the Commission Regulation is to amend the requirements in Regulation (EC) No. 853/2004 to allow food business operators to make evidence-based freezing exemptions for farmed fishery products reared under certain controlled conditions. A freezing exemption will be available for farmed fishery products exclusively reared in an environment that is free from parasites, or where food business operators can verify through appropriate procedures, designed according to the risk, that they do not present a health hazard. The introduction of this specific freezing exemption for farmed fishery products will reduce regulatory burdens on the UK fish farming industry and address a long term issue for the Scottish salmon farming sector who, under the current legislation, are required to freeze raw 'ready to eat' products derived from farmed salmon, such as sushi, sashimi and gravadlax. Research carried out by the FSA in Scotland found that the risks to human health from *Anisakid* nematodes in farmed Atlantic salmon are negligible, a conclusion also reached by EFSA following their evaluation of the FSA research. This provides the necessary evidence that will enable food business operators to apply the freezing exemption to farmed salmon.
- 2.6 The Commission Regulation maintains the existing national flexibility that allows competent authorities in Member States to authorise a freezing exemption for fishery products when sufficient epidemiological evidence is available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites, although this now specifically relates to wild catches. Retention of this national flexibility will enable the UK to consider authorising such an exemption for wild catches in the future should these be sought.
- 2.7 Freezing requirements for cold smoked fishery products will be updated to ensure they are risk-based and extended to cover all species of fish that have not undergone a heat treatment of at least 60°C, unless there is sufficient evidence of negligible risk to allow a freezing exemption to be applied. Currently, Regulation (EC) No. 853/2004 only requires that cold smoked herring, mackerel, sprat and wild Atlantic and Pacific salmon need to be frozen before consumption.
- 2.8 There is no change in the requirements applicable to marinated/salted fishery products. They will continue to be required to undergo a freezing treatment if the processing of such products is insufficient to kill viable parasites.

- 2.9 The Regulation maintains current documentation requirements for fishery products that are subject to a freezing treatment. These must be accompanied by a document from the food business operator performing the freezing treatment stating the type of treatment they have undergone, except when supplied to the final consumer. However, the Regulation introduces a new obligation on food business operators to ensure that any wild or farmed fishery products placed on the market without having undergone a freezing treatment to kill parasites originate from a fishing ground or fish farm that complies with the specific conditions set out in the exemptions. This may be met by information in commercial documentation or any other information accompanying the fishery products. Both of these requirements will ensure food business operators maintain traceability throughout the food chain and apply appropriate freezing controls to protect consumer health.
- 2.10 The updated freezing controls will ensure that adequate public health protection is maintained and the least burdensome arrangements are placed on food business operators and Local Authorities enforcing the legislation.

### **3. BACKGROUND**

- 3.1 Regulation (EC) No. 853/2004 applied from 1 January 2006 and lays down specific hygiene rules for food of animal origin, including those applicable to fishery products. Annex III, Section VIII, Chapter III, Part D.1 requires certain fishery products to be frozen under specific conditions to reduce the risk to public health from parasitic infection. These include fishery products intended to be consumed raw or almost raw, cold smoked fishery products (derived from herring, mackerel, sprat and wild Atlantic and Pacific salmon), and marinated and/or salted fishery products where the processing is insufficient to kill nematode larvae. Regulation (EC) No. 853/2004 also includes a national flexibility allowing Competent Authorities to authorise a freezing exemption for fishery products when sufficient epidemiological evidence is available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites.

#### EFSA Opinion

- 3.2 Following a request from the European Commission the EFSA Panel on Biological Hazards was asked to deliver a scientific opinion on food safety related to parasites in fishery products. They were asked to set criteria, if any, for when products intended to be eaten raw, almost raw or cold smoked from wild catch fishing grounds and from aquaculture do not present a health hazard with regard to the presence of parasites. They were specifically asked to assess the available documentation for farmed Atlantic salmon which included an



evaluation of the data from a study jointly funded by FSA in Scotland (FSAS) and the Scottish Salmon Producers' Organisation (SSPO) published in 2007 which found that the public health risks from anisakid nematodes from pellet-fed farmed Atlantic salmon in Scottish waters are negligible.

- 3.3 The panel presented its opinion on 11 March 2010 and concluded that the main parasitic risks to human health from fishery products were from the presence of cestodes, trematodes and nematodes. Anisakid worms are nematodes. The panel also concluded that only *Anisakis simplex* had been implicated in allergic reaction and that consumption of products containing viable *A. simplex* larvae presents a greater risk for allergy than consumption of products containing non-viable larvae.
- 3.4 EFSA determined that the risk to human health from parasitic nematodes in Atlantic salmon fed controlled compound diets and farmed in raised seawater pens or onshore tanks is negligible. No conclusion was reached for any other farmed species as it was determined that there was insufficient monitoring evidence available. This conclusion applied only to farmed salmon and not wild salmon as the EFSA opinion indicates that, for wild catch fish, no fishing grounds can be classed as 'parasite-free', meaning that all wild-caught seawater and freshwater fish must still be considered at risk of containing viable parasites of human health concern if to be consumed raw or almost raw.
- 3.5 EFSA identified that freezing or heat treatments remain the most effective processes to guarantee the killing of parasitic larvae. Many traditional marinating and cold smoking methods are not sufficient to kill *A. simplex* larvae. They also concluded that there is insufficient evidence to indicate whether alternative treatments such as high hydrostatic pressure, irradiation, drying or low voltage currents are effective in killing viable larvae.
- 3.6 Following publication of the EFSA opinion the Food Standards Agency wrote to enforcement authorities advising them to take account of the opinion and the Commission's ongoing review of the legislation regarding parasites in fishery products when considering whether it is appropriate to take any enforcement action where fully traceable farmed Atlantic salmon is supplied raw or almost raw to consumers without first having been frozen.

#### Working Group Discussions

- 3.7 Based on this opinion, the Commission proposed a legislative amendment that would specifically exclude farmed Atlantic salmon from the freezing requirements applied to fish to be eaten raw. This amendment was supported by Member States and is fully in line with the findings of the FSAS funded study. The Commission also tabled a proposal to remove the flexibility for Competent Authorities to

authorise exemptions from the requirement for freezing. This prompted a strong negative reaction from several Member States, particularly those that already make use of this flexibility for certain fishing grounds. The UK was strongly in favour of retaining the flexibility as it considered it was more appropriate for risk assessments to be made at a national level so local conditions can be considered. The UK also considered it was not an appropriate use of resources for all decisions to be made at an EU level, as many derogations would be relevant for either individual or a small number of Member States, and this would also delay the introduction of proportionate controls. Following discussions, the Commission agreed to consider and redraft the legislation, and set up a restricted technical Working Group to progress the dossier. The UK participated in that Working Group and was very active in securing changes to the proposal to obtain the most favourable outcome for the UK.

- 3.8 Subsequent drafts of the proposal retained the national flexibility for wild catches and extended the freezing exemption for farmed Atlantic salmon to all farmed fishery products reared under controlled conditions which meet specific criteria. The freezing requirement for cold smoked fish was also extended to all species, subject to any exemptions that may be applied. The UK was supportive of these proposed changes to the legislation.
- 3.9 A final draft Commission Regulation was presented for vote at the Standing Committee on the Food Chain and Animal Health (SCOFCAH) on 12 July 2011 and received the support of the majority of Member States, including the UK. In collaboration with Member States the Commission also produced a guidance document to accompany the updated legislation and clarify the criteria food business operators must meet before a freezing derogation can be applied. This was presented for vote at SCOFCAH on 16 November 2011 and endorsed by Member States.

### Risk Assessment

- 3.10 The risk assessments carried out by EFSA and the FSA in Scotland provide the necessary evidence to enable the UK farmed salmon sector to make use of the new freezing exemption for farmed fish, and we do not expect there to be a need for any further risk assessment on parasites in farmed salmon assuming there are no changes in farming practices.
- 3.11 Unlike the salmon sector, EFSA concluded that there is insufficient monitoring data available to provide a robust assessment of the risk from viable parasites in other species of farmed fish.<sup>3</sup> However, EFSA have established criteria for considering when fishery products

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<sup>3</sup> The FSA in Scotland has now commissioned research to assess the risks from parasites in farmed marine trout and halibut in the UK

from aquaculture do not present a health hazard with regard to the presence of parasites - principally where fish are reared in raised pens and fed on a controlled artificial diet that cannot be infected with larval parasites. If the same rearing procedures based on these criteria are followed, farmed fishery products other than Atlantic salmon may be considered to present a negligible risk for parasites that may be a risk to the health of the consumer, allowing a freezing derogation to be applied.

- 3.12 The UK farmed trout sector uses four types of production system – open sea pens, open freshwater pens, freshwater ponds, and freshwater ranks and raceways. Sea reared trout and trout reared in open freshwater pens are produced using the same production methods as farmed salmon, thereby meeting the EFSA criteria set out above. Therefore it is considered that fishery products derived from this type of farmed trout production will also present a negligible risk and will be exempt from the freezing requirements if intended to be consumed raw. As such, no additional risk assessment or verification monitoring for this type of production is considered necessary, assuming there is no change in farming practices.
- 3.13 With regard to onshore freshwater systems, EFSA concluded that trout reared in freshwater tanks, ponds or raceways are very rarely parasitized by helminths that present a risk to humans. In cases where water used for culture is drawn from lakes and reservoirs without filtration EFSA indicate that there may be a risk of infection with *Diphyllobothrium* since copepods containing infective stages may enter the system and be preyed upon by trout. Fish reared in pens in still water bodies may be at more risk of infection if they feed on infected copepods. However, scientific experts consulted by the FSA consider that there are no convincing records of the presence of *Diphyllobothrium* in the UK, and where appropriate filtration is used it is considered that onshore freshwater systems will be able to demonstrate that trout have been reared in an environment that is free from viable parasites. Therefore we anticipate that freshwater trout production will also benefit from the freezing exemption.
- 3.14 Farmed species other than salmon and trout are also reared using a mixture of floating sea pens and onshore tank based systems which are likely to meet the EFSA criteria for considering when fishery products from aquaculture do not present a health hazard with regard to the presence of parasites. Therefore it is anticipated that these production methods will enable food business operators rearing these species to meet the exemption criteria and apply a freezing derogation for any product that is supplied for raw consumption.

#### **4. DEVOLUTION**

- 4.1 Commission Regulation (EU) No. 1276/2011 will be enforced in Scotland by The Food Hygiene (Scotland) Amendment Regulations

2012. These domestic enforcement provisions will apply in Scotland only. Separate but parallel legislation will be made to provide for the enforcement of the Commission Regulation in England, Wales and Northern Ireland.

## **5. CONSULTATION**

### Within Government

- 5.1 Marine Scotland policy officials have been kept informed of EU negotiations by FSA officials. Throughout negotiations the FSA was the lead department and was aware that the proposed changes to freezing controls would result in a cost saving across industry, with no detriment to public health protection. The general principle was therefore supported by all Government partners in terms of the 'Better Regulation' agenda.

### Public Consultation

- 5.2 An early draft of the proposal was circulated for comment to all interested parties across the UK in January 2011. This was sent to 180 industry, consumer, and enforcement stakeholders. Responses were received from two of the main trade bodies with an interest in the proposal, one large affected business, and one Local Authority. These responses indicated general support for the changes, although a number of questions were raised regarding the scope of the proposal, requirements for monitoring data, and alternative treatments. These points were addressed in subsequent drafts of the proposal and draft Commission guidance.
- 5.3 A further public consultation on the partial Business & Regulatory Impact Assessment (BRIA) was held in Scotland in February 2012 to refine data gathered from previous consultation with stakeholders and ascertain whether the Agency's assumptions are a fair reflection of costs, benefits and wider impacts for stakeholders. Two comments were received during this further consultation from key trade bodies, both of whom were supportive of the BRIA analysis and recommendation to support Options 2a and 2b.

### With Business

- 5.4 The FSA has held ongoing discussions with affected industry sectors as negotiations on the Commission proposal have progressed, including individual meetings with the three main farmed fish industry bodies - the Scottish Salmon Producers' Organisation (SSPO), British Trout Association (BTA) and British Marine Finfish Association (BMFA). All three organisations are supportive of the changes and proposed freezing exemption for farmed fish.

5.5 In addition, officials from FSA Scotland have met with a number of individual affected businesses from the production, processing and retail sectors to discuss the impact of the proposals.

## 6. OPTIONS

5.1 The Options considered were:

- **Option 1:** Do nothing and leave current freezing requirements unchanged. There would continue to be a legal obligation to freeze all farmed and wild fishery products intended to be consumed raw or almost raw, unless the competent authority authorises a national exemption based on epidemiological data.
- **Option 2a:** In line with Commission Regulation (EU) No 1276/2011 support the amendments to Regulation (EC) No. 853/2004 to extend freezing controls to all cold smoked fishery products intended to be consumed without further processing.
- **Option 2b:** In line with Commission Regulation (EU) No 1276/2001 support an amendment to Regulation (EC) No. 853/2004 to provide a specific freezing exemption for farmed fishery products that meet the relevant exemption criteria.

5.2 Options 2a and 2b are the preferred options. This would bring freezing controls for cold smoked and farmed fishery products into line with current scientific evidence ensuring they are risk-based and proportionate.

## 7. SECTORS & GROUPS AFFECTED

### Industry

7.1 The introduction of a **freezing exemption** for farmed fish will affect food business operators supplying farmed fishery products intended to be consumed raw, cold smoked or marinated/salted. UK fish farming companies, fish processors, and retailers are all involved in this trade to a greater or lesser degree, and the freezing derogation will enable these businesses to make cost savings by removing the need to freeze affected fishery products.

7.2 Fish processors and smokers may also be affected by the **extension of freezing controls** to all cold smoked fishery products not intended to undergo further processing (such as cooking) before consumption. However, the impact of this change will be mitigated by the introduction of the freezing exemption for farmed fish and will only affect businesses supplying certain species of wild cold smoked fish such as trout, halibut, and cod.

## Fish Aquaculture

### *Farmed Salmon*

- 7.3 In terms of production volumes the UK fish farming industry is dominated by the Scottish farmed Atlantic salmon industry which will be the main sector to benefit from the freezing exemption. The Scottish Salmon Producers' Organisation (SSPO) has confirmed that the Scottish farmed salmon sector supplies a significant proportion of the UK market in raw 'ready to eat' products such as gravadlax, sushi and sashimi, products that previously required to be frozen before consumption. The SSPO estimate this market to be valued at £46.1M and growing at 3.3% annually<sup>4</sup>.
- 7.4 Potentially all of the larger salmon farming companies are involved in this trade, either through manufacturing of their own products, supplying to processors who manufacture raw 'ready to eat' products, supplying through wholesalers who sell product to customers involved in these different areas, or direct supply to larger sushi / sashimi restaurant chains. Although precise volume cannot be verified due to the many different routes that the raw material takes to the consumer, the SSPO estimates that between 3 – 5% of total production of Scottish farmed salmon goes for raw 'ready to eat' consumption and will benefit from the new freezing derogation.
- 7.5 A significant proportion of farmed Atlantic salmon is also supplied cold smoked although these products will not be directly affected by the freezing exemption as cold smoked farmed fishery products did not need to be frozen previously. Salmon farming businesses will also be unaffected by the extension of freezing controls for cold smoked fish as these will only affect processors cold smoking certain wild species (see below).
- 7.6 There are currently 30 Scottish companies spread across 249 sea pen sites authorised for salmon production in the UK (10 of these companies, although active and authorised, were not producing salmon for harvest in 2010), plus one further company in Northern Ireland. In 2010 production was concentrated in 9 Scottish companies, which between them accounted for over 95% of total salmon production in Scotland.<sup>5</sup> The total production of farmed Atlantic salmon in Scotland in 2010 was 154,164 tonnes, with a projected tonnage of 157,385 tonnes for 2011.<sup>6</sup>

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<sup>4</sup> Source: Scottish Salmon Producers' Organisation

<sup>5</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>6</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

7.7 The total number of salmon fish farming companies by size of business is shown in Table 1 below. Total numbers for Scotland were sourced from the Marine Scotland Science *Scottish Fish Farm Production Survey 2010 Report*<sup>7</sup>, with data on size of business provided by SSPO. Data for Northern Ireland was provided by the Department of Agriculture and Rural Development (DARD).

**Table 1 – UK Salmon Fish Farming Businesses by Country and Size**

	Micro	Small	Medium	Large	Total
England	0	0	0	0	0
Wales	0	0	0	0	0
Scotland	20	5	1	4	30
Northern Ireland	0	0	1	0	1
<b>UK Total</b>	<b>20</b>	<b>5</b>	<b>2</b>	<b>4</b>	<b>31</b>

Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

Note: totals may not sum due to rounding

### *Farmed Trout*

7.8 It is anticipated that the UK farmed trout industry will also look to benefit from the freezing exemption for farmed fish when the product is supplied for raw consumption, although the extent of the trade in farmed trout for the raw 'ready to eat' market and the likely benefits of an exemption are less clear. The British Trout Association (BTA) has been unable to confirm the amount of farmed trout that is supplied for raw consumption by trout aquaculture businesses, but an assumption can be made that similar proportions to the salmon sector are supplied, i.e. 3-5% of total farmed trout production.

7.9 A proportion of UK farmed trout will also be supplied cold smoked, but, as with salmon, these fishery products did not require to be frozen previously and any cold smoking is likely to be carried out by processors rather than trout famers.

7.10 The UK farmed trout industry is more diverse than the farmed salmon sector and the BTA have estimated that there are 199 businesses in the UK currently engaged in table production (excluding restocking sites and trout fisheries), with 90% of production concentrated in 85 businesses. They estimate that the majority of businesses are micro businesses in England with an annual turnover of less than £1M. According to farmed finfish production data published by CEFAS there was 15,531 tonnes of farmed trout produced the UK in 2009.<sup>8</sup> As with salmon, production volumes for farmed trout are greatest in Scotland,

<sup>7</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>8</sup> <http://www.cefass.defra.gov.uk/publications/finfishnews/FFN11-Web.pdf>

with 5,208 tonnes produced in 2010 spread across 40 companies and 59 sites.<sup>9,10</sup> There is less production data available for the other UK nations, but the BTA have estimated that in 2008 there was 4,981 tonnes of trout produced in England, 530 tonnes in Northern Ireland, and 500 tonnes in Wales.

7.11 The total number of trout fish farming companies by size of business is shown in Table 2 below. Total numbers for Scotland were sourced from the Marine Scotland Science *Scottish Fish Farm Production Survey 2010 Report*<sup>11</sup>, with numbers for the rest of the UK and information on size of business provided by BTA:

**Table 2 – UK Trout Fish Farming Businesses by Country and Size**

	Micro	Small	Medium	Large	Total
England	128	2	0	0	130
Wales	25	0	0	0	25
Scotland	39	1	0	0	40
Northern Ireland	4	0	0	0	4
<b>UK Total</b>	<b>196</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>199</b>

Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

Note: totals may not sum due to rounding

### *Other Commercially Farmed Species*

7.12 In addition to salmon and trout there are a number of other farmed species cultured in the UK, including arctic charr, cod, halibut, carp, catfish, sea bass and tilapia, and food business operators rearing these species may also take advantage of the freezing derogation when product is supplied for raw consumption.<sup>12</sup> The 2009 production data published by CEFAS indicates that the total UK production of farmed finfish species other than salmon and trout was 793 tonnes.<sup>13</sup> Discussions with the British Marine Finfish Association (BMFA) have confirmed that this sector is comprised mainly of small scale businesses.

### *Total Number of UK Fish Farms*

7.13 The total number of fish farming companies in the UK by species is shown in the Table 3 below. Data for Scotland has been sourced from the Marine Scotland Science *Scottish Fish Farm Production Survey*

<sup>9</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>10</sup> This comprised 5,139 tonnes of rainbow trout produced by 25 companies (with freshwater production accounting for 3,533 tonnes and seawater production for the remaining 1,606 tonnes) and 69 tonnes of brown/sea trout produced by 15 companies

<sup>11</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>12</sup> <http://www.cefass.defra.gov.uk/publications/finfishnews/FFN11-Web.pdf>

<sup>13</sup> <http://www.cefass.defra.gov.uk/publications/finfishnews/FFN11-Web.pdf>



2010 Report.<sup>14</sup> Data for England and Wales was obtained during individual meeting with UK trade organisations – SSPO, BTA, and BMFA – and extrapolated from production data in the CEFAS annual production survey for 2009. Data for Northern Ireland was obtained from DARD.

**Table 3 – Total UK Fish Farming Businesses by Species**

Country	Salmon	Trout	Arctic Charr	Cod	Halibut	Other	Total
England	0	130	0	0	0	4	134
Wales	0	25	0	0	0	1	26
Scotland	30	40	5	2	3	0	80
Northern Ireland	1	4	0	0	0	0	5
<b>UK Total</b>	<b>31</b>	<b>199</b>	<b>5</b>	<b>2</b>	<b>3</b>	<b>5</b>	<b>245</b>

N.B. All freshwater salmon farms are hatcheries only as they are then transferred to seawater pens before going for human consumption.

Note: totals may not sum due to rounding

7.14 Table 4 below shows total UK fish farms that will be affected by the freezing extension, by country and firm size.

**Table 4 - Total UK Fish Farms (Firm Size)**

	Micro	Small	Medium	Large	Total
England	131	3	0	0	134
Wales	26	0	0	0	26
Scotland	67	8	1	4	80
Northern Ireland	4	1	1	0	5
<b>UK Total</b>	<b>228</b>	<b>11</b>	<b>2</b>	<b>4</b>	<b>245</b>

Note: totals may not sum due to rounding

## Fish Processors

7.15 Fish processing businesses will benefit from the new freezing derogation if they are supplying farmed fishery products intended to be consumed raw, cold smoked or marinated/salted, whether as 'fresh' product or pre-packaged products for grocery multiples. When a freezing derogation is applied processors will need to ensure that raw product is derived from fish farms that meet the freezing exemption criteria, and appropriate commercial documentation may be required to verify this.

7.16 Processors smoking fish may also be affected by the extension of freezing controls to all cold smoked fish intended to be consumed without further processing. However, the impact of these changes will be limited to those processors cold smoking certain species of wild fish, as no species of cold smoked farmed fish were required to be frozen previously under the EU hygiene legislation and farmed fish will

<sup>14</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

continue to be exempt due to the new freezing derogation. Cold smoked wild trout is the main species likely to be affected by the extended freezing requirement. Other wild species that may be affected include cold smoked cod and Atlantic halibut if they are not intended to undergo further processing before consumption, but the production volumes for these species are estimated to be minimal. Cold smoked wild Atlantic and Pacific salmon will not be affected by the changes as these at-risk wild species were already required to be frozen.

7.17 The majority of cold smoked wild fish on sale in the UK is intended to be cooked before consumption. Whitefish species treated in this way include haddock, herring, cod, whiting, hake, saithe and ling. As these products are traditionally cooked before consumption, a heat treatment that will kill viable parasites, they are not subject to the Community freezing controls. Therefore processors supplying this type of cold smoked fishery product will be unaffected by the new proposals.

7.18 The total number of approved fish processors in the UK is shown in the table below, drawn from the list of approved premises on the FSA website.<sup>15</sup> No precise data is available on the number of approved processors supplying product for the raw, cold smoked or marinated/salted markets, and an assumption on the likely number of affected businesses has been made based on information held by the FSA on the associated activities for each premises in Scotland, Wales and Northern Ireland (this information is potentially commercially sensitive and is not publicly available on the FSA website). Information on associated activities is not available for approved premises in England, and estimated numbers have been extrapolated from the data available for approved plants in rest of the UK:

**Table 5 – UK Approved Fish Processors**

	To be Consumed Raw	Cold Smoked	Marinated/Salted	Total
England	118	177	59	354
Wales	6	9	3	18
Scotland	31	47	16	94
Northern Ireland	5	7	2	14
<b>UK Total</b>	<b>160</b>	<b>240</b>	<b>80</b>	<b>480</b>

Note: totals may not sum due to rounding

7.19 There are a total of 480 approved fish processors in the UK that will be affected by the proposal. All approved processors will be affected by the freezing exemption; whilst the freezing extension will only affect the 240 processors of cold smoked products. Table 6 below presents

<sup>15</sup> <http://www.food.gov.uk/foodindustry/farmingfood/fishapprove/>

the number of approved fish processing business by location and size of firm.

**Table 6 – Total UK Approved Fish Processors by Country and Firm Size**

	Micro	Small	Medium	Large	Total
England	186	106	53	9	354
Wales	16	2	0	0	18
Scotland	49	28	14	2	94
Northern Ireland	7	4	0	0	14
<b>UK Total</b>	<b>258</b>	<b>141</b>	<b>69</b>	<b>12</b>	<b>480</b>

Note: totals may not sum due to rounding

### Retail and Wholesale

7.20 All retail and wholesale businesses that undertake activities with fishery products intended to be consumed raw, cold smoked or marinated/salted will need to ensure that they are familiar with the new Regulation when buying in or selling on affected fishery products. This will include fish wholesalers and grocery multiples. In particular, retail businesses selling farmed fishery products that have not undergone a freezing treatment will need to ensure that farmed fish originate from production sites that meet the exemption criteria, and appropriate documentation may be required to verify this.

7.21 The total number of major retail and wholesale stores supplying sushi and chilled smoked fish is shown in the table below (note – this does not differentiate between hot and cold smoked fish):

**Table 7 –UK Retailers and Wholesalers Selling Raw and Smoked Fishery Products by Country<sup>16</sup>**

	Sushi	Chilled Smoked Salmon	Chilled Smoked Cod	Chilled Smoked Trout	Total
England	856	847	414	258	2,375
Wales	32	32	16	10	90
Scotland	186	184	90	56	515
Northern Ireland	34	34	17	10	95
<b>UK Total</b>	<b>1,108</b>	<b>1,097</b>	<b>536</b>	<b>334</b>	<b>3,075</b>

Note: totals may not sum due to rounding

7.22 Table 8 below shows the number of retailers and wholesalers affected by the proposal by country and size of firm.

<sup>16</sup> Source: Nielsen Scantrack MAT to May 2011

**Table 8 - Retailers and Wholesalers Selling Raw and Smoked Fishery Products by Country and Firm Size**

	Micro	Small	Medium	Large	Total
England	2,039	286	50	0	2,375
Wales	77	11	2	0	90
Scotland	442	62	11	0	515
Northern Ireland	82	11	2	0	95
<b>UK Total</b>	<b>2,640</b>	<b>370</b>	<b>65</b>	<b>0</b>	<b>3,075</b>

## Food Service Businesses

- 7.23 Food service businesses selling affected fishery products will need to familiarise themselves with the revised legislation. In addition, larger businesses that source farmed fish for raw consumption direct from UK production sites and currently freeze on site are likely to achieve freezing cost savings from the new freezing exemption. One major UK sushi restaurant chain has confirmed in discussions with the FSA that approximately 70-80% of the sushi/sashimi served in their restaurants is fresh Scottish farmed salmon sourced direct from the producer, and the company has welcomed the proposals to provide a freezing exemption for farmed fishery products.<sup>17</sup> These businesses will also be required to ensure that farmed fishery products are sourced from production sites that meet the exemption criteria before they can be sold without freezing.
- 7.24 The type of food service businesses likely to be affected by the proposal is set out below in table 9 using Standard Industrial Classification (SIC) codes taken from the Office for National Statistics (ONS) Inter Departmental Business Register (IDBR). Note that this is likely to be an overestimate of the number of affected businesses as only a proportion of these businesses will serve raw fish.

**Table 9 - Type of Food Service Businesses Affected<sup>18</sup>**

SIC Code	Business Type
56.10	Restaurant & Mobile Food Services
56.21	Event Catering Activities
56.29	Other Food Service Activities

- 7.25 Table 10 below shows these food business operators by Country and Firm Size.

<sup>17</sup> Other wild species served by this business as sushi/sashimi are yellow fish, tuna and halibut, all of which are already supplied block frozen.

<sup>18</sup> Source: The Inter Departmental Business Register (IDBR) - accessible via the Office for National Statistics (ONS), <http://www.statistics.gov.uk/idbr/idbr.asp>

**Table 10 – Number of affected businesses by country and size<sup>19</sup>**

	Micro	Small	Medium	Large	Total
England	58,346	16,117	1,839	92	76,395
Wales	2,910	804	92	5	3,810
Scotland	6,026	1,665	190	10	7,890
Northern Ireland	2,188	604	69	3	2,865
<b>UK Total</b>	<b>69,470</b>	<b>19,190</b>	<b>2,190</b>	<b>110</b>	<b>90,960</b>

**Notes:**

1. Totals may not sum due to rounding
2. Figures are the sum of premises listed under SIC codes as per table 4.
3. Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

**Total Number of Affected Businesses**

7.26 Under sub-option 2a the extension of freezing controls is limited to processors of cold smoked produce handling certain species of wild fish such as trout, halibut, and cod. However, using the only data available, we are unable to separate out the activity of processors handling cold smoked fish according to species. We therefore use the category of cold smoked fish handling in its entirety; aware this could be overestimating the impact for this particular sub-sector.

7.27 More extensively the freezing exemption under sub-option 2b will affect a number of businesses including fish farming companies, fish processors, retailers (fish wholesalers, grocery multiples) and food service businesses. A summary of the total number of affected businesses under respective sub options 2a and 2b are presented in tables 11 and 12 below:

**Table 11: Policy Option 2a - fish processors supplying certain species of wild cold smoked fish**

	Micro	Small	Medium	Large	Total
England	93	53	27	4	177
Wales	5	3	1	0	9
Scotland	25	14	7	1	47
Northern Ireland	4	2	1	0	7
<b>UK Total</b>	<b>126</b>	<b>72</b>	<b>36</b>	<b>6</b>	<b>240</b>

Note: totals may not sum due to rounding

<sup>19</sup> Source: IDBR (ONS)

**Table 12: Policy Option 2b - fish farming companies, fish processors, retailers and food service businesses**

	Micro	Small	Medium	Large	Total
England	60,689	16,524	1,944	101	79,258
Wales	3,026	819	94	5	3,944
Scotland	6,588	1,763	216	12	8,579
Northern Ireland	2,281	621	73	4	2,979
<b>UK Total</b>	<b>72,584</b>	<b>19,727</b>	<b>2,327</b>	<b>122</b>	<b>94,760</b>

Note: totals may not sum due to rounding

## Consumers

7.28 Consumers of raw and cold smoked fishery products will also be affected by the revised freezing controls. There is growing consumer demand in the UK for raw 'ready to eat' fishery products such as sushi and sashimi which is seen as a healthy option. The Commission Regulation will ensure that public health measures designed to protect consumers from the risks associated with this type of raw product are risk-based and targeted. The Regulation also includes more explicit obligations on food business operators to ensure that raw fishery products that have been placed on the market without freezing have been sourced from fishing grounds or fish farms that meet the exemption criteria. This will ensure that consumers are only able to eat raw fishery products that have not undergone a freezing treatment when there is sufficient evidence to demonstrate that the risks are negligible.

## Enforcement

7.29 Enforcement of the revised freezing controls across the UK will be carried out by Local Authorities who will be required to verify that freezing has taken place where necessary to ensure public health remains protected. They will also be required to verify that farmed fishery products subject to a freezing exemption are compliant with the exemption criteria. This will require an understanding of the risks associated with parasites across various aquaculture production methods and fish species and an up-to-date knowledge of the latest scientific risk assessments. The guidance document produced by the Commission to accompany the new Regulation will assist Local Authorities in assessing FBO compliance with the revised legislation. Local Authorities will also need to verify and check relevant food business operator documentation as necessary.

## 8. COSTS & BENEFITS

### COSTS

**Option 1** – is the ‘do nothing’ option.

- 8.1 There are no additional costs to business and the public sector associated with this option. However, if the amendments to freezing controls in Regulation (EC) No. 853/2004 are not implemented the regulatory burden would be kept unnecessarily high and freezing cost savings outlined below would not be realised.
- 8.2 In addition, doing nothing could result in the Commission imposing monetary sanctions on the UK for failing to comply with its Treaty obligations. The maximum fine that could be imposed on the UK is currently some €703,000 per day or some £256 million per year. Scotland would be required to pay a percentage of any UK fine (potentially up to 100%) if the infraction related to devolved matters, depending on the extent of our involvement.

**Option 2a** - support the amendments to Regulation (EC) No. 853/2004 to extend freezing controls to all cold smoked fishery products intended to be consumed without further processing

### **Industry**

#### One-Off Familiarisation Cost

- 8.3 Food business operators processing cold smoked fishery products would be required to familiarise themselves with the new freezing requirement. It is envisaged that 1 hour would be required per business to read and familiarise themselves with the new legislation, plus an additional hour to disseminate this information to staff<sup>20</sup>. This means a total of 2 hours per business to become familiar with the revised controls. There are currently 240 ‘cold smoked’ fish processing businesses operating in the UK which are directly affected by the proposal (see Table 11).
- 8.4 The total familiarisation cost is quantified by multiplying the median hourly wage rate of a manager of £26.10<sup>21</sup> by the time required to familiarise themselves with the policy (2 hours) by the total number of approved ‘cold smoked’ fish processing businesses affected in the UK (240); resulting in a familiarisation cost to the sector of £12,530<sup>22</sup>.

<sup>20</sup> While we recognise that dissemination of information will result in an opportunity cost in terms of time of key staff members we anticipate that this will be minimal and the additional hour will cover these costs.

<sup>21</sup> Wage rate obtained from the Annual Survey of Household Earnings (ASHE) 2011. Median hourly wage rate of ‘Production Manager’, £20.08, uplifted by 30% to account for overheads (20.08\*1.3) = 26.10

<sup>22</sup> 240\*2\*1\*£26.10=£12,518

Table 13a below shows the familiarisation cost to Fish Processors by country and firm size.

**Table 13a: One-Off Familiarisation Costs to Fish Processors, by Country and Firm Size**

	Micro	Small	Medium	Large	Total
England	£4,851	£2,772	£1,386	£231	£9,241
Wales	£247	£141	£70	£12	£470
Scotland	£1,288	£736	£368	£61	£2,454
Northern Ireland	£192	£110	£55	£9	£365
UK	£6,578	£3,759	£1,879	£313	£12,530

Note: totals may not sum due to rounding

- 8.5 In order for one-off costs to be compared with annual costs on an equivalent basis across the entire time span of the policy, one-off costs are transformed into Equivalent Net Annual Costs (EANC) by dividing the one-off cost by an annuity factor.<sup>23</sup>
- 8.6 The total one-off cost to industry in the UK affected by this proposal is estimated to be £12,530 which yields an equivalent annual cost of £1456 over a time period of 10 years. Table 13b shows the breakdown of EANCs by UK country

**Table 13 b: Annual Equivalent Costs (EANC) by UK Country**

	EAC
England	£1,074
Wales	£55
Scotland	£285
Northern Ireland	£42
UK	£1,456

### Ongoing Freezing Costs

- 8.7 With regard to cold smoked fishery products derived from farmed fish, no freezing was required previously under the EU hygiene legislation. As indicated above, it is fully expected that all aquaculture production methods currently in operation in the UK will be able to demonstrate that they meet the freezing exemption criteria, therefore farmed cold smoked fish will continue to be exempted from the freezing requirements and no additional freezing costs are expected for businesses supplying these products as a result of this policy option.
- 8.8 Based on the data available we are unable to separate out the activity of processors handling cold smoked fish derived from wild species. However, our assumption is that production volumes of affected wild cold smoked fishery products that will now require freezing for the first

<sup>23</sup> The annuity factor is essentially the sum of the discount factors across the time period over which the policy is evaluated. The equivalent annual cost formula is as follows:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left( \frac{1}{1+r_i} \right)$$



time are likely to be small. The main species likely to be affected are wild trout, cod and halibut. The UK's largest trout processor (who process approximately 80% of UK trout) has confirmed that they do not produce any cold smoked wild trout. They also confirmed that there is likely to be minimal amounts of cold smoked wild trout, cod and halibut produced commercially in the UK. We therefore assume that any additional freezing costs to UK industry are likely to be minimal.

## Enforcement

### One-Off Familiarisation Costs

8.9 Local Authorities enforcing the revised freezing controls would be required to familiarise themselves with the revised legislation. We assume that 1 hour would be required per Local Authority for one Environmental Health Officer (EHO) to read and familiarise themselves with the new legislation, plus an additional hour to disseminate this information to staff. It is envisaged that 434 Local Authorities will be affected by the proposed changes in the UK.

8.10 To calculate the total familiarisation cost we first need to quantify the familiarisation cost per LA. The familiarisation cost per LA is calculated by multiplying the hourly wage rate of an EHO (£20.46<sup>24</sup>) by the number of hours required for familiarisation and dissemination (2 hours), resulting in a familiarisation cost per LA of £40.92 (assuming that one official per LA will be required to familiarise themselves with the new policy). The total familiarisation cost for enforcement authorities in the UK is calculated by multiplying the familiarisation cost per LA (£40.92) by the number of LAs in the UK (434), resulting in a familiarisation cost in the UK to enforcement authorities of £17,761<sup>25</sup>. Table 14a displays the familiarisation cost to enforcement authorities broken down by country.

**Table 14a – Familiarisation cost to enforcement authorities by country**

	Number LAs	Familiarisation Cost
England	354	£14,487
Wales	22	£900
Scotland	32	£1,310
Northern Ireland	26	£1,064
<b>UK</b>	<b>434</b>	<b>£17,761</b>

Note: totals may not sum due to rounding

8.11 As with the one off familiarisation costs to industry it is necessary to equivalently annualise the one off familiarisation costs for enforcement authorities (see paragraph 60). The total one-off cost to enforcement

<sup>24</sup> Wage rate obtained from the Annual Survey of Household Earnings, 2011. (See: <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of 'Environmental health officers') £15.74 + 30% to cover overheads = £20.46).

<sup>25</sup> 434\*1\*2\*20.462=17,761

authorities under Option 2a is estimated at £17,761, which yields an equivalent net annual cost of £2,063 over a time period of 10 years. Table 14b below shows the breakdown of EANCs by UK country

**Table 14b: Equivalent Annual Costs (EAC) by UK Country**

	<b>EANC</b>
<b>England</b>	£1,683
<b>Wales</b>	£105
<b>Scotland</b>	£152
<b>Northern Ireland</b>	£124
<b>UK</b>	£2,063

### **Total Costs under Option 2a (Freezing Extension)**

8.12 In order to assess the costs over the life time of this policy it is standard HM Treasury practice to sum costs/benefits over a period of 10 years and discount to obtain the present value of these costs and benefits. Discounting adjusts for the general principle that people prefer to receive goods/services now to later.<sup>26</sup> The total one-off costs associated with policy Option 2a are estimated at £30,291, as set out in Table 15 below.

**Table 15: Total UK Costs under Option 2a (NPV)**

<b>One-Off Costs: Familiarisation</b>	<b>Year 0</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 5</b>	<b>Year 6</b>	<b>Year 7</b>	<b>Year 8</b>	<b>Year 9</b>	<b>Total Cost</b>	<b>NPV</b>
<b>Industry</b>	£12,530	£0	£0	£0	£0	£0	£0	£0	£0	£0	£12,530	£12,530
<b>Enforcement</b>	£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,761	£17,761
<b>Total</b>	£30,291	£0	£0	£0	£0	£0	£0	£0	£0	£0	£30,291	£30,291

Note: totals may not sum due to rounding

**Option 2b** - Support an amendment to Regulation (EC) No. 853/2004 to provide a specific freezing exemption for farmed fishery products that meet the relevant exemption criteria

### **Industry**

#### One-Off Familiarisation Costs

8.13 Food business operators wishing to make use of the freezing exemption would be required to familiarise themselves with the new freezing exemption. It is estimated that 1 hour would be required per business to read and familiarise themselves with the new legislation,

<sup>26</sup> Discounting is a technique used to compare costs and benefits that occur in different time periods. It is a separate concept from inflation, and is based on the principle that, generally, people prefer to receive goods and services now rather than later. This is known as 'time preference'.

plus an additional hour to disseminate this information to staff. It is estimated that 94,760 food businesses will be affected by the proposed changes (see Table 12), resulting in 189,520 hours of industry time required to become familiar with the changes. Assuming the median hourly wage rate of a food business manager of £26.10<sup>27</sup> per hour, and that one manager per FBO will be required to familiarise themselves with the policy, this would result in a familiarisation cost to industry of £4,947,230. Table 16 below shows the familiarisation costs associated with preferred sub-option 2b to Industry.

**Table 16a: One-Off Familiarisation Costs to Industry by Country and Firm Size**

	Micro	Small	Medium	Large	Total
England	£3,168,458	£862,674	£101,484	£5,285	£4,137,902
Wales	£157,978	£42,781	£4,909	£241	£205,908
Scotland	£343,945	£92,067	£11,260	£621	£447,892
Northern Ireland	£119,110	£32,401	£3,818	£199	£155,528
UK	£3,789,490	£1,029,922	£121,472	£6,346	£4,947,230

Note: totals may not sum due to rounding

- 8.14 One-off costs need to be transformed into EACs (see paragraph 60). The total one-off cost to UK industry affected by Option 2b is estimated to be £4,947,230 which yields an equivalent annual cost of £574,746 over a time period of 10 years. Table 16b below shows the breakdown of EACs by UK country.

**Table 16b: Equivalent Annual Costs to Industry under Option 2b**

	EAC
England	£480,722
Wales	£23,921
Scotland	£52,034
Northern Ireland	£18,068
UK	£574,746

### Risk Assessment & Verification Costs

- 8.15 The freezing exemption for farmed fishery products is available where fish are cultured from embryos and fed exclusively on a diet that cannot contain viable parasites that present a health hazard, and are either exclusively reared in an environment that is free from parasites, or where food business operators can verify through procedures, approved by the competent authority, that they do not present a health hazard with regard to parasites. As outlined above, it is expected that all aquaculture production methods currently in operation in the UK will meet these exemption criteria. On this basis, we envisage no additional costs to UK fish aquaculture businesses resulting from the need to

<sup>27</sup> Wage rate obtained from the Annual Survey of Household Earnings (ASHE) 2011. Median hourly wage rate of 'Production Manager', £20.08, uplifted by 30% to account for overheads (20.08\*1.3) = 26.104

carry out additional risk assessment or verification monitoring, assuming there is no change in farming practices.

## Enforcement

### Familiarisation Costs

8.16 No additional Local Authority familiarisation costs are envisaged for Option 2b in addition to those calculated for Option 2a, as EHO's will familiarise themselves with new Commission Regulation as a whole. Familiarisation costs to enforcement under Option 2b are therefore the same as under Option 2a; £17,761 (see Table 14a).

### **Total Costs under Sub-option 2b (Freezing Exemption)**

8.17 The total one-off cost (NPV) associated with policy Option 2b is estimated at £4,964,991 (see table 17).

**Table 17: Total UK Costs under Option 2b (NPV)**

UK	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	NPV
<b>One-Off Costs: Familiarisation</b>												
<b>Industry</b>	£4,947,230	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,947,230	£4,947,230
<b>Enforcement</b>	£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,761	£17,761
<b>Total</b>	£4,964,991	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,964,991	£4,964,991

### **Total Costs under Sub-options 2a and 2b (Freezing Extension and Exemption)**

8.18 The total one-off cost (NPV) associated with policy Sub-Options 2a and 2b is estimated at £4,964,991 (see table 18). Note that in calculating the total one-off familiarisation costs to industry the familiarisation costs of £12,530 under Sub-Option 2a are included in the familiarisation costs of £4,947,230 under Sub-Option 2b as all affected businesses are contained within Sub-Option 2b. Similarly, as explained in paragraph 71, familiarisation costs to Local Authorities are the same under both Sub-Options and are only calculated once, giving total familiarisation costs of £17,761.

**Table 18: Total UK Costs under combined Sub-Options 2a and 2b (NPV)**

UK	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	NPV
<b>One-Off Costs: Familiarisation</b>												
<b>Industry</b>	£4,947,230	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,947,230	£4,947,230
<b>Enforcement</b>	£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,761	£17,761
<b>Total</b>	£4,964,991	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,964,991	£4,964,991

## **BENEFITS**

**Option 1** - is the 'do nothing' option.

8.19 If the amendments to freezing controls in Regulation (EC) No. 853/2004 are not implemented businesses and the public sector would not incur one-off familiarisation costs resulting from the new Commission Regulation.

**Option 2a** - support the amendments to Regulation (EC) No. 853/2004 to extend freezing controls to all cold smoked fishery products intended to be consumed without further processing

### **Industry**

8.20 The extension of freezing controls to all wild cold smoked fishery products may provide reputational benefits to businesses producing these products as customers and consumers can be reassured that appropriate public health controls have been applied for at-risk species that have not undergone processing sufficient to kill any viable parasites that may be present.

### **Enforcement**

8.21 No additional benefits to enforcement authorities have been identified for this option.

### **Consumers**

8.22 The introduction of more risk-based controls for cold smoked fishery products will ensure that consumers are provided with an appropriate level of public health protection in relation to cold smoked products derived from wild species that will now need to be frozen to kill any viable parasites that may be present in the product.

**Option 2b** - Support an amendment to Regulation (EC) No. 853/2004 to provide a specific freezing exemption for farmed fishery products that meet the relevant exemption criteria

### **Industry**

#### **Freezing Cost Savings**

8.23 The Commission Regulation will enable food business operators in the UK to make cost savings by removing the need to freeze raw, cold smoked and marinated/salted fishery products derived from farmed fish

where the new exemption criteria are met. It is, however, difficult to attribute any potential cost savings to individual sectors – aquaculture, processing, retail and wholesale – as the obligation to freeze affected products is placed on the sector as a whole. Both the previous and revised legislation specifies that a freezing treatment must be applied to raw materials or finished product, but does not specify where in the supply chain any freezing treatment must take place. This is left to the discretion of individual food business operators who will seek to maximise efficiencies in the supply chain.

- 8.24 In addition, food business operators supplying fishery products may not necessarily know if a product is destined for raw consumption, and therefore subject to freezing controls, as this decision may be made later in the supply chain. For these reasons, estimated cost savings resulting from the new freezing exemption have been aggregated for all affected industry sectors as a whole based on total UK production data for farmed fish and an estimate of the volume entering the raw 'ready to eat' market.
- 8.25 The published CEFAS production data for 2009 indicates a total UK farmed finfish production of 160,988 tonnes.<sup>28</sup> However, this data indicates a total Atlantic salmon production 144,663 tonnes, whereas more recent Scottish data for 2010 confirms this to be 154,164 tonnes.<sup>29</sup> Therefore total UK farmed finfish production has been calculated using the latest 2010 Scottish data for farmed salmon, and 2009 CEFAS data for all other production, giving a total UK production of 170,488 tonnes. If it is assumed, based on SSPO estimates, that 3 – 5% of total production is supplied for the raw 'ready to eat' market, this would equate to between 5,114 – 8,524 tonnes per annum of farmed fish going for raw consumption that previously had to be frozen and would now benefit from a freezing exemption.<sup>30</sup>
- 8.26 Most of the UK farmed salmon industry currently use third party companies to freeze gutted, head-on salmon when required. The SSPO have indicated that the basic cost of freezing is between £0.70 and £1.00 / Kg (October 2011) plus storage costs and potentially higher distribution costs. If an average freezing cost of £0.85 / Kg is used as an estimate, the freezing exemption in the Commission Regulation would result in estimated freezing cost savings to UK industry of between £4.3M per annum (based on 3% of production going for raw consumption) and £7.2M per annum (based on 5% of production going for raw consumption). On this basis we estimate that the per annum cost saving to the UK fish industry would range from £4,347,444 to £7,245,740 with a central estimate of £5,796,592<sup>31</sup>. Table 19a below shows annual freezing cost savings broken down by country and firm

<sup>28</sup> <http://www.cefass.defra.gov.uk/publications/finfishnews/FFN11-Web.pdf>

<sup>29</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>30</sup> These estimated production volumes include raw and marinated/salted farmed fishery products only. No freezing savings have been calculated for cold smoked farmed fishery products as these products did not require to be frozen previously.

<sup>31</sup> Central Estimate obtained by: £5,796,592 = (£4,347,444 + £7,245,740) / 2

size, whilst Table 19b shows the cost to the UK industry (discounted) over a period of 10 years.

**Table 19a: Freezing Costs Savings per Country and Firm Size (£, per annum, Central Estimate)**

	Micro	Small	Medium	Large	Total
England	£3,712,433	£1,010,781	£118,908	£6,193	£4,848,315
Wales	£185,100	£50,126	£5,752	£282	£241,260
Scotland	£402,995	£107,873	£13,193	£727	£524,789
Northern Ireland	£139,559	£37,964	£4,474	£233	£182,229
UK	£4,440,086	£1,206,744	£142,327	£7,435	£5,796,592

Note: totals may not sum due to rounding

**Table 19b: Freezing Costs Savings to UK Industry (£ constant prices, discounted over 10 years)**

Industry	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Benefit	Average Annual Benefit	NPV
<b>Freezing Costs Savings to UK Industry</b>													
<i>Upper Bound</i>	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£72,457,400	£7,245,740	£62,369,058
<i>Lower Bound</i>	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£43,474,440	£4,347,444	£37,421,435
<i>Central/ Best Estimate</i>	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£57,965,920	£5,796,592	£49,895,247

Note: totals may not sum due to rounding

8.27 Potentially these savings could be even higher. One major salmon farming company representing around 24% of the total production of farmed Atlantic salmon in Scotland have estimated that as much as 25% of the total salmon they supply may be consumed raw or almost raw either as sushi/sashimi or cold smoked, therefore potential freezing cost savings could be much higher. Although a significant proportion of this is likely to be exported.

### Product Value Increase to Industry from Freezing Exemption

8.28 A freezing derogation will also increase the value of farmed fish supplied for raw consumption, as freezing turns a high quality fresh product into a cheaper frozen commodity product. Based on information provided by SSPO, the average UK spot price in 2010 for fresh salmon was £4.25 / Kg, and £3.69 / Kg for frozen salmon, giving a price differential of £0.56/Kg. If it is assumed that the price differential for fresh and frozen product is similar across all farmed species, and assuming between 5,114 and 8,524 tonnes are supplied annually to the raw 'ready to eat' market, this would result in an increase in value of between £2.8M and £4.7M for farmed fishery products intended to be consumed raw as a result of applying a freezing derogation.

8.29 On this basis we estimate a per annum incremental benefit from an increase in the value of raw farmed fish of £2,864,198 - £4,773,664 with a central estimate of £3,818,931<sup>32</sup>. Table 20a below shows the per annum benefit derived from an increase in product value as a result of the freezing exemption, based on central estimates and broken down by country and firm size. Table 20b shows the total benefits to industry discounted over a 10 year period.

**Table 20a: Product Value Increases from Freezing Exemption, by UK Country and Firm Size, (£, Central Estimate, per annum)**

	Micro	Small	Medium	Large	Total
<b>England</b>	£2,445,838	£665,927	£78,339	£4,080	£3,194,184
<b>Wales</b>	£121,948	£33,024	£3,790	£186	£158,947
<b>Scotland</b>	£265,502	£71,069	£8,692	£479	£345,743
<b>Northern Ireland</b>	£91,945	£25,011	£2,947	£154	£120,057
<b>UK</b>	£2,925,233	£795,031	£93,768	£4,899	£3,818,931

**Table 20b: Product Value Increases to UK Industry (£ constant prices, discounted over 10 years)**

Industry	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Benefit	Average Annual Benefit	NPV
<b>Product Value Increase to UK Industry</b>													
<i>Upper Bound</i>	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£47,736,640	£4,773,664	£41,090,203
<i>Lower Bound</i>	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£28,641,984	£2,864,198	£24,654,122
<i>Central/ Best Estimate</i>	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£38,189,312	£3,818,931	£32,872,163

Note: totals may not sum due to rounding

## Enforcement Freezing Exemption Cost Savings

8.30 We assume that the freezing exemption for farmed fish will reduce the level of enforcement action required to be taken against companies supplying farmed fishery products intended to be consumed raw. This will free up scarce Local Authority resources to focus on more high risk food safety issues. To calculate any potential cost savings from reduced levels of enforcement we first need to quantify the level of enforcement activity related to the previous freezing requirements.

8.31 Of the 32 Local Authorities in Scotland we are aware that 2 have spent time enforcing the previous freezing requirements. Assuming this is a typical level of enforcement across the UK, it can be estimated that around 27 of the 434 Local Authorities in the UK (6%) may have spent time to enforce the freezing requirements. Anecdotal evidence indicates that individual EHOs will spend between 0.5 – 1.5 hours on activities such as considering legislation and guidance, completion of enforcement reports, and liaising with the FSA.

<sup>32</sup> Central Estimate obtained by: £3,818,931 = (£2,864,198 (Lower Bound) + £4,773,664 (Upper Bound)) / 2



8.32 We assume that one EHO per Local Authority will be required to spend time on these enforcement issues, resulting in a range of between 13.5 – 40.5 hours of total enforcement time spent on enforcing freezing requirements across the UK. The potential cost savings from applying a freezing exemption is then derived from multiplying the total amount of enforcement time (2 hours) by the hourly wage rate of an EHO (£20.46<sup>33</sup>), resulting in a potential cost savings to UK enforcement authorities ranging between £278 - £833, with a central estimate of £555 per annum<sup>34</sup>. Table 21a below shows lower and upper bound estimates including a central estimate of these freezing exemption cost savings to Local Authorities broken down by country. Table 21b shows the total discounted freezing exemption cost savings to enforcement over a 10 year period.

**Table 21a – Freezing Exemption Cost Savings to Enforcement Authorities by UK Country**

	No. of Affected LAs	Cost Saving		
		lower bound	upper bound	Central Estimate
England	22	£226	£679	£453
Wales	1	£14	£42	£28
Scotland	2	£20	£61	£41
Northern Ireland	2	£17	£50	£33
UK	27	£278	£833	£555

**Table 21b – Freezing Exemption Cost Savings to UK Enforcement Authorities (£, discounted over 10 years)**

Enforcement	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Benefit	Average Annual Benefit	NPV
<b>Freezing Costs Savings to Enforcement</b>													
<i>Upper Bound</i>	£833	£833	£833	£833	£833	£833	£833	£833	£833	£833	£8,325	£833	£7,166
<i>Lower Bound</i>	£278	£278	£278	£278	£278	£278	£278	£278	£278	£278	£2,775	£278	£2,389
<i>Central/ Best Estimate</i>	£555	£555	£555	£555	£555	£555	£555	£555	£555	£555	£5,550	£555	£4,778

Note: totals may not sum due to rounding

## Non-monetised benefits

### Quality Issues

8.33 All industry representatives and affected business consulted in the development of this impact assessment have stressed that freezing of farmed salmon intended to be consumed raw or almost raw results in significant deterioration in the quality of the fish due to the soft, oily

<sup>33</sup> Wage rate obtained from the Annual Survey of Household Earnings, 2011.

(See: <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of 'Environmental health officers') £15.74 + 30% to cover overheads = £20.46)

<sup>34</sup> Central Estimate obtained by: £555 = £278 (Lower Bound) + £833 (upper Bound) / 2

nature of the flesh, making it very difficult to slice into sashimi. The introduction of a freezing derogation will ensure that product can be supplied fresh, avoiding this quality issue and any potential deterioration in demand for raw product.

#### *Reduced Barriers to Market Entry*

- 8.34 The freezing exemption may reduce barriers for new companies entering this raw 'ready to eat' market by removing the need to invest in freezing equipment and infrastructure. The SSPO has indicated that individual quick freezing (IQF) of raw material at the initial processing stage (immediately after gutting) is the best way to ensure optimum quality for finished raw products such as sushi and sashimi. The freezing exemption removes the potential need for any new salmon companies entering the market to invest in IQF equipment at production sites.

#### *Reputational Benefits*

- 8.35 It is likely that the new freezing exemption will help reinforce confidence in the ability of the Scottish farmed salmon industry to deliver premium fresh product in a timely manner. The SSPO have indicated that the freezing process introduces additional variability and costs into the supply chain that is not consistent with the supply of standard fresh product, and that freezing results in a loss of all the benefits of Scottish provenance and marketing. They highlight that the supply chain needs consistency and certainty of supply to operate effectively and when this consistency is compromised by additional processes, such as freezing, processors may seek alternative options to UK supply resulting in potential market deflection towards Norwegian imports. The ability of producers to carry out the freezing process also becomes a factor in the decision by retailers and food service businesses to buy UK farmed salmon. These factors have the potential to dilute the 'locally grown' and sustainability messages promoted by the Scottish industry, and could result in a fall in consumer confidence with respect to the quality of UK farmed salmon. The new freezing exemption will remove this additional variability in the supply chain and mitigate any potential impact on the reputation of the Scottish industry that may have otherwise occurred if freezing continued to be a legal requirement.

### **Consumers**

- 8.36 Provision of a freezing derogation for farmed fishery products intended to be consumed raw will provide consumers with a level of public health protection that is appropriate to the risks. The proposal only allows for fishery products to be exempted from the freezing requirements when there is sufficient evidence or risk assessment to show there are no risks to public health from parasitisation, or where those risks are

shown to be negligible, ensuring that consumers are not exposed to products that may contain live parasites without first having been frozen. The freeing up of scarce Local Authority resources to focus on more high risk food safety issues will also enable the delivery of greater long-term benefits for consumers.

## Government

8.37 The introduction of a freezing exemption for farmed fish in the UK will remove any potential reputational costs to the UK and Scottish Governments of not applying risk-based controls. As outlined above current scientific opinion considers the risks to public health from parasites in farmed fish to be negligible when certain conditions are met, and supporting this amendment will ensure that food safety policy in the UK continues to be science and evidence based.

## Total Benefits under Option 2b (Freezing Exemption)

8.38 The total benefit associated with policy Option 2b is estimated at between £62m and £103m over 10 years with a best estimate of £83m; an annual average benefit of £9,6m. Once these benefits are discounted at a rate of 3.5% over 10 years we obtain a present value total benefit of £80m. Total on-going benefits associated with option 2b are presented in table 22.

**Table 22: Summary of All UK Monetised Benefits under Option 2b**

Total Benefits	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Benefit	Average Annual Benefit	NPV
<b>Enforcement</b>													
<i>Freezing Costs Savings</i>													
<i>Upper Bound</i>	£833	£833	£833	£833	£833	£833	£833	£833	£833	£833	£8,325	£833	£7,166
<i>Lower Bound</i>	£278	£278	£278	£278	£278	£278	£278	£278	£278	£278	£2,775	£278	£2,389
<b>Central/ Best Estimate</b>	£555	£555	£555	£555	£555	£555	£555	£555	£555	£555	£5,550	£555	£4,778
<b>Total Enforcement</b>	£555	£555	£555	£555	£555	£555	£555	£555	£555	£555	£5,550	£555	£4,778
<b>Industry</b>													
<i>Freezing Costs Savings</i>													
<i>Upper Bound</i>	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£72,457,400	£7,245,740	£62,369,058
<i>Lower Bound</i>	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£43,474,440	£4,347,444	£37,421,435
<b>Central/ Best Estimate</b>	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£57,965,920	£5,796,592	£49,895,247
<i>Product Value Increase</i>													
<i>Upper Bound</i>	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£47,736,640	£4,773,664	£41,090,203
<i>Lower Bound</i>	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£28,641,984	£2,864,198	£24,654,122
<b>Central/ Best Estimate</b>	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£38,189,312	£3,818,931	£32,872,163

<b>Total Industry</b>	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£96,155,232	£9,615,523	£82,767,409
<b>Total Benefit</b>													
<i>Upper Bound</i>	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£120,202,365	£12,020,237	£103,466,428
<i>Lower Bound</i>	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£72,119,199	£7,211,920	£62,077,946
<b>Central/ Best Estimate</b>	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£96,160,782	£9,616,078	£82,772,187

## **TOTAL NET BENEFITS**

### **Option 2a – Freezing Extension**

8.39 Total costs outweigh the total benefits of preferred policy sub-option 2a generating a net negative benefit of £30,291 presented in table 23 below.

**Table 23: Total UK net benefit under Option 2a (Freezing Extension, central estimate)**

Net Benefit	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Net Benefit	NPV
<b>Industry</b>	-£12,530	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£12,530	-£12,530
<b>Enforcement</b>	-£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£17,761	-£17,761
<b>Total</b>	-£30,291	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£30,291	-£30,291

### **Option 2b – Freezing Exemption**

8.40 Total benefits outweigh the total costs of preferred policy sub-option 2b generating a net positive benefit over 10 years of £77,807,196. Table 24 below displays the net benefit of this option 2b.

**Table 24: Total UK net benefit under Option 2b (Freezing Exemption, central estimate)**

UK	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	NPV
<b>Net Benefits</b>												
<b>Industry</b>	£4,668,293	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£91,208,002	£77,820,179
<b>Enforcement</b>	-£17,206	£555	£555	£555	£555	£555	£555	£555	£555	£555	-£12,211	-£12,983
<b>Total</b>	£4,651,087	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£91,195,791	£77,807,196

Note: totals may not sum due to rounding

### **Options 2a and 2b – Freezing Extension and Freezing Exemption**

8.41 Total benefits outweigh the total costs of preferred policy sub-options 2a and 2b generating a net positive benefit of £77,807,196 (central estimate) over ten years. Table 25 below displays the net benefit of the preferred option.

**Table 25: Total UK net benefit under Options 2a and 2b (Freezing Extension and Exemption, central estimate)**

UK	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	NPV
<b>One-Off Costs: Familiarisation</b>												
<b>Industry (2a+2b)</b>	£4,947,230	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,947,230	£4,947,230
<b>Enforcement</b>	£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,761	£17,761
<b>Total</b>	£4,964,991	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,964,991	£4,964,991
<b>Ongoing Benefits: Freezing Cost Savings</b>												
<b>Industry (1)</b>	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£57,965,920	£49,895,247
<b>Industry (2)</b>	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£38,189,312	£32,872,163
<b>Enforcement Tot</b>	£555	£555	£555	£555	£555	£555	£555	£555	£555	£555	£5,550	£4,778
<b>Total</b>	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£96,160,782	£82,772,187
<b>Net Benefits</b>												
<b>Total</b>	£4,651,087	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£91,195,791	£77,807,196

Note: totals may not sum due to rounding

## 9. SCOTTISH FIRMS IMPACT TEST

- 9.1 As outlined above, during development of the Commission Regulation the FSA in Scotland met with six affected firms from the production, processing and retail sectors to discuss the impact of the planned changes on their business. These were located in Stirling, Lairg (in Sutherland), and Aberdeen. All of those consulted were supportive of the freezing exemption for farmed fish which was viewed as a positive step in which European legislation was 'catching up' with the latest scientific evidence. All businesses consulted were supportive of the Commission proposals being put forward.
- 9.2 We are not aware of any new administrative burdens on Scottish businesses as a result of the introduction of these measures. Providing a freezing derogation for farmed Atlantic salmon will reduce the regulatory burden on affected Scottish businesses without compromising public health protection and is fully in line with the Government's reducing regulation agenda.

### Competition Assessment

- 9.3 Using the Office of Fair Trading (OFT) competition assessment Framework, it has been established that the preferred policy option (Options 2a and 2b) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

### Test Run of Business Forms

- 9.4 The documentation requirements in the new Regulation are the same as the previous legislation – affected fishery products must be accompanied by a document issued by the food business operator performing the freezing treatment stating the type of treatment applied, except when supplied to the final consumer. Therefore no test run of business forms will be required.
- 9.5 Where fishery products that have not undergone a freezing treatment are placed on the market the new Regulation requires that food business operators ensure that they originate from a fishing ground or fish farm that meet the exemption criteria. The new Regulation does not set down any mandatory requirements for how this obligation should be met; only indicating that this provision may be met by information in commercial documentation or by any other information accompanying the fishery products. It would be a commercial decision for food business operators as to whether additional documentation is provided. Therefore no test run of business forms is required.

## **10. LEGAL AID IMPACT TEST**

- 10.1 The domestic enforcement Regulations do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This draft BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the Commission Regulation.

## **11. ENFORCEMENT, SANCTIONS AND MONITORING**

- 11.1 Commission Regulation (EU) No. 1276/2011 will be enforced in Scotland by The Food Hygiene (Scotland) Amendment Regulations 2012. Enforcement will be the responsibility of Local Authority Environmental Health Departments.
- 11.2 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.
- 11.3 The effectiveness and impact of the Commission Regulation will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys, and general enquiries from the public.

## **12. IMPLEMENTATION AND DELIVERY PLAN**

- 12.1 Commission Regulation (EU) No. 1276/2011 applied directly in the UK from 29 December 2011 (i.e. 20 days after being published in the EU Official Journal on 9 December 2011).
- 12.2 The Food Hygiene (Scotland) Amendment Regulations 2012 providing for the domestic enforcement of the Commission Regulation are due to come into force on 1 April 2012 and will be communicated to stakeholders by email, letter and via the Agency's website etc.

### Post-Implementation Review

- 12.3 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in December 2016 (i.e. 5 years from the direct application of Regulation (EU) No. 1276/2011 in the UK).
- 12.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## **13. SUMMARY AND RECOMMENDATION**

- 13.1 The Commission Regulation introduces more risk based and proportionate freezing controls for fishery products intended to be consumed raw or almost raw in light of the latest scientific evidence. Provision of a risk-based freezing derogation for farmed fish will reduce the regulatory burden on the UK and Scottish fish farming industries supplying the raw ready to eat market without compromising public health protection. This will be of particular benefit to the Scottish farmed salmon industry which supplies an increasing amount of product for raw consumption.
- 13.2 Therefore the Agency recommends Options 2a and 2b to support the Commission Regulation and provide for domestic enforcement measures in The Food Hygiene (Scotland) Amendment Regulations 2012.
- 13.3 Taking this option allows the Scottish Government to fulfil its obligations to implement EU law and is fully in line with the Government's reducing regulation agenda. Implementation of the Commission Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.
- 13.4 A summary of total costs and benefits is provided in the table below.

**Table 26: Summary of Total Costs and Benefits**

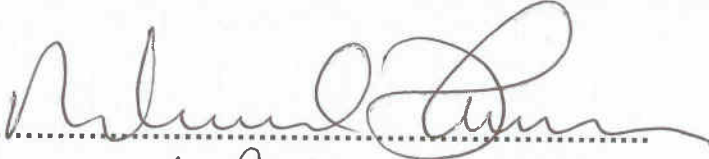
<b>Option</b>	<b>Total Costs</b>	<b>Total Benefits</b>
<p><b>Option 1</b> – is the ‘do nothing’ option.</p>	<p>Regulatory burden would be kept unnecessarily high and freezing cost savings would not be realised.</p> <p>Risk of infraction proceedings for failure to implement (EC) 1020/2008. Possible fines of up to €703,000 per day.</p>	<p>Businesses and the public sector would not incur one-off familiarisation costs.</p>
<p><b>Option 2a</b> - support extension of freezing controls to all cold smoked fishery products intended to be consumed without further processing</p>	<p>Estimated one-off familiarisation costs to UK industry of £12,530.</p> <p>Estimated one-off familiarisation costs to UK enforcement authorities of £17,761</p> <p>Estimated total UK one-off familiarisation costs of £30,291.</p>	<p>May provide reputational benefits to businesses producing affected products.</p> <p>Ensures that consumers are provided with an appropriate level of public health protection in relation to cold smoked products.</p>
<p><b>Option 2b</b> - support introduction of a specific freezing exemption for farmed fishery products that meet the relevant exemption criteria</p>	<p>Estimated one-off familiarisation costs to UK industry of £4,947,230</p> <p>Estimated one-off familiarisation costs to UK enforcement authorities of £17,761</p> <p>Estimated total UK one-off familiarisation costs of £4,964,991</p>	<p>Estimated annual freezing cost savings to UK industry of £5,796,592.</p> <p>Estimated annual product value increases to UK industry of £3,818,931.</p> <p>Estimated annual cost savings to UK enforcement authorities of £555.</p> <p>It is likely that UK industry will also gain product quality and reputational benefits from this option, and reduced barriers to market entry.</p> <p>Consumers will be provided with a level of public health protection that is appropriate to the risks.</p> <p>Removal of potential reputational costs to the UK and Scottish Governments of not applying risk-based controls.</p>
<p><b>Options 2a and 2b</b> – support both the freezing extension and freezing exemption</p>	<p>Estimated one-off familiarisation costs to UK industry of £4,947,230</p> <p>Estimated one-off familiarisation costs to UK enforcement authorities of £17,761</p> <p>Estimated total UK one-off familiarisation costs of £4,964,991</p>	<p>Estimated total net benefits to UK in Year 0 of £4,651,087.</p> <p>Estimated total annual net benefit to UK in Years 1-9 of £9,616,078</p> <p><b>Estimated total net benefit to UK over 10 years of £91,195,791 (NPV - £77,807,196)</b></p>



## 14. DECLARATION

I have read the Business and Regulatory Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options and that the benefits of supporting Options 2a and 2b justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Minister's Signature.....



Ministers Title .....

Minister for Public Health

Date.....

29/2/12

### Contact

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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

### **FOOD BUSINESS OPERATORS UNDERTAKING THE CERTIFICATION OF THE CORRECT SLAUGHTER AND BLEEDING OF FARMED GAME (Regulation (EU) No. 150/2011 and Regulation (EU) No. 151/2011)**

### **The Food Hygiene (Scotland) Amendment Regulations 2012**

**File No:** SPARD/FSAS  
**Date:** February 2012  
**Stage:** Final  
**Source of intervention:** EU  
**Contact for enquiries:** Karen Robertson  
**Phone No:** 01224 288362  
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## 1. Title of Proposal

- 1.1 The Food Hygiene (Scotland) Amendment Regulations 2012.
- 1.2 The above instrument provides for the enforcement of a range of EU measures and implements a national measure. This BRIA only relates to those EU measures to allow food business operators (FBOs) to continue to carry out the certification of the correct slaughter and bleeding of farmed game, including the date and time of slaughter at the place of origin, subject to the FBO or their slaughterer having had appropriate training, rather than it be necessary for this to be carried out by a veterinarian.

## 2. Purpose and Intended Effect

### Objectives

- 2.1 Under transitional arrangements, in place from 1 January 2006 until 31 December 2009, FBOs were able to undertake the certification of the correct slaughter and bleeding and the date and time of slaughter of farmed game<sup>1</sup> at the point of origin. The transitional arrangements allowed practices to continue that were in place before 1 January 2006 (i.e. the date at which Regulation (EC) No. 853/2004 and Regulation (EC) No. 854/2004 applied).
- 2.2 To ensure that FBOs carrying out the certification of farmed game at the point of origin could continue to do so after 31 December 2009 (i.e. when the transitional arrangements expired), government intervention in the form of amendments to Regulation (EC) No. 853/2004 and Regulation (EC) No. 854/2004 were required. Otherwise, it would have become a requirement for the certification task to be performed by an Official Veterinarian (OV) or Approved Veterinarian (AV) at additional cost to the industry with no improvement in public health protection.
- 2.3 During negotiations at EU level, the UK's intention was to maintain sufficient official controls at the place of origin (i.e. place of slaughter) to ensure that public health is protected, while at the same time ensuring these controls were not unnecessarily burdensome for the FBOs affected nor for the Food Standards Agency (FSA) which is the competent authority on farms where farmed game (in Scotland this is almost exclusively deer) are slaughtered for human consumption. Slaughter of farmed game animals is carried out on farm as this is beneficial from an animal welfare perspective.
- 2.4 There are two linked Regulations (Regulation (EU) No. 150/2011 and Regulation (EU) No. 151/2011<sup>2</sup>) that, from March 2011, amended the EU food hygiene Regulations (Regulation (EC) No. 853/2004<sup>3</sup> and Regulation (EC) No. 854/2004<sup>4</sup>) respectively, which allow FBOs to certify that the correct slaughter

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<sup>1</sup> "Farmed game" is defined in Regulation (EC) 853/2004, Annex 1 as farmed raptures (ostriches) and farmed land mammals (e.g. deer and alpacas) *but does not include* domestic ungulates, porcine, ovine, caprine and domestic solipeds. Bison also are not taken to slaughterhouses because it is unsafe to do so.

<sup>2</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:046:0014:0016:EN:PDF>  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:046:0017:0020:EN:PDF>

<sup>3</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0055:0205:EN:PDF>

<sup>4</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0083:0127:EN:PDF>

and bleeding of farmed game has taken place and the date and time of slaughter. These Regulations now require the FBO or those carrying out the slaughter and bleeding of the animals to be competent to perform these tasks. They also require regular checks by Official or Approved Veterinarians (OVs or AVs) to assess the performance of those who shoot and bleed farmed game on the farm.

- 2.5 Regulation (EU) No. 150/2011 and Regulation (EU) No. 151/2011 also make some amendments to the requirements for wild game. They allow the whole heads of wild animals susceptible to *Trichinella* infestation, such as wild boar, to be sent to an establishment for producing a hunting trophy, pending the result of the required test for *Trichinella*, provided that there is full traceability. They also allow for a single declaration by a trained person to cover a number of large wild game animals, rather than requiring a declaration for each animal to be provided. The declaration indicates that no evidence has been found following examination after killing that the meat presents a health risk and that the animal displayed no abnormal behaviour before it was shot.
- 2.6 These arrangements were introduced in June 2011.

## Background

- 2.7 Regulation (EC) No. 854/2004 applied from 1 January 2006 and lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. It requires the 'competent authority' (in Scotland, the FSA) to ensure sufficient official controls are undertaken at the place of origin where farmed game is slaughtered, to protect public health.
- 2.8 A transitional measure in Regulation (EC) No. 2076/2005<sup>5</sup>, in place until 31 December 2009, provided for an amendment to Regulation (EC) No. 854/2004 therefore continuing the arrangements that were in place under the previous hygiene legislation prior to 1 January 2006. This transitional measure waived the requirement for an Approved Veterinarian (AV) or an Official Veterinarian (OV) to be present when the animals were shot and bled following the ante mortem inspection of the animals, which the AV or OV would otherwise have been required to carry out. If the transitional measure had not been in place, the OV or AV would have been required to certify that correct slaughter and bleeding had taken place or to certify the date and time of slaughter - instead, the transitional measure allowed this to continue to be done by the FBO. Regulation (EU) No. 150/2011 and Regulation (EU) No. 151/2011 allow the continuation of this practice subject to the FBO or their slaughterer having had appropriate training and being subjected to regular verification checks by the OV/AV; this has been welcomed by farmed game businesses.
- 2.9 Before the four year exemption provided by Regulation (EC) No. 2076/2005 expired on 31 December 2009, the UK sought to continue the transitional arrangements but the European Commission indicated that these would not be extended. The UK therefore presented a proposal to the Commission in May 2009 to allow the FBO to certify the slaughter and bleeding of farmed wild game, subject to certain conditions. The UK's proposal was discussed at the Commission Working Group meeting on

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<sup>5</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:338:0083:0088:EN:PDF>

21 September 2009 and received a large majority support from the Member States. Based on this support, the Commission agreed to take this issue forward and it put forward a suitable proposal at the Commission Working Group meeting on 11 November 2009. There were a number of subsequent Commission Working Group meetings as well as meetings of the Standing Committee on Food Chain and Animal Health (SCOFCAH) to discuss a number of additional proposals, some of which related to wild game. The proposed measures were adopted at a meeting of SCOFCAH in September 2010 and were adopted and published in the EU Official Journal on 15 February 2011 (i.e. as Regulation (EU) No. 150/2011 and Regulation (EU) No. 151/2011).

### Rationale for Government Intervention

2.10 Consumers, retailers and food manufacturers need to be confident that meat is of the nature, substance and quality that they wish to buy, but they cannot assess this fully from its appearance when it is offered for sale. Government intervention in the form of regulation is needed to ensure that farmed game slaughtered on farm is killed and bled correctly to ensure that the meat is of the necessary hygienic standard. Government intervention therefore ensures that public confidence is maintained, and that the risk of meat-borne disease is managed appropriately. Consequently, meat official controls are carried out by competent authorities in order that these objectives are achieved. These controls need to be risk-based and proportionate, with all the costs of compliance fully justified by the benefits.

2.11 This is in accordance with the Scottish Government's national performance framework target to increase economic sustainable growth in Scotland. Without intervention from the FSA, FBOs would not be permitted to continue to undertake the certification of the correct slaughter and bleeding of farmed game at the place of origin. Deer farmers maintain that this would make the farmed deer business uneconomic and would not provide a public health benefit.

### Devolution

2.12 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

## **3. Consultation**

### Within Government

3.1 Scottish Government officials from the Health, Rural Affairs and Enterprise Directorates were kept informed of the development of the European Regulation during the negotiating process in Brussels. FSA also consulted closely with the Scottish Government Rural Directorate (SGRD) regarding those FBOs who slaughter and bleed farmed game to be included in the arrangements that SGRD are working on to implement the new animal welfare at slaughter Regulation ((EC) No. 1099/2009) as Regulations (EU) No. 150/2011 and (EU) No. 151/2011 refer to Council Regulation (EC) No. 1099/2009 on the protection of animals at the time of killing, which will take effect from 1 January 2013.

- 3.2 The Food Standards Agency (FSA) consulted the Scottish Government's Better Regulation and Industry Engagement team during the preparation of the consultation and Officials from the Legal Directorate were closely involved in the drafting of the Scottish Statutory Instrument. Scottish Government officials from the Health, Rural Affairs and Legal Directorates were included in the recent consultation on the draft Regulations.

### Public Consultation

- 3.3 An initial informal public consultation was launched on 20 April 2011 with no comments received. The Agency then undertook an additional 10 week public consultation from 13 December 2011 to 21 February 2012 on the current draft of the Food Hygiene (Scotland) (Amendment) Regulations 2012 due to come into force on 1 April 2012. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

### With Business

- 3.4 The original UK proposal was developed with the knowledge and support of the farmed game sector which was worried about the increased cost likely to arise following the end of the transitional measure. Individual FBOs of on-farm slaughter facilities and the British Deer Farmers Association (BDFFA) - the trade association for the farmed deer industry - have worked together with the FSA to drive this forward and fully supports the way that the UK has sought to keep additional burdens on the industry to a minimum during negotiations, as they believed that the additional cost of requiring a veterinarian to come to a farm to attest to the correct slaughter, and bleeding and the time and date of slaughter, would have rendered their businesses uneconomic.
- 3.5 The FSA have continued to consult with the farmed game sector on these measures, in particular regarding the requirement for those slaughtering and bleeding farmed game to be competent to do so. All 10 FBOs of approved on-farm slaughter facilities received both consultations. No responses were received.

## **4. Options**

- 4.1 The options considered were:

Option 1: Do nothing. Following the expiry of the transitional measures on 31 December 2009, simply continue the practices that had been permitted by the transitional measures in non-compliance with Regulation (EC) 853/2004 and Regulation (EC) 854/2004. This would have meant no additional burdens for FBOs and competent authorities but was not permissible for any sustained length of time without approval from the European Commission.

Option 2: Following the expiry of the transitional measures on 31 December 2009, apply the requirements of Regulations 853/2004 and 854/2004 for the first time. This would have required an OV or AV to confirm that the animals were correctly slaughtered and bled at the place of origin from that date and would have meant additional unnecessary burdens for FBOs and the

competent authority. This option would also have become non-compliant from 11 March 2011.

Option 3: In line with the now adopted Regulations (EU) 150/2011 and (EU) 151/2011, allow the certification of the correct slaughter and bleeding at the place of origin under the supervision of the FBO, subject to the FBO or their slaughterer having had appropriate training and being subject to regular verification checks by the OV/AV. Provide for national legislation to give effect to these Regulations.

4.2 Option 3 is the preferred option. By comparison with Option 2, the cost to FBOs would be lower and the necessary level of public health protection would be maintained.

## Sectors and groups affected

### Industry

4.3 The major industry stakeholder in the UK representing the farmed game sector is the British Deer Farmers Association (BDFA). Informal consultation with the BDFA indicated that there are between 500 and 600 deer farmers and approximately 35,000 farmed deer in the UK, of which approximately 10,000 are slaughtered annually. In Scotland, there are 10 approved on-farm slaughter facilities for farmed deer.

4.4 The FSA considered that the rules covering the slaughter of farmed game in Regulation (EC) 853/2004 were disproportionate when seen with comparative rules covering wild game and the domestic slaughter of cattle, sheep, goats and pigs, which are killed with no veterinary involvement in the assessments of the correct slaughter and bleeding.

4.5 All farmed deer slaughtered on-farm in the UK are shot by trained marksmen/women holding a recognised qualification which includes the ability to bleed deer in the correct manner. An additional feature of the new legislation requires these trained marksmen/women to be authorised in the same way as slaughtermen working in an abattoir. This could be verified by a veterinarian and subject to a regular check to assess the performance of these marksmen/women.

4.6 Only trained marksmen/women who are proficient in the use of firearms and who hold an appropriate firearms certificate can currently carry out field slaughter of farmed deer with rifles. The adopted proposal would require those who shoot and bleed game on farm to hold a certificate of competence and be authorised in the same way as abattoir slaughtermen to carry out slaughter operations. This reflects the requirements in the new EU welfare at slaughter Regulation (1099/2009) which comes into force on 1 January 2013 and which will require the authorisation of all those who slaughter animals for human consumption whether they work in a slaughterhouse or on farm.

4.7 The number of on-farm slaughter establishments affected by the proposal is set out below in table 1 by country and size of business.

**Table 1 - Number of on-farm slaughter establishments by country**

Location/Firm Size	Micro	<20	Small	Medium	Large	Total
<b>Scotland</b>	<b>9</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>10</b>
England	25	0	6	0	0	31

Wales	0	0	0	3	0	3
Northern Ireland	0	0	0	0	0	0
UK	34	0	7	3	0	44

*Note: Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees: <20 – 10-20 employees; Small – 20-49 employees; Medium – 50-249 employees; Large – more than 250 employees. Distribution of size of business is based on an estimate using FSA Operations data on approved establishments and previous consultation responses.*

## **Enforcement**

4.8 There should be no additional enforcement costs arising from these measures.

## **Consumers**

4.9 Consumers can be reassured that the new measures require those carrying out the slaughter and bleeding of farmed deer to be competent to do so to the same standard as those carrying out these activities in a slaughterhouse.

## **Benefits**

### **Option 1**

4.10 There are no benefits associated with this option.

### **Option 2**

#### **Industry**

4.11 Compared to option 3 this is a more costly option with little or no additional benefit. Industry may benefit in terms of public perception over animal welfare as option 2 would require an AV and OV to confirm that animals were correctly slaughtered and bled in line with animal welfare considerations.

4.12 No additional benefit would have arisen from the need for an OV or AV to verify that animals were slaughtered and bled correctly as the OV in a slaughterhouse is not required to provide similar verification that all animals were slaughtered and bled correctly in a slaughterhouse. Regular OV/AV verification checks may benefit industry in terms of public perception over the welfare and slaughter conditions of animals, but this is difficult to quantify.

#### **Enforcement**

4.13 No particular benefits for enforcement were envisaged although the cost of this option would be much greater for the industry, with little or no additional benefit in public health terms.

#### **Consumer**

4.14 The benefit for the consumer arises from the requirement for farmed deer to be slaughtered and bled correctly, and for this to be verified. This provides assurance that farmed deer are slaughtered and bled by competent persons in the same way that animals in a slaughterhouse would be, and ensures that animal welfare is not compromised and that the animals are bled hygienically.



### **Option 3**

#### **Industry**

4.15 The main benefit for industry arising with this option is reduced costs when compared with option 2.

#### **Enforcement**

4.16 There are no particular benefits for enforcement.

#### **Consumer**

4.17 The benefit for the consumer arises from the requirement for farmed deer to be slaughtered and bled correctly and for this to be verified. This provides assurance that farmed deer are slaughtered and bled by competent persons in the same way that animals in a slaughterhouse would be and ensures that animal welfare is not compromised and that the animals are bled hygienically.

### **Costs**

#### **Option 1**

4.18 Although there would have been a benefit of no additional costs arising from this option, it does not comply with the requirements of the EU Regulations and the UK could be subject to infraction proceedings. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>6</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.

#### **Option 2**

#### **Industry**

##### *Inspection costs*

4.19 Farmers would have incurred inspection costs for an OV or AV carrying out an ante mortem inspection per slaughtering occasion. An average of 5-10 animals are slaughtered and inspected per occasion. It is assumed that 10,000 farmed deer are slaughtered annually in Great Britain (GB) at 44 approved on-farm slaughter facilities; approximately 227<sup>7</sup> animals per farm per annum. On average this equates to between approximately 23 - 45 slaughtering occasions per year.

4.20 It is envisaged that a typical inspection will last one hour with an additional two hours for travelling to and from the location; meaning a total inspection time of 3 hours. The cost per inspection can be quantified by multiplying the time a typical inspection takes (3

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<sup>6</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

<sup>7</sup> 10,000 animals slaughtered per annum / 44 on-farm slaughter GB establishments = 227

hours) by the hourly wage rate of an AV (£22.57<sup>8</sup>), which results in a cost per inspection of £67.70<sup>9</sup>. To quantify the annual inspection cost per farm we multiply the number of inspections carried out per farm (ranging from 23 – 45 per year) by cost per inspection (£67.70). We estimate an average inspection cost per farm of approximately £1,557 to £3,047 per year. In Scotland we estimate the total average annual cost of inspections to farmers would range from £15,572 - £30,467<sup>10</sup>. Taking the midpoint we derive a best estimate of £23,019<sup>11</sup>. Table 2 displays the number of farms and the range of inspection costs by country.

**Table 2 – Inspection costs broken down by country**

Country	Total cost of inspections (Lower Bound)	Total cost of inspections (Upper Bound)	Total cost of inspections (Best Estimate)
<b>Scotland</b>	<b>£15,572</b>	<b>£30,467</b>	<b>£23,019</b>
England	£48,273	£94,447	£71,360
Wales	£4,672	£9,140	£6,906
GB	£68,516	£134,054	£101,285

Note: Figures may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

### Certification costs

4.21 We assume that the requirement for certification of slaughter and bleeding would have increased the cost from £45 per consignment of animals by an additional £45 - £90, depending on how long the process would have taken. Taking the midpoint we derive a best estimate of £67.50<sup>12</sup>. We estimate that between 230 and 450 slaughtering occasions would be carried out each year in Scotland<sup>13</sup>; with an incremental annual total cost to industry for certification of around £10,350 - £40,500 per year. Taking the midpoint we derive a best estimate of £25,425<sup>14</sup>. Table 3 displays the incremental cost of certification.

**Table 3 – Cost of certification broken down by country**

Country	Total cost of certification (Lower Bound)	Total cost of certification (Upper Bound)	Total cost of certification (Best Estimate)
<b>Scotland</b>	<b>£10,350</b>	<b>£40,500</b>	<b>£25,425</b>
England	£32,085	£125,550	£78,818
Wales	£3,105	£12,150	£7,628
GB	£45,540	£178,200	£111,870

<sup>8</sup> Wage rate obtained from The Annual Survey of Household Earnings (2010) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of ‘Veterinarians’ is used (£17.36 plus 30% overheads)

<sup>9</sup> 3 hours \* £22.57 = £67.70

<sup>10</sup> Lower bound estimate (£15,572) = Cost per inspection per farm (£1,557.19) \* Number of on-farm slaughter establishments in Scotland (10)

Upper bound estimate (£30,467) = Cost per inspection per farm (£3,046.68) \* Number of on-farm slaughter establishments in Scotland (10)

<sup>11</sup> Calculated by taking the midpoint of the range: (£15,572+ £30,467)/2 =£23,019

<sup>12</sup> Calculated by taking the midpoint of the range: (£45 + £90)/2 = £67.50

<sup>13</sup> Lower bound estimate (230) = 23 inspections per annum per farm \* 10 on-farm slaughtering establishments in Scotland

Upper bound estimate (450) = 45 inspections per annum per farm \* 10 on-farm slaughtering establishments in Scotland

<sup>14</sup> Calculated by taking the midpoint of the range: (£10,350 + £40,500)/2 = £25,425

*Note: Figures may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.*

## Familiarisation Costs

4.22 There would have been a reading and familiarisation cost to farmed game establishments for reading Regulation (EC) 853/2004. It is estimated that it would have taken 1 hour per business to read and become familiar with the Regulation's requirements and disseminate this through the business. Based on current estimation there are 10 farmed game establishments operating in Scotland that would have been directly affected. To quantify the one off familiarisation cost to industry we calculated the familiarisation cost per business by multiplying the hourly wage rate of a farm manager (£16.94)<sup>15</sup> by the one hour taken to understand the regulation, resulting in a familiarisation cost per business of £16.94<sup>16</sup>. To estimate the overall one off familiarisation cost to industry we multiply the familiarisation cost per firm by the number of businesses in Scotland (10) affected by the regulation; which results in a one-off familiarisation cost to businesses of £169. Table 4 displays the familiarisation cost to industry broken down by country.

**Table 4 – Industry familiarisation cost by country**

Country	Number of Farmed Game Establishments	Total Familiarisation Cost
<b>Scotland</b>	<b>10</b>	<b>£169</b>
England	31	£525
Wales	3	£51
GB	44	£745

*Note: Figures may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.*

## Enforcement

### Certification costs

4.23 There would have been no additional cost associated with the need to verify the competence including checks on certification of those who slaughter and bleed farmed deer as this could have been done when the AV or OV carries out an ante mortem inspection of the animals prior to slaughter.

### Familiarisation Costs

4.24 There would have been a familiarisation cost to the FSA as OV's and AV's would have been required to read and familiarise themselves with Regulation (EC) 853/2004 and Regulation (EC) 854/2004 and any relevant national legislation as they applied to this industry sector. We estimate that each OV would have invested 1 hour reading and familiarising themselves with the Regulations and disseminating to key staff in the organisation. To quantify the familiarisation cost to the FSA we need to calculate the

<sup>15</sup> Wage rate obtained from The Annual Survey of Household Earnings (2010) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of a 'Managers In Farming, Horticulture, Forestry And Fishing' is used (£13.03 plus 30% overheads)

<sup>16</sup> 1 hour \* £16.94 = £16.94

familiarisation cost per OV reading the regulation. An hourly wage rate of £22.57<sup>17</sup> has been applied to an OV, and when multiplied by the reading time equates to a familiarisation cost per OV of £22.57. To quantify familiarisation costs to the FSA in Scotland we multiply the familiarisation cost per OV by the number of OV's in Scotland (52), which equates to a one-off familiarisation cost of £1,174<sup>18</sup>. Table 5 displays the number of OV's along with the familiarisation cost for the FSA broken down by country.

**Table 5 – Familiarisation cost to the FSA**

Country	Number of OV's	Total Familiarisation Cost
<b>Scotland</b>	<b>52</b>	<b>£1,174</b>
England	271	£6,116
Wales	35	£790
GB	358	£8,079

Note: Totals may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

## **Total Cost of Policy Option 2**

4.25 The total cost, for GB, associated with policy Option 2 is estimated at between £803,580 and £2,199,971 over 10 years with a best estimate of £1,501,775; an annual average cost of £150,178. Once these costs are discounted at a rate of 3.5% over four years we obtain a present value total cost of £1,292,681. Total one-off and on-going costs associated with option 2 are presented in table 6.

**Table 6 – Total Cost, for GB, of Policy Option 2**

Costs	Year 0 2010/11	Year 1 2011/12	Year 2 2012/13	Year 3 2013/14	Year 4 2014/15	Year 5 2015/16	Year 6 2016/17	Year 7 2017/18	Year 8 2018/19	Year 9 2019/20	Total Cost	Average Annual	NPV
<b>One-off Costs</b>													
Familiarisation cost to industry	£525										£525	£525	£525
Familiarisation cost to Enforcement	£6,116										£6,116	£6,116	£6,116
Total One-off Costs	£6,641										£6,641	£6,641	£6,641
<b>On-going Costs</b>													
<i>Industry - Inspection</i>													
Best Estimate	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£713,600	£71,360	£614,245
Lower Bound	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£482,730	£48,273	£415,518
Upper Bound	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£944,471	£94,447	£812,971
<i>Industry - Certification</i>													
Best Estimate	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£788,175	£78,818	£678,436
Lower Bound	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£320,850	£32,085	£276,178
Upper Bound	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£1,255,500	£125,550	£1,080,695
<b>Total Cost</b>													
Best Estimate	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£1,501,775	£150,178	£1,292,681
Lower Bound	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£803,580	£80,358	£691,696
Upper Bound	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£2,199,971	£219,997	£1,893,666

## **Option 3**

4.26 This is the preferred option as it will allow FBOs to continue to carry out on-farm slaughter while ensuring the burden on the farmed game industry is minimised and with the adequate protection of public health remaining in place.

<sup>17</sup> Wage rate obtained from The Annual Survey of Household Earnings (2010) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of a 'Veterinarians' is used (£17.36 plus 30% overheads)

<sup>18</sup> 52 \* £22.57 = £1,174

## Industry

### *Verification costs*

4.27 There may be some small additional costs for the FBO. There will be an additional cost arising from the verification check on the competence of the person carrying out slaughter and bleeding operations. Although this will fall to a person, who is unlikely in most cases to be the FBO, the cost is likely to be passed on to the FBO as part of the overall cost of carrying out this work. The verification checks will need to be carried out on a regular basis but could be once every 2-3 years at a cost of about £20 - £30 each time. Taking the midpoint we derive a best estimate of £25 per verification. To account for the uncertainty surrounding the frequency and cost of verification checks, ranges have been applied. With the frequency of verification checks ranging from every 2 to 3 years; we estimate that between 3 to 5 on-farm slaughter establishments in Scotland will be verified each year. Table 7 displays the number of establishments verified each year by country.

**Table 7 – Number of establishments verified each year**

	Number of Verifications - Lower Bound	Number of Verifications - Upper Bound	Number of Verifications - Best Estimate
<b>Scotland</b>	<b>3</b>	<b>5</b>	<b>4</b>
England	10	16	13
Wales	1	2	1
GB Total	15	22	18

*Note: Totals may not sum due to rounding.*

4.28 To calculate the average annual cost to industry we multiply the upper and lower bound annual frequency of verification checks as shown in table 7 by the cost per verification, which results in an average annual verification cost in Scotland of £67 to £150. Taking the midpoint we derive a best estimate of £108. Table 8 displays the average annual cost of verification by country.

**Table 8 – Verification costs to industry by country**

	Lower Bound Verification Cost	Upper Bound Verification Cost	Best Estimate Verification Cost
<b>Scotland</b>	<b>£67</b>	<b>£150</b>	<b>£108</b>
England	£207	£465	£336
Wales	£20	£45	£33
GB Total	£293	£660	£477

*Note: Totals may not sum due to rounding.*

### *Training Costs*

4.29 There may be a small additional burden for those that undertake the slaughter and bleeding to undertake the necessary training. However, for those who currently carry out this work the FSA will seek to establish whether the training that they have carried out in the past is sufficient to meet the needs of this element of the proposal, that such people who slaughter and bleed farmed game are competent to do so. We understand that a number of those who carry out this work are already trained to act as the trained person in wild game hunting parties. We have assumed that one employee per business will attend initial training. It is estimated that the average one-off training cost to industry in Scotland would equate to approximately £1,795. The cost of training is based on the

opportunity cost of a farmer attending training for two days. The training cost applied is quantified by multiplying two working days of a farmer lost to training (14 hours) by the hourly wage rate of a farmer (£12.82)<sup>19</sup>, which equates to a cost per farmer being trained of £179.45. Table 9 displays the training costs to business by country.

**Table 9 – Training costs to industry by country**

	Training Cost
<b>Scotland</b>	<b>£1,795</b>
England	£5,563
Wales	£538
GB	£7,896

Note: Totals may not sum due to rounding.

### **Total Cost of Policy Option 3**

4.30 The total cost, for GB, associated with policy Option 3 is estimated at between £7,630 and £10,213 over 10 years with a best estimate of £8,921; an annual average cost of £892. Once these costs are discounted at a rate of 3.5% over four years we obtain a present value total cost of £7,872. Total one-off and on-going costs associated with option 3 are presented in table 10.

**Table 10 – Total Cost, for GB, of Policy Option 3**

Costs	Year 0 2010/11	Year 1 2011/12	Year 2 2012/13	Year 3 2013/14	Year 4 2014/15	Year 5 2015/16	Year 6 2016/17	Year 7 2017/18	Year 8 2018/19	Year 9 2019/20	Total Cost	Average Annual	NPV
<b>One-off Costs</b>													
Training costs to industry	£5,563	£0	£0	£0	£0	£0	£0	£0	£0	£0	£5,563	£5,563	£5,563
Total One-off Costs	£5,563	£0	£0	£0	£0	£0	£0	£0	£0	£0	£5,563	£5,563	£5,563
<b>On-going Costs</b>													
<i>Industry - Verification</i>													
Best Estimate	£336	£336	£336	£336	£336	£336	£336	£336	£336	£336	£3,358	£336	£2,309
Lower Bound	£207	£207	£207	£207	£207	£207	£207	£207	£207	£207	£2,067	£207	£1,421
Upper Bound	£465	£465	£465	£465	£465	£465	£465	£465	£465	£465	£4,650	£465	£3,196
<b>Total Cost</b>													
Best Estimate	£5,899	£336	£336	£336	£336	£336	£336	£336	£336	£336	£8,921	£892	£7,872
Lower Bound	£5,770	£207	£207	£207	£207	£207	£207	£207	£207	£207	£7,630	£763	£6,984
Upper Bound	£6,028	£465	£465	£465	£465	£465	£465	£465	£465	£465	£10,213	£1,021	£8,759

## **5. Scottish Firms Impact Test**

5.1 This proposal has been driven by individual FBOs of on-farm slaughter facilities who approached the FSA regarding concerns on additional costs they would face if they were no longer permitted to certify the correct slaughter and bleeding of farmed game.

5.2 Approximately 500 farmers are engaged in deer farming in the UK and most are small enterprises. Throughout 2009, the FSA consulted with deer farmers through their trade association, the British Deer Farmers Association (BDFA). The BDFA believed that the additional cost of requiring a veterinarian to come to a deer farm to attest to the correct slaughter and bleeding and the time and

<sup>19</sup> Wage rate obtained from The Annual Survey of Household Earnings (2010) (<http://www.statistics.gov.uk/StatBase/Product.asp?vink=15313>). Median hourly wage of a 'Farmers' is used (£9.86 plus 30% overheads)

date of slaughter would have rendered the deer farming business uneconomic. The BDFA was keen for the Agency to submit a proposal to the Commission in May 2009 that allowed the FBO to continue to certify that correct slaughter and bleeding had taken place, once it became clear that the transitional arrangements could not be extended.

- 5.3 Since the proposals are only placing a minor additional cost on business and since each of the 10 FBOs affected were consulted with, it was not considered proportionate to carry out additional face-to-face interviews with individual businesses.

### Competition Assessment

- 5.4 Using the Office of Fair Trading (OFT) competition assessment framework, it has been established that the preferred policy option (option 3) is unlikely to have any material impact on competition. We assert that the requirements of Regulations 150/2011 and 151/2011 are not expected to either directly or indirectly limit the number or range of suppliers. It should not limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously.
- 5.5 As a result of the application of the new EU regulations, the market for FBOs or those undertaking the certification of correct slaughter and bleeding or the date and time of slaughter should actually open and encourage competition. This would encourage efficiency in official controls in the farmed game sector. As the number of deer farmers in the UK is estimated at between 500 and 600, there is obviously a limited number of trained marksmen/women who are proficient in the use of firearms and who hold an appropriate firearms certificate to carry out field slaughter with rifles. This will encourage an ongoing level of turnover that will support a small market for training and/or contracting. That market will be open to all interested parties.

### Test Run of Business Forms

- 5.6 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

## **6. Legal Aid Impact Test**

- 6.1 The amending regulations do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

## **7. Enforcement, Sanctions, and Monitoring**

- 7.1 The FSA must remain responsible for enforcement of official controls. FBOs performing official control duties will do so subject to the FBO or their slaughterer having had appropriate training and the FBO or those that slaughter and bleed the animals being subject to regular verification checks by the OV or AV.

- 7.2 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.
- 7.3 The effectiveness and impact of the 2012 amending regulations will be monitored via feedback from stakeholders, as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys, and general enquiries from the public.

## 8. Implementation and Delivery Plan

- 8.1 The EU Regulations 150/2011 and 151/2011 applied directly in the UK from 11 March 2011 (i.e. 20 days after being published in the EU Official Journal on 19 February 2011).
- 8.2 The publication of the Food Hygiene (Scotland) Amendment Regulations 2012, providing for the enforcement in Scotland of Regulations (EU) 150/2011 and 151/2011, will be communicated to stakeholders by email, letter and via the Agency's website.

### Post-Implementation Review

- 8.3 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in March 2016 (i.e. 5 years from the direct application of Regulations (EU) 150/2011 and 151/2011 in the UK).
- 8.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## 9. Summary and Recommendation

- 9.1 The Agency recommends Option 3, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EU) No. 150/2011 and Regulation (EU) No. 151/2011.
- 9.2 Taking this option allows the Government to fulfil its obligations to implement EU law.
- 9.3 Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.
- 9.4 Summary Costs and Benefits Table

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social  - Policy and Administrative



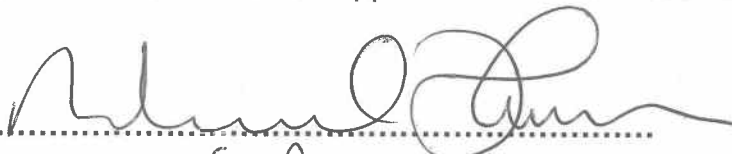
<p>1. Do Nothing</p>	<p>No benefits have been identified.</p>	<p>Risk of infraction proceedings for failure to implement Regulations (EU) 150/2011 and 151/2011. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>20</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.</p>
<p>2. Following the expiry of the transitional measures on 31 December 2009, apply the requirements of Regulations 853/2004 and 854/2004 for the first time.</p>	<p>Regular OV/AV verification checks may benefit industry in terms of public perception over the welfare and slaughter conditions of animals, but this is difficult to quantify.</p> <p>No particular benefits for enforcement were envisaged although the cost of this option would be much greater for the industry, with little or no additional benefit in public health terms.</p> <p>The benefit for the consumer arises from the requirement for farmed deer to be slaughtered and bled correctly, and for this to be verified.</p>	<p>Compared to option 3 this is a more costly option with little or no additional benefit.</p> <p>Farmers would have incurred inspection costs for an OV or AV carrying out an ante mortem inspection per slaughtering occasion. Inspection costs are quantified in table 2; certification costs in table 3; Industry familiarisation costs in table 4 and familiarisation costs to the FSA in table 5.</p> <p>Comments were sought from stakeholders on all these costs identified but no responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.</p>
<p>3. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</p>	<p>FBOs will benefit by being able to continue to carry out on-farm slaughter. The burden on the farmed game industry is minimised and with the adequate protection of public health remaining in place.</p> <p>The main benefit for industry</p>	<p>There may be some small additional costs for the FBO. There will be an additional cost arising from the verification check on the competence of the person carrying out slaughter and bleeding operations. These can be found in table 8.</p>

<sup>20</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

	<p>arising with this option is reduced costs when compared with option 2.</p> <p>There are no particular benefits for enforcement.</p> <p>The benefit for the consumer arises from the requirement for farmed deer to be slaughtered and bled correctly, and for this to be verified.</p>	<p>There may be a small additional burden for those that undertake the slaughter and bleeding to undertake the necessary training – these costs are quantified in table 9. However, for those who currently carry out this work the FSA will seek to establish whether the training that they have carried out in the past is sufficient to meet the needs of this element of the proposal, that such people who slaughter and bleed farmed game are competent to do so.</p> <p>Comments were sought from stakeholders on these costs but no responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.</p>
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**10. Declaration and Publication**

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature.....

Ministers Title.....*Minister for Public Health*

Date.....*29/2/12*

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## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

### IMPORTS OF COMPOSITE PRODUCTS (SANCO/10492/2010)

- proposal to amend Decision 2007/275/EC and Regulation (EC) No 1162/2009 as regards health conditions and certification requirements for imports of food containing a combination of processed foods of animal and plant origin

<b>File Ref. No:</b>	FSMP/SHU/0028
<b>Date:</b>	February 2012
<b>Stage:</b>	Consultation
<b>Source of intervention:</b>	EU
<b>Type of measure:</b>	Other
<b>Cleared by:</b>	Sandy McDougall
<b>Contact for enquiries:</b>	Dr Will Munro 01224 285161 <a href="mailto:will.munro@foodstandards.gsi.gov.uk">will.munro@foodstandards.gsi.gov.uk</a>

## 1. Title of Proposal

- 1.1. Changes to import certificates for 'composite products' (SANCO/10492/2010) - proposal to amend Decision 2007/275/EC and Regulation (EC) No 1162/2009 as regards health conditions and certification requirements for imports of food containing a combination of processed foods of animal and plant origin

## 2. Purpose and intended effect

- 2.1. Currently there is inconsistency between the requirements for animal health purposes and public health purposes relating to the importation of products of animal origin. 'Composite products' (i.e. foodstuffs made both of processed food of animal origin (FOAO) and food of vegetable matter) are not subject to the same official animal health control checks at EU borders as is FOAO due to an exemption in place until December 2012 allowing exporters in third countries to the EU time to adjust to changes in EU food hygiene rules which they would otherwise have to meet. In light of the exemption ending, Government intervention is required to ensure that regulations covering these areas are harmonised and consistent.

- **Objectives**

- 2.2. The underlying policy objective is to ensure that all food products entering the European Union are produced safely, hygienically and present no risk to human health. By harmonising the requirements for animal health and composite food products, this will ensure that all foods which contain foods of animal origin are treated in the same manner and should ensure that food safety for consumers is improved.

- **Background**

- 2.3. There has been a derogation (provided for in Regulation (EC) No 1162/2009) in place exempting food businesses operators (FBOs) in 3rd countries from meeting article 6.4 of Regulation (EC) No 853/2004 which requires that importers of 'composite products' should ensure that the animal content of a composite product satisfies the requirements relating to import conditions and that is demonstrated by the appropriate documentation of certification. This requires that FOAO comes from an approved 3rd country and, where applicable, an approved establishment.
- 2.4. The European Commission has proposed that the transitional measures allowing the derogation (provided for in Regulation (EC) No 1162/2009) to exempt composite products from meeting the requirements laid down in Article 6.4 Regulation (EC) No 853/2004 should fall by 1 January 2012. This proposal is to harmonise the requirements for the importation of food containing both processed foods of animal origin and foods of plant origin into the European Union with the existing requirements for animal health purposes.

- **Rationale for Government intervention**

- 2.5. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable and so not readily identifiable by consumers. In most cases it is not possible for FBOs to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies government intervention is required as Regulation (EC) No 853/2004 is directly applicable. This means that there is a benefit from government intervention both to require proof that the appropriate hygiene standards are being met in the form of the production of a health

certificate from the FBOs and that enforcement agencies are being provided with suitable information to enable them to enforce the requirements.

- 2.6. If the UK does not take the necessary steps to implement the requirement, it would mean that the UK would be in breach of European legislation which could lead to infraction proceedings being brought against the UK. It could also lead to the Industry in the UK being put at a disadvantage as it would no longer be able to trade composite products across Member States if they are not accompanied by the correct certification when entering another Member State.
- 2.7. This is in accordance with the Scottish Government's national performance framework target to increase sustainable economic growth and contribute to living longer, healthier lives in Scotland.

### 3. Consultation

- **Within Government**

- 3.1. Scottish Government officials and other Government Departments such as DEFRA and other devolved administrations have been kept informed of EU negotiations by Food Standards Agency officials.

- **Public & Business**

- 3.2. The Agency informed industry, trade bodies, enforcement bodies and other government departments of EU negotiations and issued an interested parties letter to 91 stakeholders on 15 June 2010.
- 3.3. The Agency undertook a 10 week public consultation from 13 December 2011 to 21 February 2012 on the current draft of the Food Hygiene (Scotland) (Amendment) Regulations 2012 due to come into force in April 2012. (The documents for this consultation can be found at: <http://www.food.gov.uk/consultations/consultscot/2011/foodhygieneregs2012scot>) There were no responses received.

### 4. Options

- 4.1. Four options have been considered. Two of these (options 3 and 4) are not recommended at this stage as they would not achieve the policy objective. As explained later in this document, the introduction of guidance is not a viable option as guidance is not legally binding and therefore not enforceable. Member States agreed to the measures at the time the original legislation was adopted with the understanding that the derogation would expire at the given date; so allowing the derogation to fall without putting the mechanisms in place to be able to enforce the requirement would fail to meet the policy objective.
- 4.2. **Option 1** - Do nothing; allow the current derogation to fall at the end of 2011.  
**Option 2** – Comply with the obligation to meet the requirements of Article 6.4 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply.  
**Option 3** – Issue guidance to industry.  
**Option 4** – Negotiate in the European Commission to extend the derogation.

Each option is outlined below setting out alternative methods for ensuring that all food products entering the European Union are safe for human consumption.

**Option 1 - Do nothing**

4.3. Doing nothing would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. This would leave the UK unable to trade in composite products across the EU and the UK Government open to monetary sanctions by the European Commission. The maximum fine that could be imposed on the UK is currently some €703,000 per day or some €256 million per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.

**Option 2 - Apply the rules on the coming into force of the Regulation**

4.4. Support the obligation for third country importers into the EU to meet the requirements of Article 6.4 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply. This period would run from 1 January 2012 until 31 December 2012 and would provide time to consider what public health measures are appropriate for composite products. This is the preferred policy option as it would:

- allow the UK to fulfil the UK's obligations under EU law;
- require that composite products which are imported into the EU which contain any processed meat, and composite products which contain half or more processed milk or fishery or egg product or other FOAO content, and composite products which contain less than half milk product which does not meet certain conditions will need to be accompanied by a health certificate. This will enhance current food safety measures by ensuring that composite products which are manufactured in third countries are produced to the same hygiene standards as stipulated in EU Regulations and further protect human health by doing so;
- harmonise the public health requirements with the animal health requirements with advantages for the efficacy of enforcement of the animal health rules.

**Option 3 – Issue guidance to industry**

4.5. This option has been considered and rejected on the grounds that guidance provided would have no legal standing and therefore would not be legally binding. It would not be a sufficient discharge of our obligation to recommend compliance with the legislation without having the systems in place to be able to enforce the Regulation (EC) No 853/2004 if necessary.

**Option 4 – Negotiate within the European Commission to extend the derogation**

4.6. This option has been considered and rejected on the grounds that the original derogation was granted in order to allow Member States time to explore the most appropriate measures needed to apply the requirement. Member States, including the UK, agreed during the negotiations that this measure should be included in the final version of Regulation (EC) No 853/2004 as it would strengthen the measures which could be used to assist in the protection of human health. During the original negotiations, it was understood that the health import requirements for food of animal origin would not be completely harmonised for certain types of products and the import conditions applicable to such products during the transitional period should be made clear. Therefore, it was agreed during the original negotiations that this derogation was a transitional measure which would come to an end at this time.

**Costs and benefits**

- **Sectors and groups affected**

Industry

- 4.7. Industry will have to ensure that all such products are imported using the new health certificate. This will mean that the FBO importer will need to be satisfied that all of the relevant foods of animal origin which are required to have the health certificate are sourced from approved premises in approved countries.
- 4.8. Informal consultation with enforcement officers at a Border Inspection Post (BIP) indicated that the majority of composite products imported in the European Union are already accompanied with a health certificate although currently they do not actually require one. If this is the case, then the impact of the proposal on industry should be minimal.

**Table 1 – Number of firms affected by proposal, by location and size.**

Location/ Firm Size	Micro	Small	Medium	Large	Total
England	1049	368	155	59	1630
Wales	87	30	13	5	135
Scotland	212	74	31	12	329
N. Ireland	77	27	11	4	120
<b>UK</b>	<b>1425</b>	<b>500</b>	<b>210</b>	<b>80</b>	<b>2215</b>

Source: The Inter Departmental Business Register is accessible via the Office for National Statistics, <http://www.statistics.gov.uk/idbr/idbr.asp>

Notes:

- 1) Totals may not sum due to rounding
- 2) Figures are the sum of premises listed under SIC 10.13 Production of meat and poultry meat products, SIC 10.20 Processing and preserving of fish, crustaceans and molluscs, SIC 10.51 Operation of dairies and cheese making, SIC 10.52 Manufacture of ice cream, SIC 10.85 Manufacture of prepared meals and dishes and SIC 10.89 Manufacture of other food products n.e.c.
- 3) Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

Enforcement

- 4.9. There should be a minimal impact on LAs or enforcement authorities as officials at BIPs already check existing health certificates when food is imported. This proposal would replace and widen the remit of foodstuffs which require a health certificate. Inland LAs are only likely to look at the certificate during any investigations inland (for example an investigation of suspected illegal imports when they may seek documentation to show it was legal). This should not differ from the existing position.

Consumers

- 4.10. The main impacts for consumers would be that this is a further measure to ensure the safety of food for human consumption entering the EU. It would also provide reassurance that the hygiene requirements in the countries where the products are produced would need to meet the same requirements as within the EU. These measures should also increase consumer confidence in the product.

- **Costs**

- 4.11. **Option 1** – do nothing; allow the current derogation to fall at the end of 2011. This is the baseline to which the other options are being compared. There would be potential costs to



Government of infraction fines and to businesses being unable to trade with other Member States.

- 4.12. **Option 2** – Comply with the obligation to meet the requirements of Article 6 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply.

#### Industry

- 4.13. This will have a cost implication for businesses as they will need to ensure that their suppliers and the sources of their suppliers all meet the requirements of Article 6 of Regulation (EC) No 853/2004.
- 4.14. There will be a one-off cost to industry for reading and familiarising themselves with the Regulation. It is estimated that it will take 1 hour per business to read and familiarise themselves with the new arrangements and a further 1 hour disseminating to key staff. This means a total of 2 hours for familiarising. There are currently 329 food businesses operating in Scotland which are directly affected by the proposal. Table 1 shows the number of businesses affected broken down by location and size.
- 4.15. To quantify the one off familiarisation cost to industry we calculate the familiarisation cost per business by multiplying the hourly wage rate of a ‘business manager’ of £25.39 by the 2 hours taken to understand the new charging arrangements, resulting in a familiarisation cost per business of £50.78. To quantify the overall one off familiarisation cost to industry we multiply the familiarisation cost per firm by the number of businesses affected by the regulation. This results in an average one off familiarisation cost in to Scottish businesses of £16,707. Table 2 shows the familiarisation cost to industry broken down by location and size.

**Table 2 Option 2 - Familiarisation costs to industry by location and business size**

Location/ Firm Size	Micro	Small	Medium	Large	Total	Total rounded
England	£53,248	£18,684	£7,847	£2,989	£82,768	£83,000
Wales	£4,410	£1,547	£650	£248	£6,855	£7,000
Scotland	£10,765	£3,758	£1,574	£609	£16,707	£17,000
N. Ireland	£3,920	£1,375	£578	£220	£6,093	£6,000
<b>UK</b>	<b>£72,343</b>	<b>£25,364</b>	<b>£10,649</b>	<b>£4,066</b>	<b>£112,423</b>	<b>£113,000</b>

Notes:

- 1) Totals may not sum due to rounding
- 2) Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

- 4.16. In order for ‘one-off’ transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to ‘equivalently annualise’ costs using a standard formula. Under Standard HMT Green book guidance a discount rate of 3.5% is used.
- 4.17. A total one-off cost to industry affected by this proposal in Scotland is an estimated £16,707. This yields an EAC for of approximately £2,015 in Scotland over 10 years. Table 3 displays the breakdown of the EAC per country.

**Table 3 – Option 2 - Equivalent annual costs to industry by location**

Location	Industry EAC
England	£9,952
Wales	£824
Scotland	£2,015
NI	£733
<b>UK</b>	<b>£13,524</b>

Note: Totals may not sum due to rounding

### Enforcement authorities

- 4.18. This will have cost implications for Local Authorities (LAs) as they will need to ensure that FBOs are compliant with the requirements of Article 6 of Regulation (EC) No 853/2004.
- 4.19. There will be a one-off cost to enforcement authorities for reading and familiarising themselves with the Regulations but this will only apply to officers working in Environmental Health Departments or at a BIP.
- 4.20. It is expected that one Environmental Health Officer (EHO) will read the Regulations and disseminate the information to staff. It may materialise that enforcement of the regulation might be carried out by an EHO or a Trading Standards Officer (TSO). We have used the wage rate of an EHO to calculate the familiarisation costs because it is a higher wage rate value than the TSO wage rate, which means the costing covers either an EHO or TSO reading the regulation. We estimate that an officer will invest 30 minutes to read and familiarise themselves with the Regulations, and a further one hour disseminating to other authorised officers in the organisation. This means a total of one and a half hours for familiarisation. The familiarisation cost per enforcement authority is calculated by multiplying the reading time, one and a half hours, by the average hourly wage rate applied to an Environmental Health Officer of £20.45, generating a familiarisation cost per enforcement authority of £30.67. To quantify the overall familiarisation cost to enforcement authorities we multiply the familiarisation cost per LA by the number of LAs in Scotland. There are 32 LAs in Scotland with responsibility for the enforcement of food hygiene legislation, who will need to familiarise themselves with this proposal. The total one off familiarisation cost for enforcement authorities in Scotland totals £982. Table 4 displays the number of enforcement authorities per country with familiarisation cost.

**Table 4 Option 2 - Familiarisation cost to Enforcement Authorities in the UK**

Location	Number of LA's	Familiarisation cost	Rounded familiarisation cost
England <sup>1</sup>	393	£12,055	£12,100
Wales <sup>2</sup>	23	£705	£700
Scotland	32	£982	£1,000
NI	26	£798	£800
<b>UK</b>	<b>474</b>	<b>£14,539</b>	<b>£14,500</b>

1. Includes 39 Port Health Authorities

2. Includes 1 Port Health Authority

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in a rounding error.

- 4.21. In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a

standard formula. Under Standard HMT Green book guidance a discount rate of 3.5% is used.

- 4.22. The total one-off familiarisation cost to enforcement authorities affected by this proposal in Scotland is an estimated £982. This yields an EAC of approximately £118 in Scotland over 10 years. Table 5 displays the breakdown of the EAC per country.

**Table 5 – Equivalent Annual Cost (EAC) for Enforcement Authorities by location**

Location	Enforcement Authorities EAC
England	£1,449
Wales	£85
Scotland	£118
NI	£96
<b>UK</b>	<b>£1,748</b>

Note: Totals may not sum due to rounding

- **Benefits**

- 4.23. **Option 1** – do nothing; allow the current derogation to fall at the end of 2011. There are no benefits associated with this option.
- 4.24. **Option 2** - Comply with the obligation to meet the requirements of Article 6 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply.

Industry

- 4.25. Help facilitate trade as FBOs would be able to trade composite products across Member States if they are compliant with the correct certification when entering another Member State.
- 4.26. Harmonising the requirements, so that foods containing both foods of animal origin and processed foods of animal origin being imported in the European Union require the same certification as for animal health purposes and be subject to veterinary checks at BIPs, will enhance and strengthen current food safety measures, protect human health and assist with traceability of foods. In the longer term, once producers are used to having these types of products certified in this manner, it should assist them in their processes as they will know all of their composite products which contain processed foods of animal origin and contain half or more processed milk or fishery or egg product will be treated the same as foods of animal origin.

Consumer

- 4.27. **Option 2** would deliver public health benefits as it will minimise the potential health risk to consumers posed by FBOs handling imports of composite FOAO into the EU. Although the benefits of this option are unquantifiable, any option which contributes towards a reduction in foodborne disease is likely to have a significant economic benefit.

- **Scottish Firms Impact Test**

- 4.28. This proposal will affect a large number of micro, small and medium-sized businesses. From the statistics it appears that the main sector likely to be impacted by the proposal is micro firms (firms that have less than 10 employees). However, it would not be appropriate to exempt such businesses from the requirements of the legislation. Risk must be the main criterion in considering what food safety procedures food businesses are required to undertake and the level of risk does not depend on the number of employees or turnover.

There is evidence that some small businesses do undertake high-risk activities and have been responsible for food poisoning cases.

4.29. The main impact will be the effect on importers of composite products. Importers may take a while to adapt to the revised requirements as up to now, other foods of animal origin such as cheese and milk have not been required to have health certification if it forms part of a composite product. Approximately a quarter of the food consumed in the UK is imported from 3<sup>rd</sup> countries; of this there will be a high percentage of composite products which will have to meet the requirements.

- **Competition Assessment**

- Using the Office of Fair Trading (OFT) competition assessment framework<sup>1</sup>, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

- **Test run of business forms**

4.30. Model Health Certificates are defined in the Annexes to the regulation; these have been agreed following negotiation at EU level.

- **Legal Aid Test**

4.31. The Scottish Government Legal Aid Team has confirmed that these regulations will not introduce new criminal sanctions or civil penalties and therefore there are no legal aid implications.

## 5. Enforcement, sanctions and monitoring

- **Enforcement**

5.1. Enforcement of the harmonised arrangements will be carried out by Enforcement Officers working at BIPs. It is envisaged that it would take an half an hour for an Enforcement Officer to become familiar with the revised requirements. Companies who import composite products from 3<sup>rd</sup> countries will need to be made aware of the requirements and ensure that the correct health certificates are completed prior to the consignments being imported into the EU.

- **Sanctions**

5.2. No changes are being proposed to the criminal sanctions or civil penalties contained in the existing legislation.

- **Monitoring**

5.3. The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. Agency mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

## 6. Implementation and delivery plan

6.1. The derogation provided for in Regulation (EC) No 1162/2009 has now fallen and Article 6.4 of Regulation (EC) No 853/2004 is directly applicable across the EU and harmonises the

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<sup>1</sup> [http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft876.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf)

requirements for the importation of food containing both processed foods of animal origin and foods of plant origin into the EU. The requirement for the certification for composite product imports has been given effect by Commission Regulation (EU) No 28/2012 of 11 January 2012<sup>2</sup>.

## 7. Post-implementation review

- 7.1 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in January 2017 (i.e. 5 years from the direct application of Regulation (EU) No. 28/2012 in the UK).
- 7.2 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## 8. Summary & recommendation

- 8.1. The Agency recommends Option 2 to allow the UK to fulfil the UK's obligations under EU law. The requirement for a health certificate for imported composite products will enhance current food safety measures by ensuring that composite products which are manufactured in third countries are produced to the same hygiene standards as stipulated in EU Regulations and this will harmonise the public & animal health requirements and enhance the efficacy of enforcement.

## 9. Summary costs & benefits table

Options	Total Benefit per annum: (Economic, environmental, social)	Total cost per annum: (Economic, environmental, social, policy and administrative)
<b>Option 1</b> – do nothing.	<ul style="list-style-type: none"> <li>• There are no benefits associated with this option.</li> </ul>	<ul style="list-style-type: none"> <li>• The UK would be unable to trade in composite products across the EU.</li> <li>• The UK Government would be open to EC monetary sanctions of up to €703,000 per day or €256 million per year.</li> <li>• Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters.</li> </ul>
<b>Option 2</b> – Comply with the obligation to meet the requirements of Article 6.4 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply.	<ul style="list-style-type: none"> <li>• Allows the UK's obligations to be fulfilled under EU law.</li> <li>• Enhances current food safety measures by ensuring that composite products manufactured in third countries are produced to the same hygiene standards</li> </ul>	<p><b>Cost to industry (Scotland):</b></p> <p>Familiarisation: £17,000.</p> <p>EAC: £2,015</p> <p><b>Cost to enforcement authorities (Scotland):</b></p>

<sup>2</sup> COMMISSION REGULATION (EU) No 28/2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009

	<p>as stipulated in EU Regulations.</p> <ul style="list-style-type: none"> <li>• Harmonises the public and animal health requirements, enhancing the efficacy of enforcement of the animal health rules.</li> </ul>	<p>Familiarisation: £1,000. EAC: £118</p>
<b>Option 3</b> – Issue guidance to industry.	<ul style="list-style-type: none"> <li>• There are no benefits associated with this option.</li> </ul>	<ul style="list-style-type: none"> <li>• The guidance provided would have no legal standing and would not be legally binding.</li> <li>• Insufficient discharge of our obligation to recommend compliance with the legislation without having the systems in place to enforce the Regulation.</li> </ul>
<b>Option 4</b> – Negotiate in the European Commission to extend the derogation.	<ul style="list-style-type: none"> <li>• There are no benefits associated with this option.</li> </ul>	<ul style="list-style-type: none"> <li>• This would not achieve the policy objective.</li> </ul>

### Declaration

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's signature



Minister's title

Minister for Public Health

Date:

29/2/12

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## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

### The Food Hygiene (Scotland) Amendment Regulations 2012

To provide for the enforcement, in Scotland, of European Commission Regulations 558/2010 and 505/2010 amending annexes III of Regulation 853/2004 and Annex II of 854/2004 regarding live bivalve molluscs.

<b>File Ref. No:</b>	FSMP/SHU/0028
<b>Date:</b>	February 2012
<b>Stage:</b>	Final
<b>Source of intervention:</b>	EU
<b>Type of measure:</b>	Other
<b>Cleared by:</b>	Sandy McDougall
<b>Contact for enquiries:</b>	Jennifer Howie 01224 285157 <a href="mailto:jennifer.howie@foodstandards.gsi.gov.uk">jennifer.howie@foodstandards.gsi.gov.uk</a>

## 1. Title of Proposal

1.1 The Food Hygiene (Scotland) Amendment Regulations 2012.

## 2. Purpose and intended effect

### Objectives

- 2.1 To provide for the enforcement, in Scotland, of European Commission Regulations 558/2010 and 505/2010 amending annexes III of Regulation 853/2004 and Annex II of 854/2004 respectively. This BRIA concerns only those amendments relating to Live Bivalve Molluscs (LBMs).
- 2.2 The Regulations make amendments to specific rules and controls on products of animal origin. This includes amendments to rules on temperature controls on meat from ungulates and poultry and lagomorphs. There are also some changes to specific requirements for LBMs, live marine gastropods, live tunicates and echinoderms, (GTEs) as regards microbiological classification and packaging. This BRIA focuses on the changes to LBMs and gastropods

### Background

- 2.3 The changes regarding classification reflect agreement at EU level on the most appropriate manner in which official health controls should be applied to gastropod species such as periwinkle.
- 2.4 Filter feeding shellfish such as LBMs can accumulate micro-organisms which can pose a risk to public health. This risk is lowered in non-filter feeding species such as the periwinkle (which is the only commercially harvested species in Scotland currently affected by these changes). As such it is considered unnecessary to classify areas on the basis of flesh testing for the bacteriological hygiene indicator *E.coli*. This is because there is no epidemiological data available to link the provisions for classification of production areas with risks for public health associated with such species.
- 2.5 Such species have now been removed from the provisions on the classification of production areas as laid down in Ch. II, Section VII of Annex III to Regulation 853/2004. The rules setting down official controls for such species have therefore also been amended to reflect that areas commercially fished for such species no longer require to be classified. The official controls for such species now match those which apply to wild pectinidae, that is, they are applied on shore in fish auctions, dispatch centres and processing establishments. Local Authorities (LAs) will therefore continue to undertake official controls in such premises, as they do currently.
- 2.6 A further change has been introduced to extend the requirement to keep all packages of LBMs closed and remain closed when leaving a dispatch centre until presented to the final consumer. Previous regulations required that only consumer sized packages remain so closed. This amendment better reflects



the traceability and hygiene provisions which are already in place for such products.

- **Rationale for Government intervention**

- 2.7 Given the risks associated with non-filter feeding gastropods the Food Standards Agency (FSA) supports the change in legislation. The changes reflect a risk-based approach to food safety enforcement in line with certain other shellfish species. The result means that controls will now be moved on shore into premises already approved and enforced by LAs.
- 2.8 These requirements are not expected to incur extra costs for LAs and will also reduce costs associated with sample collection. The changes support both the Purpose of Scottish Government and National Performance Framework target by removing barriers to businesses involved in fishing such species. This will generally assist the sustainable economic growth of fishing in some of Scotland's more economically fragile areas. The cost savings to industry, LAs and the FSA are outlined below.

### **3. Consultation**

- **Within Government**

- 3.1 Scottish Government Marine Directorate was kept fully informed during the initial discussion stages of the proposal. Marine Scotland was advised of the changes after they were introduced. LAs were also advised of the change and supportive of it. Throughout negotiations FSA was the lead department and was aware that the changes to the classification requirement would result in a cost saving across Government and Industry, with no detriment to public health protection. The general principle was therefore supported by all Government partners in terms of the 'Better Regulation' agenda.

- **Public Consultation**

- 3.2 Consultation on the proposals was informal throughout the negotiating process which culminated in the changes being made in 2010. However when the original proposal to remove the classification requirement from such species was published by the Commission in 2008, key Scottish stakeholders were asked to provide a view on the suggested UK negotiating line. These stakeholders included: LAs, the Royal Environmental Health Institute of Scotland (REHIS), Scottish Fish Hygiene Working Group (SFHWG), Seafood Scotland, Seafood Shetland, Scottish Fishermen's Federation, Association of Scottish Shellfish Growers, Shetland Aquaculture, Shetland Fishermen's Association, Scallop Association and the Scottish Shellfish Marketing Group.
- 3.3 Replies were received from South Ayrshire council, REHIS, Scallop Association, Seafood Shetland and the Scottish Fish Hygiene Working Group –

all in support of the proposal which has culminated in the publication of Regulation (EU) 558/2010.

- 3.4 The FSA conducted a full public consultation which ran for 10 weeks from 13 December 2011 until 21 February 2012. 255 stakeholders were consulted. No responses were received to this formal consultation. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

- **Business**

- 3.5 As the proposals on classification affect wild shellfisheries, (areas where shellfish grow naturally), there is little in the way of formal industry representation for the sector. However informal feedback in Scotland suggested that the requirement for classification was disproportionate to the risks involved. Many of the 28 sites which were classified for periwinkle production as at April 2010 followed an application by a LA who had noted potential activity in their area or whom had been approached by individuals to process an application for classification with the FSA.
- 3.6 The shellfisheries involved are largely located on the west coast of Scotland, Western and Northern Isles, with some commercial fishing done in Fife. When the original measure to introduce classification in this sector was introduced, contact with Skye and Shetland fishermen suggested that the requirement was not considered a business burden.
- 3.7 Key stakeholders in the shellfish industry were consulted as part of the above mentioned public consultation. No responses were received, indicating that the industry has no further objections to this change in policy.

#### **4. Options**

Option 1: Do nothing (i.e. maintain classifications and packaging requirements in contravention of EC law)

Option 2: Do not classify gastropod production areas and extend packaging requirements in accordance with EC law.

- **Sectors and groups affected by Option 2**

- 4.1 The Shellfish industry and LAs will no longer require to be involved in procedures set down by the FSA for the classification of such species under food hygiene legislation. As such there will be a degree of cost saving for industry and better targeted enforcement by food authorities to areas of recognised risk. The FSA will no longer have to pay LAs and Official Control laboratories for the uplift and testing of such samples. Official Control laboratories will however lose income from analysis of such samples in future.

Consumers will have increased protection as the requirement to seal all packaging of LBMs will ensure that all products reaching the final consumer comes from an approved establishment and has not been tampered with.

- **Benefits and costs**

**Benefits:**

**Option 1: Maintain classifications and packaging requirements in contravention of EC law**

- 4.2 When the original requirement to classify such sites was introduced in Scotland, the measure was in fact welcomed by some industry sectors, as registration documents which provided a degree of Competent Authority assurance on the provenance of the product had been requested by some European markets. However, now that the requirement for such classification has been removed this perceived benefit is no longer relevant as there is now a wholly level playing field across Europe. This may mean that whilst Scotland loses any advantage it may have had from classifying such areas where other markets did not, conversely it allows Scotland to compete on a similar footing with immediate access to market, which was not previously the case.
- 4.3 The benefits associated with the extension of the packaging requirements are not known. Industry was unable to provide data on this during the initial discussions or the public consultation.

**Option 2: Do not classify non-filter feeding gastropod production areas and extend the packaging requirements in accordance with EU law.**

- 4.4 The change in classification requirements will save local authorities and the FSA at least £127,000 per annum. This figure includes £116,000 which has been allocated by FSAS for both biotoxin method development and biotoxin analysis for existing gastropod production areas. In addition *E. coli* analysis of such species for 2009-10 cost FSAS approximately £11,000. In addition to this LAs were paid by FSA to collect the samples and LAs themselves will make a saving in terms of enforcement time dedicated to these areas.
- 4.5 In general terms, the fact that businesses no longer have to ensure that such species are fished from classified areas means that they can access markets immediately (notwithstanding any local fishery management controls that may be in place). Industry also benefits by not having to provide samples in order to achieve classification, which will result in some transport and marginal product savings.
- 4.6 This measure affects businesses in some of Scotland's more remote rural communities – up and down the west coast and Western Isles. It will enable

them to access markets more quickly and to exploit a natural resource in areas where economic opportunities are limited. This benefit has not been quantified.

- 4.7 LAs would no longer have to devote resources to both collecting samples and enforcing the classification requirements for these species. It was exceptionally difficult to collect verified official control samples from some very remote locations and LAs largely relied on businesses to provide samples on shore. This practice did not comply with Regulation (EC) 882/2004 chapter II article 4 which is explicit in the responsibility that the competent authority must ensure impartiality of official controls at all levels, free from any conflict of interest. In addition, ensuring that classified area boundaries are adhered to in the sector requires considerably more resource from LAs than land based checks, for no discernable public health gain. It is not possible to quantify this benefit at this stage. In addition, taking such species outwith the classification requirement means that such areas no longer attract the other official controls which apply to LBMs – for example the requirement for sanitary survey and chemical contaminant work to be undertaken, as well as biotoxin analysis. By removing this requirement, industry, LAs and the FSA can better and more efficiently work together to ensure that robust public health controls are maintained at point of risk.
- 4.8 Extending the requirement to seal all packages of LBMs will ensure full traceability of the product from the dispatch centre to the retailer. This will lead to increased retailer and consumer protection.

### **Costs:**

#### **Option 1: Do nothing (i.e. maintain gastropod classifications and LBM packaging requirements in contravention of EU law)**

- 4.9 As at April 2010 there were 28 classified gastropod areas in Scotland. To maintain these classifications would be to 'gold plate' the requirements set out in EU law. The costs to industry have not been quantified. However, classification samples for new sites required the harvester to take his boat to site, collect and return, with no harvesting possible until a classification had been awarded. Costs included fuel and labour.
- 4.10 Between April 2009 and October 2010, 219 *E. coli* flesh samples were taken at a cost to the FSA (for analysis alone) of £10,950. Maintenance of classification (10-12 samples are required annually) would mean that this annualised cost to the FSA would remain. There would also be a requirement for a sanitary survey and chemical contaminants monitoring for a new site at a 'one off' cost of £16,495.
- 4.11 Further resource would be required to ensure that appropriate monitoring tools were in place to manage the risk from marine biotoxins in accordance with the

previous requirements set out for such classified areas. Approximately £116,000 was allocated by the FSA on biotoxin monitoring in this sector in 2010-11, a sum which is now no longer required.

- 4.12 By failing to extend the packaging requirements for LBMs, the UK would be in breach of the requirements of EU hygiene legislation and the UK could be subject to infraction proceedings. The maximum fine that could be imposed on the UK is currently some €703,000 per day<sup>1</sup> or some €256 million per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.

#### Option 2: Do not classify gastropod production areas and extend the LBM packaging requirements in accordance with EU law.

- 4.13 A possible cost to the Shellfish industry is that of the loss of the perceived market advantage in terms of the quality control aspect that classified status brings to products in Scotland. Informal soundings from industry elsewhere in the UK suggested that, as Scotland previously classified all of its shellfisheries, this 'certification' provided an additional marketing angle. Removing the classification requirement for such production areas removes this market advantage.
- 4.14 The Official Control Laboratory which undertakes analysis on behalf of the FSA will no longer receive an income from periwinkle samples in Scotland. The analysis costs in this sector in 2009-10 came to approximately £11,000.
- 4.15 There will be a cost to the FSA in producing the amendment to the regulations. This will comprise of printing costs amounting to £290 plus undetermined legal fees.
- 4.16 The costs associated with the change in packaging requirement are not known at this stage. These were not quantified by industry during the formal public consultation.

### **5. Scottish Firms Impact Test**

- 5.1 The change in classification requirement will remove administrative burdens to industry in terms of having to apply for classified status and provide samples in support of that application. It is not known at this stage what the impact of the extension in packaging requirement will be.
- 5.2 As indicated in section 3, during the Commission negotiation stage the FSA engaged with a range of industry representatives. The FSA has engaged face to face with industry in the course of routine contact with fishermen and industry

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

groups. No negative feedback has been received in relation to this regulatory change.

- **Competition Assessment**

5.3 These measures apply to the shellfish sector involved in the supply of non-filter feeding gastropods and LBMs across Europe. Using the Office of Fair Trading (OFT) competition assessment framework<sup>2</sup>, it has been established that policy option 2 is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

5.4 Whilst the legislation changes the requirement that such shellfish must come from classified areas, the material change itself largely affects the Competent Authority function in relation to classification procedures, sample collection and analysis. The impact on business of the change to the packaging requirement is not known at this stage.

- **Test run of business forms**

5.5 No new forms are being introduced.

## **6. Legal Aid Impact Test**

6.1 The proposed amendments to the Regulations do not introduce new criminal sanctions or civil penalties; therefore, there are no legal aid implications. This draft BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

## **7. Enforcement, sanctions and monitoring**

- **Enforcement**

7.1 Enforcement of the Regulations in Scotland will be the responsibility of Local Authority Environmental Health Departments. Powers will be drawn down from the SSI.

- **Sanctions**

7.2 No changes are being proposed to the criminal sanctions or civil penalties contained in the Food Hygiene (Scotland) Regulations 2006.

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<sup>2</sup> [http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft876.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf)

- **Monitoring**

- 7.3 The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. Feedback from LAs will be received through the Scottish Fish Hygiene Working Group. Feedback from industry will be received through the Scottish Government's Shellfish Stakeholders Forum.

## **8 Implementation and delivery plan**

- 8.1 Regulation (EU) 558/2010 has applied directly in the UK from 15 July 2010 (i.e. 20 days after their publication in the Official Journal on 25 June 2010).
- 8.2 The coming into force of The Food Hygiene (Scotland) Amendment Regulations 2012 will be communicated to stakeholders by email, letter and via the Agency's website etc.

## **9 Post-implementation Review**

- 9.1 A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulations, will take place in July 2015 (i.e. 5 years from the direct application in the UK of Regulation (EU) 558/2010).
- 9.2 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## **10 Summary and Recommendation**

- 10.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EU) 558/2010.
- 10.2 Taking this option allows the Government to fulfil its obligations to implement EU law.
- 10.3 Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

## 11 Summary Costs and Benefits Table

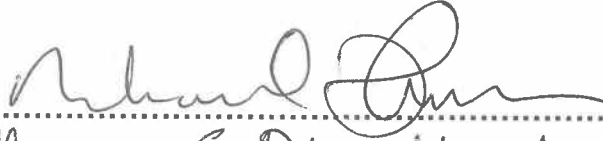
Option	Total Benefit per annum: <b>-Economic, environmental, social</b>	Total Cost per annum: <b>-Economic, environmental, social</b>  <b>- Policy and Administrative</b>
<b>1. Do Nothing</b>	Competent Authority assurance of the health standards of GTEs provides market advantage	Risk of infraction proceedings for failure to implement (EC) 1019/2008. Possible fines of up to €703000 per day.  Unquantified fuel and labour costs for harvesters in providing official control samples.  £127000 cost per year for FSA for official control sampling
<b>2. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</b>	Allows the Government to meet its commitment to fulfil its EU obligations.  £127000 cost saving per year for FSA  Immediate market access for FBOs  LAs/ shellfish sampling officers can focus resources on LBM classified areas  Full traceability of LBMs from dispatch centres to the retailer, improving consumer protection	Loss of perceived market advantage based on the quality and health standard assurance provided by the competent authority official control sampling  £11000 per year loss to the Scottish laboratory involved in analysis of official control samples



## 12 Declaration

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature



Ministers Title

Minister for Public Health

Date

29/2/12

### **Contact point**

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## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

### THE EXTENSION OF PROVISION FOR SERVICE OF REMEDIAL ACTION NOTICES TO ALL FOOD BUSINESSES

**File No:** SPARD/FSAS  
**Date:** February 2012  
**Stage:** Final  
**Source of intervention:** EU  
**Contact for enquiries:** Claire Moni  
**Phone No:** 01224 285158  
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## **1. Title of Proposal**

1.1 The Food Hygiene (Scotland) (Amendment) Regulations 2012 to extend the scope of application of Remedial Action Notice (RAN) enforcement sanctions to all food businesses.

## **2. Purpose and Intended Effect**

2.1 To enhance public health, protect business reputation and improve consumer confidence by providing for immediate, proportionate, intervention tools to be available for enforcers in all food business sectors, thereby allowing them to deal effectively and consistently with recalcitrant, significantly non-compliant businesses.

### **2.2 Objectives**

- To ensure that all food businesses that breach food hygiene legislation take prompt corrective action where it is in the public interest for them to do so, and where businesses are not prepared to, take such action voluntarily.
- To provide a consistent approach to enforcement across all industry sectors.
- To minimise the burden on the Scottish judicial system with respect to reducing the prospect of emergency notices being submitted to the Sheriff Court and / or reports being submitted to the Procurator Fiscal service by non-police reporting organisations.
- To provide reassurance to businesses, through a compensation scheme, that there will be effective safeguards against misuse of the new powers.

## **Background**

2.3 When the EU food hygiene Regulations came into effect on 1 January 2006, domestic food hygiene Regulations were introduced to provide for their execution and enforcement. This included the creation of offences and penalties and provided authorised officers with enforcement powers for use in non-compliant establishments. These domestic regulations maintained a range of enforcement powers which had previously been contained in the Food Safety Act 1990<sup>1</sup> and had applied to all food businesses.

2.4 In the case of approved meat plants subject to veterinary supervision an additional enforcement tool, a “stop notice” (commonly known as a “regulation 10 notice”) was also in use before 2006. In carrying this forward into the new domestic legislation, the “stop notice” became known as the RAN.

2.5 As the EU legislation now applied horizontally across all UK food business sectors, rather than vertically by commodity sector such as meat, dairy and fish, it was inappropriate for the RAN to continue to be limited to approved meat establishments only - it could apply to:

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<sup>1</sup> Food Safety Act 1990 <http://www.legislation.gov.uk/ukpga/1990/16/contents>

- all establishments subject to approval (including fish and dairy establishments in addition to meat, for example); or
- all food establishments regardless of whether or not they were subject to approval (a wider scope including the retail, catering and farming sectors).

2.6 In the public consultation<sup>2</sup> for the domestic hygiene Regulations the FSA proposed that RANs should be introduced to all food establishments on the basis that they would provide a proportionate and effective tool for authorised officers to control certain non-compliances without the need to escalate issues to a Sheriff's Court, unless the FBO chose to appeal. Scottish representative bodies of the local food authorities and local authority authorised officers were strongly in support of this proposal. The timescale for consultation, receipt and analysis of comments from consultees before the introduction of the Regulations in Scotland was very compressed for reasons outside of the FSA's control, and during the consultation there was limited response received from the Scottish business sector. However, the FSA UK consultation received very strong representation from the retail sector opposing the introduction of RANs to their trade sector. In view of the strength of opposition and the very tight timeframe for discussion, the FSA limited the use of RANs to establishments subject to approval with a commitment to review the position of their wider application based on data from at least one year's use of RANs in all approved establishments.

### Food Hygiene Delivery Programme

2.7 There were very serious food borne *E.coli* outbreaks in Scotland during 1996 and Wales during 2005, both of which resulted in the deaths of some affected individuals and in serious long-term health problems for others. In March 2009, Professor Hugh Pennington completed his Public Inquiry into the September 2005 outbreak of *E.coli* O157 in South Wales<sup>3</sup>, which built on his previous report following the Scotland outbreak. In response to the Inquiry's recommendations, the FSA set up the Food Hygiene Delivery Programme (FHDP) to prioritise, direct and measure progress in an ambitious and comprehensive programme of work to improve food hygiene delivery and enforcement across the UK, covering all foodborne pathogens and all food groups.

2.8 Through the FHDP, the FSA committed to reviewing the adequacy of the existing legislation as it relates to the effectiveness of official controls delivery in protecting public health, set within the context of its wider strategy for compliance and enforcement. The FSA has also developed guidance on control of cross-contamination risks of *E.coli* O157 under FHDP. Both the Scotland and Wales outbreaks were attributed to cross-contamination from poorly managed food handling practices. RANs are seen as an important tool to help address such issues.

### Use of RANs in establishments subject to approval

2.9 The FSA now has the benefit of a history of service of RANs in establishments subject to approval by the former Meat Hygiene Service (MHS)<sup>4</sup>, the Department of

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<http://www.food.gov.uk/multimedia/pdfs/consultation/extenremedialactionnoticescot.pdf>

<sup>3</sup> <http://wales.gov.uk/ecolidocs/3008707/reporten.pdf?lang=en>

<sup>4</sup> The MHS merged with the Food Standards Agency in April 2010

Agriculture and Rural Development (DARD) in Northern Ireland and local authorities across the UK. Two specific data collection exercises have been carried out – a recent UK-wide survey of RANs used in 2008/09, and a similar exercise carried out by the FSA in 2006/07.

2.10 The 2006/07 data shows that 300 RANs were issued by the MHS/DARD, and 24 by LAs, across the twelve month period. The 2008/09 exercise shows a sharp decline in use, particularly by the MHS/DARD, indicating that 36 RANs were issued by the MHS/DARD and 17 by LAs. The decline in use was partly due to the MHS escalating enforcement action against establishments in 2008/09, as appropriate under the hierarchy of enforcement action, instead of issuing multiple RANs as was the practice in 2006/7.

The figures are presented in table 1 below.

**Table 1 – RANs issued by enforcement authorities**

	2009 Survey	2006 Survey
LA RANs	17	24
MHS RANs	34	300
DARD RANs	2	0
<b>Total</b>	<b>53</b>	<b>324</b>

2.11 The key findings and indications from the data are;

- The use of RANs has not been excessive, and has declined, indicating careful consideration of use;
- Most MHS/DARD RANs issued in slaughterhouses were resolved quickly, frequently on the same day (probably because the RAN in this type of establishment may be used to slow the production line and thereby provide a clear incentive to FBOs to act quickly, and because there is a daily presence of authorised officers in these premises);
- RANs served by LAs were in force for comparatively longer – very few were issued and resolved on the same day; and
- No RANs were appealed during the survey years.

2.12 The Scottish Food Enforcement Liaison Committee (SFELC) and Local Authority Authorised Officers remain strongly in support of extending the RANs provision to establishments not subject to approval. The new proposals have also been welcomed by the majority of Scottish food businesses contacted during the formal consultation exercise, including those small businesses contacted during the face to face visit element of this BRIA development. In addition the proposal has been discussed informally with Scottish Government better regulation advisors who have indicated that they are content that it is aligned with wider Scottish Better Regulation objectives.

### 3. Rationale for Government Intervention

- 3.1 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. This means that there is a benefit from government intervention both to require appropriate hygiene standards of food business operators and to have effective means to enforce them.
- 3.2 The respective Food Hygiene Regulations 2006 in Scotland, England, Northern Ireland and Wales provide authorised officers in each country with powers to ensure FBO compliance with the food hygiene regulations. The key powers are detailed at Annex 1.
- 3.3 The enforcement of food law is structured around a hierarchy of enforcement actions. Most non-compliances are rectified by the FBO voluntarily by following the authorised officers advice. In the majority of cases this is the most effective way of achieving compliance, and the FSA's guidance on enforcement powers stresses the importance of trying to gain voluntary corrective action from the FBO through informal advice.
- 3.4 In those circumstances where the FBO will not voluntarily take corrective action, authorised officers may need to use enforcement tools to secure compliance. On occasion, authorised officers find breaches of the hygiene legislation where the current powers are not proportionate or effective, and this can act as a disincentive for their use.
- 3.5 The Hygiene Emergency Prohibition Notice (HEPN) requires the authorised officer to demonstrate "imminent risk of injury" to Sheriff in Scotland, before the Court will confirm the authorised officer's decision. Involving the Courts in dealing with FBO non-compliances can be disproportionate where the non-compliance is more limited in extent, or of a lesser, but still significant risk, and this acts as a disincentive against their use. There are circumstances where "imminent risk of injury" cannot always be readily demonstrated to the Court for such breaches, although there is still a potential risk to public health. Addressing these non-compliances through use of the HEPN can therefore be disproportionate and / or inappropriate.
- 3.6 The current alternative for the authorised officer is the service of a Hygiene Improvement Notice (HIN). However, this permits a minimum period of 14 days for the FBO to take corrective action and therefore lacks immediate effect. It is effective in dealing with non-compliances that are low-risk and where a longer time-period can be permitted. However, where action needs to be taken immediately to protect public health this tool is ineffective.
- 3.7 There are therefore non-compliances where action needs to be taken immediately, but involving the Courts in resolving the issue is disproportionate. Examples of these non-compliances are set out in the paragraph below. RANs fill this gap in the existing enforcement tools, but they are currently only available for use in establishments subject to approval.
- 3.8 Examples of where a RAN might be a more appropriate enforcement tool for instances of unhygienic practices or risk of cross contamination include:
  - A lack of proper cook or chill temperature control which allows the growth of pathogenic organisms with a risk for consumers;

- Cleaning issues which pose a risk of cross contamination of food for human consumption and require immediate attention;
- A lack of hot water supply which prevents hygienic production and poses a risk of cross contamination; and
- Pest infestation and drainage defect issues which create an unhygienic environment where food is produced with a risk of cross contamination.

3.9 A recent example reported to the FSA where a RAN would have proved a more effective means of securing compliance and protecting public health was of an establishment found with accumulations of grease, dust and food debris on the floors, walls, and ceiling. Advice and guidance was given to the FBO about what should be done to resolve the problem, and a voluntary compliance period of 24 hours was agreed. The inspector visited the premises on three occasions in the same week and observed very little progress towards achieving compliance. It eventually took five days to bring the kitchen up to an acceptable standard, during which time the FBO was able to continue to sell food to the public. If RANs had been available, they could have been used to require the kitchen to be cleaned to an acceptable standard immediately.

3.10 RANs will be available for use on all businesses regardless of size. There is no evidence that micro food businesses pose less of a safety risk than other businesses. RANs can be used to prohibit the use of certain equipment or part of an establishment without prohibiting the use of the entire establishment. For example, an authorised officer could issue a RAN to prohibit the use of a particular machine used for slicing cooked meats at a delicatessen counter until it is cleaned to acceptable standard to protect public health, but without shutting the counter or store. RANs therefore allow an authorised officer to take proportionate and targeted action against non-compliances within an establishment.

3.11 Following the extension of RANs, HEPNs will remain the key enforcement tool for dealing with immediate significant contraventions, where imminent risk of injury is clear and where the involvement of the Court and access to high levels of sanctions are important. HINs will remain the main tool for dealing with low-risk breaches of the hygiene requirements that can be permitted to persist for 14 days before being rectified. RANs will not replace either of these sanctions but will fill the gap between them. Voluntary corrective action from the FBO will continue to be the main method of securing compliance.

3.12 The extension of RANs to the unapproved sector is not specifically required under EU food official control regulations, but would be consistent with these regulations which require that, amongst other things, official action to deal with non-compliance shall include the suspension of operation or closure of all or part of the business concerned for an appropriate period of time.

3.13 Intervention to update EU legislation is also in accordance with the Scottish Government's national performance framework target and will contribute to Scotland's growth and productivity targets by reducing the regulatory burden on affected Scottish businesses. This will help to make Scotland an attractive place for doing business in Europe and contribute to realising our full economic potential.

## 4. Devolution

- 4.1 This Business Regulatory Impact Assessment (BRIA) considers extending the legislative proposal and the availability of RANs for use in establishments not subject to approval in Scotland. A separate Impact Assessment is being produced by the FSA in England, Wales, and Northern Ireland where there are similar policy proposals.

## **5. Consultation**

### With Government

- 5.1 FSA in Scotland consulted with the Scottish Government officials from Health Protection, Rural Directorate and Criminal Justice on the extension to RANs, as part of the 12 week consultation during February - May 2011.
- 5.2 During the development of the partial BRIA, FSA in Scotland contacted the Scottish Government Food and Drink Industry Unit to inform them of the FSA proposals and also requested assistance with identifying businesses with which to engage. The Industry Liaison Division were content with this consultation and provided contacts for trade bodies. FSA in Scotland also involved Scottish Government Better Regulation and Industry Engagement Unit leads in the drafting of the partial BRIA.

### Public Consultation

#### Consultation in Scotland

- 5.3 A public consultation was carried out in Scotland on an earlier draft of the Business and Regulatory Impact Assessment (BRIA) from February - May 2011. FSA in Scotland received 24 responses in total, from 21 individual Local Authorities, 2 Food Liaison Groups and 1 industry stakeholder.
- 5.4 All 21 Local Authorities and 2 Food Liaison Groups were in agreement that the RANs should be extended to establishments not subject to approval. Many also provided examples of where the extension to RANs would be important and also effective in closing the gap between Hygiene Improvement Notices and Hygiene Emergency Prohibition Notices. Many considered this proposal as an effective tool, in supporting the better regulation agenda and the Food Hygiene Information Scheme.
- 5.5 The one comment from industry agreed that the extension of RANs would provide greater consumer protection but they expressed concern it might not be used appropriately and questioned the availability of an authorised officer to lift the RAN once it had been applied. The consultation documents are available at:  
<http://www.food.gov.uk/multimedia/pdfs/consultation/extenremedialactionnoticescot.pdf>
- 5.6 In addition to the formal written consultation FSA in Scotland, in compliance with Scottish Government BRIA procedures carried out, during March 2011, face-to-face meetings, with 7 small business representatives from a range of industry sectors to discuss the potential impact of the proposal. With one exception, industry representatives were very supportive of the principle of extension of RANs. Further details are given in paragraph 8 on the Scottish Firms Impact Test.



### Consultation in England, Wales and Northern Ireland

5.7 FSA in England, Wales and Northern Ireland, received 50 responses in total, consisting of 10 Food Liaison Groups, 25 individual Local Authorities, 2 consumer groups, 1 lobby group, and 12 industry responses. The responses demonstrated strong and unanimous enforcement and consumer group support for the extension of RANs to all food establishments.

5.8 The responses from industry were mixed. All 13 industry responses called for greater safeguards to be put in place to protect them from the possibility of misuse of RANs. There were also concerns about the practicalities of RANs. Two industry respondents supported the extension in principle, on the grounds that it would help to ensure that their competitors did not gain an unfair advantage by not complying with the law.

### Safeguards: Appeals and Compensation

5.9 Industry consultation responses indicated uncertainty over the appeals procedure for RANs. RANs can be appealed. The appeal is heard by a Court, and, if upheld, the RAN is lifted. However, to obtain compensation for losses incurred, a business needs to undertake further legal action.

5.10 Having considered the consultation responses, we agree that where an appeal is upheld, compensation for losses incurred should be available at the Court hearing. This would provide business with a safeguard against misuse, and would be consistent with existing provisions, e.g. for Emergency Prohibition Notices, which can be used where an imminent risk for public health can be demonstrated.

5.11 Introducing a compensation clause will require an amendment to the Food Hygiene Regulations in Scotland. The new compensation clause would apply to RANs issued in approved establishments, as well as the unapproved sector.

### Hierarchy of Enforcement and Consistency

5.12 There were industry concerns raised, particularly in England, that RANs may be issued indiscriminately, or in circumstances where informal enforcement would be more appropriate.

5.13 The statutory Food Law Code of Practice and associated Practice Guidance for Scotland<sup>5</sup> requires that, except where circumstances indicate that a significant risk warrants immediate action, officers should operate a graduated and educative approach to enforcement. This should begin with advice and education and informal action, and move to more formal action only where the informal action does not achieve the desired effect. The FSA will continue to encourage this approach through guidance and audit.

5.14 Evidence of current application of RANs indicates careful use by authorised officers. Local authorities have responsibility for about 10,000 approved establishments, and the FSA / DARD have responsibility for about 1,000. In 2008/09, Local Authorities issued 17 RANs. In establishments for which the FSA is responsible 34 were issued, and two were issued by DARD in Northern Ireland. None of the RANs were appealed.

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<sup>5</sup> <http://www.food.gov.uk/enforcement/enforcework/foodlawcop/copscotland/>

5.15 In order to drive consistency in the application of RANs, if this enforcement tool is extended to all establishments, the FSA will issue guidance on how and when to issue a RAN (based on the high level principles at Annexe B). The FSA will also review the relevant sections of the statutory CoP, which sets out the processes for issuing a RAN. Consistency will be supported further by the existing competency framework for authorised officers, which requires that an authorised officer must have two years post qualification experience to be able to issue a RAN.

#### Process for lifting a RAN

5.16 In order to issue a RAN, the authorised officer must specify which provisions of the hygiene legislation are being breached, and what is needed to rectify the non-compliance. Once the non-compliance has been rectified, the RAN can be lifted by any officer at the enforcing authority. Some consultation responses from industry were concerned about how long this process might take.

5.17 The statutory CoP requires that the RAN must be withdrawn as soon as the authorised officer is satisfied that the action specified in the notice has been taken. The need for an authorised officer to lift the RAN quickly when they are satisfied the business has rectified the non-compliance will be further emphasised in the FSA guidance.

## **6. Options**

### **Option 1: Do nothing.**

6.1 This option would maintain the status quo and there would be no incremental monetised costs associated with this option. Option 1 would mean that authorised officers continue to use existing enforcement tools to require compliance with the hygiene legislation for the approved sector. As set out in paragraph 3 on rationale for government intervention, there are certain circumstances where the current tools can be inappropriate or overly bureaucratic.

### **Option 2: Take action short of legislation, issue new guidance to food businesses and/or enforcers**

6.2 This option considers taking action short of legislation to meet the policy objective. For the purposes of this consultation, FSA has considered providing new or revised guidance to:

- food businesses on the importance of complying with the hygiene regulations in order to control risks even where there is no easily demonstrable “imminent risk of injury”
- competent authorities on addressing breaches of the hygiene legislation where “imminent risk of injury” would be difficult to prove but corrective action is required immediately.

6.3 Local Authorities provide the first point of contact for food businesses not subject to approval, offering practical advice during audits carried out on a risk basis. To support local authorities and help food businesses comply with the law and maintain

safe and hygienic working practices, the FSA has issued guidance for businesses on the hygiene legislation. For example, Cooksafe in Scotland<sup>6</sup>, Safer Food, Better Business in England and Wales and Safe Catering in Northern Ireland) was developed to help small businesses put in place food safety management procedures based on HACCP principles and comply with food hygiene regulations. It focuses on practical application of the hygiene regulations and is designed to meet the specific needs of different food businesses. There are packs for small catering businesses, small retail businesses, and restaurants and takeaways that serve different cuisines, such as Chinese or Indian, Pakistani, Bangladeshi and Sri Lankan cuisines. There is also a pack for childminders and a supplement for care homes that is designed to be used with the pack for caterers. In addition to this, the FSA in Scotland<sup>7</sup> provides other guidance on specific issues, including guidance on setting up a food business.

- 6.4 All of this guidance and advice seeks to influence or change behaviour and make non-compliances less likely, resulting in benefits for public safety. However, non-compliances still arise, and there are occasions where the food business operator will not take voluntary action to correct the non-compliance. In those cases it is important that the authorised officer has proportionate and appropriate powers to require that action is taken.
- 6.5 Option 2 as set out is therefore unlikely to lead to an improvement in standards, and would not meet the policy objective. It is, however, important for us to consider this option so that we do not legislate where a non-legislative option would be more appropriate. No non-regulatory options that would achieve the policy objective of closing the gap between HINs and HEPNS were proposed to the FSA's public consultation on this issue.

**Option 3: Extend RANs to establishments not subject to approval, which will provide consistent enforcement powers across all food businesses, a strengthened process to address breaches of the hygiene legislation, introduce a compensation clause to protect industry from potential misuse and where effective the notice procedure would achieve compliance without the need for formal judicial proceedings.**

- 6.6 This option extends the use of RANs to establishments not subject to approval, which will provide a strengthened process to address breaches of the hygiene legislation. This option requires an amendment to the Food Hygiene Regulations 2006 in Scotland, England, Northern Ireland, and Wales, and also an amendment to the statutory Code of Practice for enforcers.
- 6.7 The FSA would also amend the Food Law Practice Guidance to clearly set out how authorised officers might use RANs in establishments not subject to approval to ensure such use is appropriate and proportionate. RANs would not be introduced to replace any existing power – for example, HEPNS would remain as the required tool to

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<sup>6</sup> Cooksafe for Scotland is available at;  
<http://www.food.gov.uk/foodindustry/regulation/hygleg/hyglegresources/cookretailscotland/cooksafe/>

<sup>7</sup> List of FSA guidance for Scotland is available at: <http://www.food.gov.uk/scotland/regsscotland/regsguidscot/>  
UK wide guidance is available at: <http://www.food.gov.uk/foodindustry/guidancenotes/>

deal with any breach of the hygiene legislation where there is an “imminent risk of injury” and HINs would continue to be used where it is appropriate to allow at least 14 days for the non-compliance to be rectified.

6.8 The FSA consulted in all of the 4 UK countries on the extension to RANs in 2011, and the FSA Board considered the consultation responses at its open meeting on 7<sup>th</sup> September 2011. At the meeting, the Board agreed that RANs should include a compensation clause to protect industry from potential misuse. In taking this decision, the Board noted that the available evidence suggested that RANs were currently being used appropriately where they were available, and that the addition of a compensation clause should not provide a burden on local authorities or the FSA.

6.9 As a result, **Option 3** is the preferred option that would extend RANs to establishments not subject to approval, which would provide consistent enforcement powers across all food businesses, a strengthened process to address breaches of the hygiene legislation, introduce a compensation clause to protect industry from potential misuse and potentially reduce the number of occasions matters require to be formally reported to the Scottish judiciary.

### Sectors and groups affected

6.10 The legislation will affect food businesses that do not take voluntary action to rectify a non-compliance, consumers and enforcement authorities.

### Industry

6.11 The proposal will apply to all food businesses in the UK, but will only directly affect those that are not complying with the hygiene regulations and are not voluntarily taking corrective action.

**Table 2 – Number of Businesses Affected, by Country and Business Size (IDBR 2011)<sup>8</sup>**

	Micro	Small	Medium	Large	Total
England	111,096	19,060	1,991	488	132,635
Wales	6,676	1,145	120	29	7,970
Scotland	11,077	1,900	198	49	13,225
NI	4,247	729	76	19	5,070
<b>UK</b>	<b>133,096</b>	<b>22,834</b>	<b>2,385</b>	<b>585</b>	<b>158,900</b>

Note: Totals may not sum due to rounding

Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees; Small – 20-49 employees; Medium – 50-249 employees; Large – more than 250 employees.

Number of businesses derived from the IDBR register of businesses

### Consumers

<sup>8</sup> Figures retrieved from Inter Departmental Business Register (IDBR 2011) from the Office of National Statistics (ONS): <http://www.statistics.gov.uk/idbr/idbr.asp>. The (IDBR) is a list of UK businesses which combines the former Central Statistical Office (CSO) VAT based business register and the former Employment Department (ED) employment statistics system. The IDBR covers businesses in all parts of the economy representing nearly 99 per cent of UK economic activity. However, some micro businesses and non-profit organisations have been omitted i.e. organisations operating without VAT or PAYE schemes; self employed and those with low turnover and without employees.

6.12 The measure proposed will lead to increased food establishment compliance with the hygiene regulations, which will contribute to greater public health protection.

### Enforcement Authorities

6.13 Access to RANs will enable local authorities to take proportionate and appropriate action in the circumstances set out in paragraph 3. RANs are already available for use in approved establishments, where Local Authorities, DARD, and the FSA undertake official controls.

### **Benefits**

#### **Option 1: Do nothing**

6.14 There are no incremental benefits. This option is the baseline for comparison. There would be no benefits to the consumer, since the risk to their health could be compromised as a result of the potential health risk to consumers posed by food business operators with poor hygiene practices. With respect to businesses without the extension of RANs certain businesses could continue operating with lower standards.

#### **Option 2: Take action short of legislation, issue new guidance to food businesses and / or enforcers**

### Consumers

6.15 There will be limited improvement in consumer safety from issuing FBOs and enforcement authorities with new or revised guidance on compliance, as guidance is already available to FBOs on meeting legal hygiene requirements. The current tools would continue, in the circumstances set out in paragraph 3.8 above, to be overly bureaucratic and time consuming for enforcement authorities and food businesses. This option would therefore not meet the policy objective.

### Industry

6.16 There would be no benefit to industry from Option 2. Guidance is already available to FBOs on meeting legal hygiene requirements. Refreshed or new guidance might encourage some businesses to take corrective action in circumstances where they have not in the past, but it does not guarantee this.

#### **Option 3: Extend (RANs) to establishments not subject to approval**

### Consumers

6.17 The FSA estimates that in 2009 there were 132,000 cases of food poisoning disease in Scotland, resulting in 2330 hospital admission and around 50 deaths. This is estimated to be equivalent to a cost of approximately £140 million to the Scottish economy. These estimates are based on the numbers of confirmed laboratory reports which were published by Health Protection Scotland. Option 3 would deliver public health benefits as it will minimise the potential health risk to consumers posed by food business operators with poor hygiene practices. However, these benefits are unquantifiable as we are unable to attribute the exact impact of this policy option in reducing these risks.

## Industry

6.18 Industry is likely to benefit from increased consumer confidence in food safety and improved protection to reputation, thus facilitating trade. Also the RAN does not lead to a Court hearing for which a food business operator is likely to need to spend time preparing for and attending, and can be lifted quickly and simply when the non-compliance has been resolved.

6.19 All FBOs are required to meet the same standards. The extension of RANs will help address those businesses operating with lower standards and decrease risks of potential market distortion.

## Enforcement Authorities

6.20 Long-run improvement in compliance levels enabling enforcement authorities to free up resources and target high-risk establishments.

## **Costs**

### **Option 1 – Do nothing**

6.21 There are no incremental costs. This is the baseline against which other costs are compared.

### **Option 2 - Take action short of legislation – issue new guidance to food businesses and / or enforcers**

## Industry

### Familiarisation costs

6.22 Under option 2, the FSA would look to identify whether new guidance or amendments to existing guidance might be developed to encourage businesses voluntarily to address non-compliances with the hygiene legislation.

6.23 The FSA has already published freely available guidance in this area, and it is thought that any changes would be minimal. The FSA would not be introducing any new requirements in the guidance – it would only be looking to clarify the existing message about the importance of compliance with the existing hygiene legislation.

6.24 There might still however be a minimal cost associated with familiarisation for those food businesses that do not already recognise the benefits of voluntarily taking action to comply with the hygiene legislation. As there would be no new requirements for industry to follow, there would be no adaptation costs.

6.25 On this basis we envisage a small one-off cost to industry for reading and familiarising themselves with the new guidance. It is estimated that it will take 15 minutes per business to read and familiarise themselves with the new arrangements and a further 15 minutes disseminating to key staff<sup>9</sup>. This means a total of 30 minutes

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<sup>9</sup> While we recognise that dissemination of information will result in an opportunity cost in terms of time of key staff members we anticipate that this will be minimal and the additional hour will cover these costs.

for familiarising. There are currently 13,225 food businesses operating in Scotland directly affected by the proposal. Table 2 above displays the number of businesses affected in the UK broken down by location.

6.26 We assume that one official per business will be required to familiarise himself/herself with the new guidance. We further assume that the official will be a Business Manager. To quantify the one-off familiarisation cost to industry we calculate the familiarisation cost per business by multiplying the hourly wage rate of a 'business manager' of £26.10<sup>10</sup> by the 30 minutes taken to understand the new charging arrangements, resulting in a familiarisation cost per business of £13.05<sup>11</sup>. To quantify the overall one-off familiarisation cost to industry we multiply the familiarisation cost per firm by the number of businesses affected by the regulation. The one off familiarisation cost to industry in Scotland is £172,613. Table 3 displays the familiarisation cost to industry broken down by location.

**Table 3 – Option 2 - Familiarisation Costs to Industry by Location and Business Size**

	Micro	Small	Medium	Large	Total
England	£1,450,026	£248,770	£25,983	£6,373	£1,731,152
Wales	£87,132	£14,949	£1,561	£383	£104,024
<b>Scotland</b>	<b>£144,582</b>	<b>£24,805</b>	<b>£2,591</b>	<b>£635</b>	<b>£172,613</b>
NI	£55,428	£9,509	£993	£244	£66,174
<b>UK</b>	<b>£1,737,167</b>	<b>£298,033</b>	<b>£31,128</b>	<b>£7,635</b>	<b>£2,073,963</b>

Note: Totals may not sum due to rounding

### Equivalent Annual Net Costs (EANC)

6.27 In order for 'one-off' familiarisation costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula<sup>12</sup>. Under Standard HMT Green book guidance a discount rate of 3.5% is used.

6.28 A total one-off familiarisation cost to industry in Scotland affected by this proposal is an estimated £172,613. This yields an EANC for of approximately £20,053 in the Scotland over 10 years. Table 4 displays the breakdown of the EANC by location.

<sup>10</sup> Wage rate obtained from The Annual Survey of Household Earnings (2011) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of a production manager (£20.08 which has been up-rated by 30% to cover overheads: £20.08 \* 1.3 = £26.10

<sup>11</sup> 26.10\*0.5=13.05

<sup>12</sup>

EANCB = PVNCB/a<sub>tr</sub>, Where a<sub>tr</sub> is the annuity rate given by:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left( \frac{1}{1+r_i} \right)$$

PVNCB is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

**Table 4 – Option 2 - Equivalent Annual Net Costs to Industry by location**

Country	England	Wales	Scotland	NI	UK
Total Familiarisation cost	£1,731,152	£104,024	£172,613	£66,174	£2,073,963
<b>EANC</b>	<b>£201,117</b>	<b>£12,085</b>	<b>£20,053</b>	<b>£7,688</b>	<b>£240,943</b>

### **Costs to enforcement authorities**

6.29 Under Option 2, the FSA would look to identify whether new guidance or amendments to existing guidance might be developed to assist authorised officers using the existing enforcement sanctions (HEPNs and HINs) to secure compliance.

6.30 The FSA has already developed the Food Law Practice Guidance which sets out how the enforcement tools should be used. We have not identified any amendments that would enable proportionate and effective action to be taken in all cases for the kind of issues set out in paragraph 3.8 above.

### **Option 3: Extend Remedial Action Notices (RANs) to establishments not subject to approval**

#### Industry

6.31 The FSA believes that this proposal places no new burdens on compliant businesses. Costs from this option will fall only on businesses that are not complying with the hygiene legislation to a degree that requires immediate intervention by an authorised officer. There are no new requirements for businesses to familiarise themselves with, as the legislative requirements and associated offences remain unchanged. Only businesses that breach the existing hygiene legislation requirements and do not take voluntary corrective action will require to familiarise themselves with RANs. Such costs could be justified since any FBO that is non-compliant should be taking action to rectify the non-compliance. The purpose of the RAN is solely to ensure that this corrective action takes place.

#### Enforcement Authorities

##### Familiarisation costs

6.32 There will be a small one-off cost to enforcement authorities for reading and familiarising themselves with RANs, but this will only apply to officers working in local authorities (LAs) who deal only with establishments not subject to approval – i.e., those officers not already familiar with RANs from their use in approved establishments. As RANs are already available for use in approved establishments, there are no associated costs for the FSA or DARD.

6.33 It is expected that one Environmental Health Officer (EHO) from each LA will be required to read the Regulations and disseminate the information to staff. The amendment to the text of the Regulations is not extensive and we estimate that an officer already familiar with the service of RANs will invest 30 minutes reading and familiarising themselves with the Regulations and revisions to the Food Law Code of Practice and Practice Guidance, and a further one hour disseminating to other



authorised officers in the organisation<sup>13</sup>. This means a total of 90 minutes for familiarisation.

6.34 The familiarisation cost per enforcement authority is calculated by multiplying the familiarisation time, 90 minutes, by the average hourly wage rate applied to an Environmental Health Officer of £20.70<sup>14</sup>, generating a familiarisation cost per enforcement authority of £31.04<sup>15</sup>. To quantify the overall familiarisation cost to enforcement authorities we multiply the familiarisation cost per LA by the number of LAs in the UK.

6.35 There are 32 Local authorities in the Scotland with responsibility for the enforcement of food hygiene legislation who will need to familiarise themselves with this guidance. Table 5 displays the number of Local authorities across the UK.

**Table 5 Local Authorities (LAs) by Location**

Country	England	Wales	Scotland	NI	UK
Local Authorities	354	22	32	26	434

The total one-off familiarisation cost for enforcement authorities in Scotland is £982.00. Table 6 displays the familiarisation costs to Local Authorities across the UK

**Table 6 Option 3 - Familiarisation cost to Local Authorities (including Port Health Authorities) in the UK.**

Country	England	Wales	Scotland	NI	UK
Local Authorities	£10,865	£675	£982	£798	£13,351

Notes: Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 decimal places and when grossed may result in a rounding error.

Equivalent Annual Net Costs (EANC)

6.36 In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula<sup>16</sup>. Under Standard HMT Green book guidance a discount rate of 3.5% is used.

6.37 A total one-off cost to enforcement authorities affected in the Scotland by this proposal is an estimated £982.00. This yields a total EANC in Scotland of

<sup>13</sup> While we recognise that dissemination of information will result in an opportunity cost in terms of time of key staff members we anticipate that this will be minimal and the additional hour will cover these costs.

<sup>14</sup> Wage rate obtained from the Annual Survey of Household Earnings (2009) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of a 'Environmental health officer' is used, £15.92, plus 30% overheads totalling £20.70.

<sup>15</sup> 1.5 hours \* £20.70 = £31.04

<sup>16</sup>

EANCB = PVNCB/a<sub>tr</sub>, Where a<sub>tr</sub> is the annuity rate given by:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left( \frac{1}{1+r_i} \right)$$

PVNCB is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

approximately £114.00 and the breakdown of the EANC across the UK is given in Table 7.

**Table 7 – Equivalent Annual Net Cost (EANC) for Enforcement Authorities by Location**

Country	England	Wales	Scotland	NI	UK
<b>EANC</b>	<b>£1,262</b>	<b>£78</b>	<b>£114</b>	<b>£93</b>	<b>£1,548</b>

Note: Totals may not sum due to rounding

## 7. Compensation Clause Costs

7.1 In the event that a business wishes to challenge a RAN, the Regulations provide an appeal mechanism. Appeals are heard by a Sheriff in Scotland. If the appeal upholds the business’s complaint, the RAN is lifted.

7.2 At present, where RANs are available in approved establishments, the FBO would need to take further action to acquire compensation if the Court upheld the appeal. The introduction of a compensation clause under option 3 will allow for compensation for costs to be granted to the business at the appeal hearing. If the appeal is upheld compensation will be available for both approved and unapproved establishments; imposing a potential incremental cost to enforcement authorities.

7.3 However, from information gathered from all Scottish Local Authorities, the FSA in Scotland has established that, since their introduction in approved establishments there have been no appeals against RANS issued by Scottish Local Authorities. In addition, neither of the two RANS appealed, which were served by the former MHS /FSA, identified in table 8 below originate from approved Scottish meat plants. It is therefore difficult to quantify any projected future compensation costs for enforcement bodies in Scotland, since there is no data available for Scotland to draw on.

7.4 As part of the Westminster UK Impact assessment the FSA has attempted to obtain an estimate of potential costs associated with this compensation clause on a UK-wide basis. This has been done by extrapolating data which is based only on enforcement activity in England and it may not therefore be appropriate to the Scottish situation. It has been included in this impact assessment principally as a best guess at possible costs should any future appeals occur. The approach adopted has been to consider an estimate of the proportion of RANs that might be expected to be appealed in non-approved, the proportion of those appeals that are successful; as well as the average cost of compensation for those appeals that are upheld. This data has then been extrapolated proportionately to estimate the number of future RANS served and appealed for the industry sector as a whole including both approved and non-approved establishments.

7.5 The FSA’s UK surveys of RANs issued by Local Authority, DARD and MHS/FSA in 2006 and 2009 (see Table 1) looked at data from 377 RANs, none of which had been appealed. These surveys considered information from all 10,000 approved establishments. The data from Local Authorities was gathered through a survey, based on information on the Agency’s LAEMs database on enforcement activities. The LAEMs database does not collate information on appeals or compensation, which is why surveys needed to be carried out to gather this data.

7.6 FSA historical time series data for MHS/FSA supervised establishments also shows that there is little evidence that RANs are issued when there is no breach of the legislation. This data, which relates to the FSA’s own enforcement activities in 1000 approved establishments, has been considered back to 2003/04, and includes data on appeals. Since 2003, 2,193 RANs (or Regulation 10 Notices, as they were known before 2006) have been issued, out of which only two have been appealed. Also the number of RANs issued has fallen quite significantly over the last eight years due in part to the move to escalated enforcement action instead of issuing multiple Notices. This is presented in Table 8 below.

**Table 8: Regulation 10 Notices / RANs issued in Great Britain by the FSA**

Financial Year	RANs	
	Issued	Appealed
2003/04	580	0
2004/05	670	1
2005/06	345	0
2006/07	300	0
2007/08	165	0
2008/09	36	0
2009/10	73	0
2010/11	97	1
<b>Total</b>	<b>2,193</b>	<b>2</b>

Source: FSA Historical Data

*Estimating number of appeals*

7.7 To obtain a lower bound estimate of the number of appeals for approved and non-approved FBOs, we use data from the Inter Departmental Business Register (IDBR 2011) and data on the number of RANs issued and appealed. According to the IDBR there are 158,900 food establishments in the UK, of which 10,000 of these require approval. We therefore estimate that there are approximately 148,900 food establishments in the non-approved sector. The decline in use since 2006/07 was partly due to the MHS moving to escalated enforcement action against establishments as appropriate under the hierarchy of enforcement action, instead of issuing multiple Notices, and we envisage the number of RANs being issued is now at a stage where it is beginning to level out. On this basis and for the purpose of obtaining consistent and robust estimates, we therefore base our analysis on the last two years of data (2009/10 - 2010/11).

7.8 Based on these two years of data, we estimate that approximately 8.5%<sup>17</sup> of approved FBOs would be issued with a RAN, of which 0.6%<sup>18</sup> would be subject to appeal per annum. Assuming a similar percentage of non-approved FBOs are likely to be issued with a RAN and attempt to appeal one; we estimate that approximately 12,660 RANs would be issued to non-approved FBOs. This is calculated by multiplying the proportion of approved FBOs issued with a RAN (8.5%) by the number of non-approved FBOs (148,900). We then estimate that of the 12,660 RANs issued to non-approved FBOs, that approximately 76 will be subject to appeal. This is calculated by

<sup>17</sup>  $(73 \text{ (RANs Issued 2009/10)} + 97 \text{ (RANs Issued 2010/11)}) / 2 / 1000 \text{ (approved FBOs – survey sample)} = 85 / 1000 = 8.5\%$

<sup>18</sup>  $(0 \text{ appeals (2009/10)} + 1 \text{ appeal (2010/11)}) / 2 / (73 \text{ (RANs Issued 2009/10)} + 97 \text{ (RANs Issued 2010/11)}) / 2 = (0.5 / 85) * 100 = 0.6\%$

multiplying the proportion of RANs issued to approved FBOs that are likely to be appealed (0.6%) by the number of RANs issued to non-approved FBOs (12,660). In using the figures from use of Notices in FSA approved establishments to provide the basis of our analysis, we recognise that we are making an over-estimate of the number of RANs that will be issued. This is because it is not possible to provide a like-for-like comparison between approved establishments and non-approved establishments. The FSA has a permanent presence at approved establishments and will therefore issue Notices to address non-compliances more frequently than where establishments are visited as part of an inspection regime. The evidence in Table 1 supports this assumption. In both 2006 and 2009, Table 1 demonstrates that LAs issued fewer RANs, despite being responsible for a far greater number of establishments - in 2009, only 53 RANs were issued in 10,000 approved establishments.

7.9 This data on RANs is the best data we have available. The data shows us that, historically, very few RANs have been subject to appeal. To provide a sensitivity test, we use historical FSA data on Hygiene Improvement Notices (HINs)<sup>19</sup>, which we know are issued with a higher frequency, and historically have been subject to appeal more frequently. This is presented in Table 9 below.

**Table 9: HINs issued in Great Britain by the FSA**

Financial Year	HINs	
	Issued	Appealed
2003/04	1046	0
2004/05	1264	0
2005/06	587	0
2006/07	777	3
2007/08	564	1
2008/09	121	0
2009/10	186	1
2010/11	133	2
<b>Total</b>	<b>4,678</b>	<b>7</b>

Source: FSA Annual Report 2010/11

7.10 HINs require remedial work to be undertaken but allow food business operators at least 14 days to take the specified action, failing which they are guilty of an offence. If the FBO disagrees with this, the FBO may choose to appeal the HIN to a court. This makes the HIN more comparable to a RAN (which FBOs may also choose to appeal) than a HEPN (which is always considered by a court after being issued). This is why we have also included data on the number of HINs that have been appealed. As set out in paragraph 7.7 above, assumptions based on this data need to be treated with caution. Comparing HINs served by the Agency in approved establishments comparison with RANs that might be served in establishments where there is no permanent presence will provide a considerable overestimate of the number of RANs likely to be issued.

<sup>19</sup> Hygiene Improvement Notices (HINs) can be used as an enforcement tool in circumstances where the FBO refuses to take voluntary action. In contrast to RANs, they permit a minimum of 14 days for the FBO to take corrective action and therefore lack the immediate effect of RANs. Despite this fact we believe they are similar enough to RANs to provide an upper bound value, given their characteristics with regards to the frequency of appeals.

7.11 We use data on the number of HINs issued and appealed to provide upper bound estimates. Using a similar approach as per paragraph 7.7 based on the last two years of data (2009/10 – 2010/11); we estimate, on average, that approximately 23,824<sup>20</sup> RANs would be issued to non-approved FBOs, out of which approximately 223<sup>21</sup> would be subject to appeal per annum.

7.12 In all we estimate, on average, that the number of RANs that would be subject to appeal would range between 76 (lower bound) and 223 (upper bound); a best estimate of 150 appeals per annum<sup>22</sup>. FSA data shows that no RAN has so far been appealed successfully. The only successful appeal in the data is an appeal against a Regulation 10 Notice in 2005. On this basis we assume that between approximately 0.3%<sup>23</sup> and 1 %<sup>24</sup> of appeals would be successful and granted compensation; a best estimate of 0.7%. Using this best estimate (0.7%) we calculate and estimate the range of the number RANs appealed that are likely to be upheld and result in compensation. We estimate the number of successful appeals would range between 1 (lower bound)<sup>25</sup> and 2 (upper bound)<sup>26</sup>, a best estimate of 2<sup>27</sup> per annum.

### Estimating costs associated with compensation

7.13 In the case where an appeal is successful, compensation will be limited to direct costs incurred by the business arising from the issue of the RAN, in the same way that compensation is provided for under Hygiene Emergency Prohibition Notices (HEPNs<sup>28</sup>) provisions. The compensation awarded in these circumstances will vary on a case-to-case basis. The BRC have provided figures which show that closing a busy supermarket delicatessen counter would cost approximately £50,000 per week. This is likely to be at the top end of potential costs to business. However, where the food hygiene legislation had not been breached and the business was challenging the enforcement authority over it, it would be unlikely that the RAN would remain in place for a full week before it was lifted. The only successful appeal was against a Regulation 10 Notice in 2005. This appeal resulted in a cost to enforcement authorities of £21,000.

7.14 Due to uncertainty around the average cost of compensation per an appeal; we use the only data we have available to construct a range of estimates using the information set out in paragraphs 7.7. Taking £21,000<sup>29</sup> as our lower bound estimate

<sup>20</sup>  $186 \text{ (HINs Issued 2009/10)} + 133 \text{ (HINs Issued 2010/11)/} 2 / 1000 \text{ (approved FBOs – survey sample)} = (160/1000) * 148,900 \text{ (non-approved FBOs)} = 23,824$

<sup>21</sup>  $3 \text{ (appeals)} / (186 \text{ (HINs Issued 2009/10)} + 133 \text{ (HINs Issued 2010/11)/} 2) = (1.5/160) * 23,824 \text{ HINs (average annual estimate)} = 223 \text{ appeals}$

<sup>22</sup>  $76 \text{ (lower bound)} + 223 \text{ (upper bound)} / 2 = 150 \text{ (best estimate) appeals per annum}$

<sup>23</sup>  $1 \text{ successful appeal as per Regulation 10 Notice (proxy for successful appeal)} / (186 \text{ (HINs Issued 2009/10)} + 133 \text{ (HINs Issued 2010/11)}) = (1/319) * 100 = 0.3\%$

<sup>24</sup>  $1 \text{ successful appeal as per Regulation 10 Notice (proxy for successful appeal)} / (73 \text{ (RANs Issued 2009/10)} + 97 \text{ (RANs Issued 2010/11)}) = (1/170) * 100 = 0.6\% \approx 1\%$

<sup>25</sup>  $0.7\% \text{ (best estimate)} * 76 \text{ (number of appeals (lower bound))} = 0.53 \approx 1$

<sup>26</sup>  $0.7\% \text{ (best estimate)} * 223 \text{ (number of appeals (upper bound))} = 1.6 \approx 2$

<sup>27</sup>  $1 \text{ (lower bound)} + 2 \text{ (upper bound)} / 2 = 1.5 \approx 2 \text{ successful appeals (best estimate)}$

<sup>28</sup> A Hygiene Emergency Prohibition Notice is an enforcement tool that authorised officers can use to secure compliance. In contrast to RANs and HINs, HEPNs require the authorised officer to demonstrate “imminent risk of injury” to a Magistrate (Sheriff in Scotland) before the court will confirm the authorised officer’s decision.

<sup>29</sup> Regulation 10 Notice in 2005 only successful appeal - cost to enforcement authorities of £21,000 (lower bound estimate)

of the cost of compensation per an appeal; and £50,000<sup>30</sup> as our upper bound estimate; we estimate the average cost of compensation ranges between £42,000<sup>31</sup> and £100,000<sup>32</sup> per annum, a best estimate of £71,000<sup>33</sup>. This equates to a total cost of approximately £710,000 over 10 years; an annual average cost of £71,000 (see Table 10). However, these are presented as indicative estimates only, given the lack of available data, and should therefore be treated with caution.

**Table 10 – Cost of Compensation**

Cost of Compensation Clause	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total Cost	Average Annual Cost	Present Value
<b>Number of Successful Appeals</b>													
Best Estimate	2	2	2	2	2	2	2	2	2	2	N/A	N/A	N/A
<b>Compensation Costs</b>													
Upper Bound	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£1,000,000	£100,000	£860,769
Lower Bound	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£420,000	£42,000	£361,523
Best Estimate	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£710,000	£71,000	£611,146

## Total costs

7.15 The total cost associated with policy Option 3 is estimated at between £433,321 and £1,013,321 over 10 years with a best estimate of £732,321; an annual average cost of £72,332. Once these costs are discounted at a rate of 3.5% over 10 years we obtain a present value total cost of £624,467. Total one-off and on-going costs associated with option 3 are presented in table 11.

**Table 11 – Total cost of policy option 3**

Cost of Compensation	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total Cost	Average Annual Cost	Present Value
<b>One-off Cost</b>													
Familiarisation cost to Authorities*	£13,321	£0	£0	£0	£0	£0	£0	£0	£0	£0	£13,321	£1,548	£13,321
Total One-off Cost	£13,321	£0	£0	£0	£0	£0	£0	£0	£0	£0	£13,321	£1,548	£13,321
<b>Compensation Costs</b>													
Best Estimate	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£710,000	£71,000	£611,146
Upper Bound	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£1,000,000	£100,000	£860,769
Lower Bound	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£420,000	£42,000	£361,523
<b>Total Costs</b>													
Best Estimate	£84,321	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£71,000	£723,321	£72,332	£624,467
Upper Bound	£113,321	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£100,000	£1,013,321	£101,332	£874,089
Lower Bound	£55,321	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£42,000	£433,321	£43,332	£374,844

\* Average annual cost of familiarisation to Authorities is based on Equivalent Net Cost

## 8. Scottish Firms Impact Test

8.1 As part of the Scottish Government BRIA engagement process, face to face meetings were arranged with the affected Scottish business sector. FSA officials met to discuss the Regulations with a butcher, a pub owner, a fishmonger, a restaurant, two cafes owners and a training advisor to bakers. Apart from one café owner interviewed all supported the extension to RANs as a positive enforcement tool safeguarding consumers and protecting them against reputational damage.

<sup>30</sup> Based on figures from BRC, which show closing a busy supermarket deli counter would cost approximately £50,000 (upper bound estimate)

<sup>31</sup> £21,000 (lower bound compensation) \* 2 (number of successful appeals (best estimate)) = £42,000

<sup>32</sup> £50,000 (upper bound compensation) \* 2 (number of successful appeals (best estimate)) = £100,000

<sup>33</sup> £42,000 (lower bound compensation) + £100,000 (upper bound compensation) / 2 = £71,000 (best estimate)



- 8.2 The butcher stressed that the current enforcement tools take too long and considered that the HINs were not as effective as the RANs which would lead to immediate change. The training advisor also agreed that the RANs would be a better enforcement tool than the HIN and the HEPN which would not require Court action and therefore would reduce the costs to businesses. The butcher considered extending RANs to all businesses would make the system fairer for the compliant businesses (as they will no longer compete with businesses which are cutting costs by cutting corners with regards to hygiene).
- 8.3 There was general agreement that the RANs would benefit consumers and only affect those few businesses that were non –compliant. Two (cafés) expressed concerns that the enforcement authorities might use the RANs indiscriminately which would have an impact on even the compliant businesses. One café was against the extension of RANs and considered it as an additional legislative burden and that food businesses with poor hygiene practices should be dealt at a Community level, by another means.

## **9. Competition Assessment**

- 9.1 Using the Office of Fair Trading (OFT) competition assessment framework it has been established that the preferred policy option is option 3 and is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

## **10. Test Run of Business Forms**

- 10.1 No new business forms will be introduced by the extension of RANs to all food businesses.

## **11. Sustainability**

- 11.1 In our view there is no indication at this time of an impact of this policy on sustainability issues.

## **12. Legal Aid Impact Test**

- 12.1 The amendments to the Regulations do not introduce new criminal sanctions or civil penalties; therefore, there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the amendments.

## **13. Enforcement, Sanctions, and Monitoring**

### **Enforcement**

- 13.1 Enforcement of the Regulations is primarily for Local Authorities as defined by the Food Safety Act 1990 and designated in our Regulations. Whilst the making of legislation in Scotland is the function of the Scottish Government, the enforcement of food is primarily (but not solely) the responsibility of the 32 LAs in Scotland. The extension of RANs to non-approved premises will primarily affect the local authorities, since they carry out enforcement functions in these premises. The new

compensation clause applies to all premises and will therefore affect both the FSA and local authorities.

13.2 No changes to the existing penalties are being proposed to those contained in the current Regulations. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990. Details of the sanctions currently available to Authorised Officers and sanctions imposed by the Court are provided for information in Annex 2.

### Monitoring

13.3 The extension of the Remedial Action Notices will be achieved through the introduction of the SSIs amending the Food Hygiene Regulations 2006 in Scotland. Monitoring data for Local Authority enforcement is gathered annually via the Local Authority Enforcement Monitoring Scheme (LAEMS). Local Authorities use the LAEMS system to upload data from enforcement activities. The data is then analysed by the FSA before being published on the Agency's website. More information on LAEMS and annual returns can be found at: <http://www.food.gov.uk/enforcement/auditandmonitoring/>

13.4 The FSA will work with enforcement authorities where problems arise. The effectiveness of the proposed Regulations will also be monitored via feedback from stakeholders as part of the ongoing policy process. The FSA shall continue to regularly communicate with industry to ensure that no unforeseen difficulties arise from the proposed Regulations, which will be reviewed one year after implementation. The FSA carry's out a formal audit function of the local authorities which includes scrutiny of application of formal notice procedures and adherence to the Food Law Code of Practice.

## **14. Implementation and Delivery Plan**

14.1 The Food Hygiene (Scotland) Amendment Regulations 2012 will come into force by the 1 April 2012.

14.2 The publication of the Food Hygiene (Scotland) Amendment Regulations 2012 will be communicated to stakeholders by email, letter and the monthly Enforcement Report. This will be done shortly after publication on legislation.gov.uk website.

14.3 The Food Safety Act Code of Practice and associated practice guidance will be amended shortly after the legislation is introduced to provide additional guidance on the use of RANs to ensure consistent and proportionate application.

14.4 The FSA will work with enforcement authorities where problems arise or suspected infringements of the instrument arise.

## **15. Post Implementation Review**



- 15.1 It is anticipated that the Food Hygiene (Scotland) Amendment Regulations 2012 will be reviewed not less than five years after 1 April 2012 (i.e. the date from which the Food Hygiene Amendment Regulation applies in Scotland).
- 15.2 The review will aim to assess whether the Remedial Action Notices are being applied appropriately and whether they are having a positive effect in improving business standards. The review will look at how RANs are used in all types of food establishments and that no burdens are being placed on compliant businesses.
- 15.3 The FSA will gather data on the number of RANs (other enforcement tools) issued and survey enforcement authorities for data on the number of appeals that have taken place and whether and why such appeals were successful. FSA will continue to consult formally with industry, consumers and enforcement groups to assess the impact and gather views on the extension in a qualitative manner. We will review how the compensation clause has worked in practice and whether this indicates any issues with certain sectors.

## 16. Summary and Recommendation

- 16.1 The existing Food Hygiene Regulations in Scotland, Wales, Northern Ireland and England restrict the use of (RANs) to establishments subject to approval under EC Regulation 853/2004. This means that they can only be used in certain establishments producing or handling products of animal origin, such as slaughterhouses, cutting plants and fishery product plants.
- 16.2 The extension of RANs to the unapproved sector is considered necessary to close a gap in the current enforcement powers, provide for consistent and proportionate enforcement for all food businesses, strengthen consumer protection and protect businesses from reputational damage. This is because there are certain breaches of the hygiene legislation where the current enforcement powers may be overly bureaucratic or disproportionate, or provide too long a time-limit to rectify the non-compliance which may present a risk to public health. In some situations where a Food Business Operator refuses to take voluntary action to rectify a non-compliance, a RAN provides a more effective, timely and proportionate enforcement tool for achieving compliance than the alternative enforcement tools that exist.
- 16.3 The FSA recommends Option 3 which will extend RANs to establishments not subject to approval, which will provide consistent enforcement powers across all food businesses, a strengthened process to address breaches of the hygiene legislation, and introduce a compensation clause to protect redress from potential misuse.

## 17. Summary Costs and Benefits Table

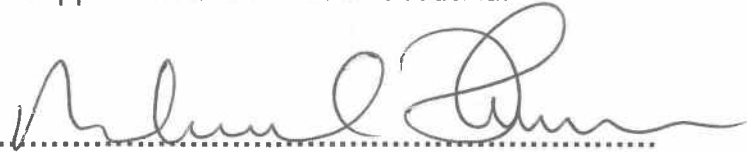
Option	Benefit	Cost
1 Do nothing	No incremental benefits	Enforcement Authorities would continue to use existing enforcement tools to

	<p>Continue to use existing enforcement tools</p>	<p>require compliance with the hygiene legislation. These might be inappropriate or overly bureaucratic.</p> <p>Consumers would be exposed to the risk of significant non-compliance in businesses not covered by the RANS procedure.</p>
<p><b>2 Issue new or revise guidance to food businesses and enforcement</b></p>	<p>Limited benefits to consumer safety</p> <p>Continue to use existing enforcement tools</p> <p>Guidance is already available, does not guarantee corrective action being taken by food business</p> <p>No legislation/regulation required</p> <p>No new requirements for industry</p> <p>Revise or reissue new guidance seeks to influences and helps to change behaviour make non compliances less likely</p>	<p>Small cost for industry to familiarise themselves with new guidance.</p> <p>Minimal costs for food business operators, associated with familiarisation of the benefits of voluntarily taking action</p> <p>Non compliances still arise when FBO not take voluntary action to correct non compliance</p> <p>Cost to enforcement in Scotland as they do not have proportionate and appropriate powers to take action</p> <p>Unlikely to improve standards and would not meet policy objectives</p> <p>Public safety affected</p>

<p><b>3 Extend the RANs to all establishments</b></p>	<p>Extend the RANs to all establishments not subject to approval</p> <p>No new burdens on already compliant food businesses</p> <p>Strengthen process to address breaches of hygiene legislation</p> <p>Introduce compensation clause to protect industry and improved protection against reputational damage from recalcitrant businesses.</p> <p>Greater public health protection</p> <p>Minimise costs and times associated with reports to Procurator Fiscals and courts for EPN's and offences for non compliance with the Hygiene Regulations</p>	<p>No costs for legally compliant businesses. Costs to food business, that <b>do not</b> comply and do not take voluntary corrective action to comply and costs incurred are to rectify a non compliance</p> <p>Cost to Enforcement authorities who would have to intervene immediately if there is no compliance and familiarisation costs for officers who work in LA and only deal with establishments not subject to approval.</p> <p>Compensation Clause – Potential costs to enforcement authorities in the event that an appeal is successful. Based on the experience in the approved sector this is anticipated to be extremely rare and will only apply in cases of mis-application of RANS by enforcement officers.</p>
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**18. Declaration and Publication**

I have read the Business and Regulatory Impact Assessment and I am satisfied that, (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy and (b) that the benefits justify the costs I am satisfied that the business impact has been assessed with the support of businesses in Scotland.

Minister's Signature 

Ministers Title *Minister for Public Health*

Date.....29/2/12.....

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**Annex 1: Details of sanctions currently available**

Authorised officers of enforcement authorities (including the FSA) have a variety of enforcement tools available to them ranging from informal oral advice to prosecution, a number of other sanctions may be imposed by a court.

Sanctions available to Authorised Officers

- Hygiene Improvement Notices: these enable authorised officers to issue notices requiring remedial works to be undertaken but allow food business operators at least 14 days to take specified remedial action, failing which they are guilty of an offence.
- Remedial Action Notices: these permit authorised officers of enforcement authorities to require food business operators running establishments subject to approval to remedy contraventions. They have immediate effect, stopping or reducing an activity until compliance is regained.
- Hygiene Emergency Prohibition Notices : these enable authorised officers to impose an immediate appropriate prohibition on a food business, including closure, where there is imminent risk of injury to health.
- Detention Notices: these enable authorised officers of enforcement authorities to detain animals or food at premises for the purposes of examination.

Sanctions imposed by a Court

- Hygiene Prohibition Orders:
  - (1) where a food business operator is convicted of an offence under the Food Hygiene Regulations 2006, the Court must — if it is satisfied that the construction, state or condition of premises used for the purposes of the business or the use of any process, equipment or treatment for the purposes of the business involves a risk of injury to health — make an order prohibiting the use of the process, premises, equipment or treatment concerned.

- (2) where a food business operator is convicted of an offence under the Food Hygiene Regulations 2006, the Court may prohibit him from being involved in the management of a food business.
- Post-conviction confiscation under the Proceeds of Crime Act 2002: the Court can make a confiscation order where it concludes that the offender has benefited from –
  1. A general criminal lifestyle ; or
  2. Particular criminal conduct.

The Court can order that the offender pay a recoverable amount, representing the benefit of what he has obtained from criminal conduct. Confiscation orders are only available following conviction before the Crown Court or where a magistrates' court commits the offender for sentence to the Crown Court. The usual means of enforcing the order is to treat the value of the order as a fine. Failure to satisfy the order will result in an additional mandatory prison sentence.

## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

### The Food Hygiene (Scotland) (Amendment) Regulations 2012

To provide for the enforcement, in Scotland, of a national measure that lays down the format of an identification mark for animals slaughtered outside of an approved slaughterhouse.

**File No:** SPARD/FSAS  
**Date:** February 2012  
**Stage:** Final  
**Source of intervention:** EU  
**Contact for enquiries:** Karen Robertson  
**Phone No:** 01224 288362  
**Email:** [karen.robertson@foodstandards.gsi.gov.uk](mailto:karen.robertson@foodstandards.gsi.gov.uk)

## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### **1. Title of Proposal**

- 1.1 The Food Hygiene (Scotland) (Amendment) Regulations 2012.
- 1.2 The above instrument provides for the enforcement of a range of EC measures and implements a national measure. *This BRIA only relates to the national measure concerning a special health and identification mark.*

### **2. Purpose and Intended Effect**

#### Objectives

- 2.1 The objective is to implement, in Scotland, a national measure under Article 10 of Regulation (EC) No. 853/2004 to provide a statutory basis for the format of the special health mark required to be applied to carcasses of animals that have undergone emergency slaughter outside the slaughterhouse, and the identification mark on packages of minced meat, meat preparations, mechanically separated meat and meat products produced from such carcasses.
- 2.2 This will enable the identification of carcasses subject to emergency slaughter outside a slaughterhouse so the meat and products derived from such carcasses can be distinguished from other meat and ensure that they are restricted to the national (UK) market in accordance with EU legislation. It will also inform processors and consumers on the source of such meat, which may be perceived to be of lower quality.

#### Background

- 2.3 New food hygiene rules contained in Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004 and Regulation (EC) No. 854/2004 came into force on 1 January 2006. These lay down hygiene requirements for all food businesses, additional hygiene requirements for food businesses dealing in products of animal origin and rules for the organisation of official controls on products of animal origin for human consumption respectively.
- 2.4 Annex III, Section I, Chapter VI of Regulation (EC) No. 853/2004 sets out the requirements relating to emergency slaughter of animals outside the slaughterhouse. The slaughter of an animal outside the slaughterhouse is restricted to an otherwise healthy animal which has suffered an accident that prevented its transport to the slaughterhouse

for welfare reasons. A veterinarian must carry out an ante-mortem inspection of the animal prior to slaughter. The slaughtered and bled animal must then be transported hygienically to the slaughterhouse without undue delay.

- 2.5 Point 9 of Chapter VI requires that food business operators may not place meat from animals having undergone emergency slaughter on the market unless it bears a special health mark which cannot be confused with the health mark provided for in Regulation (EC) No. 854/2004 or with an identification mark provided for in Annex II, Section I to Regulation (EC) No. 853/2004. It also requires that such meat may be placed on the market only in the Member State where slaughter took place and in accordance with national law.
- 2.6 Ensuring that carcasses are correctly health marked is important to provide information about the source of the meat. The meat from such animals will be considered fit for human consumption as the health mark is only applied to carcasses that have received a satisfactory post mortem inspection. During negotiations on Regulation (EC) 853/2004 some Member States considered that slaughter outside a slaughterhouse as a result of an accident that prevents transport of the animal to the slaughterhouse may result in meat of a lower standard. The UK view – that official controls are such that there is only one standard of meat for human consumption – did not prevail and it was argued successfully by a number of member states that the meat should be marked differently and restricted to the national market. The requirements for emergency slaughter introduced by Regulation (EC) 853/2004 are much more restrictive than applied previously to what were termed ‘casualty’ animals. The impact of these new requirements has already been assessed; they were implemented in January 2006.
- 2.7 The format of the special health mark to be used has already been determined by the Agency and was included in its Guide to Food Hygiene and other Regulations for the UK Meat Industry (MIG) issued in December 2006 to food business operators (FBOs) at abattoirs and cutting plants. The Guide provides advice on what FBOs should do to comply with the requirements of the EU Regulations. The format that is required is a square mark containing in legible form the letters “UK” in the upper part, the approval number of the premises in the centre and the letter “N” in the lower part. This format is the same format as a ‘national’ mark used under previous legislation for a similar purpose, thus keeping costs to business to a minimum.

#### Rationale for Government intervention

- 2.8 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Consumers are not usually able to observe this, and it is difficult for food business operators to credibly inform consumers how far food safety risks have been



minimised. Government intervention is necessary to address this information asymmetry.

- 2.9 In this case, a health mark is applied to the carcasses of animals to show that they have passed official controls. Normally, only meat from animals slaughtered in approved slaughterhouses, and which have passed official controls, may bear the mark and be placed on the market. However, under special circumstances animals may be slaughtered outside a slaughterhouse and their meat placed on the market. There is a need, therefore, to lay down the format of the special mark in such circumstances. This is in accordance with the Scottish Government's national performance framework target to ensure that we live longer and healthier lives.

### Devolution

- 2.10 The proposed regulations will apply in Scotland only. England, Wales and Northern Ireland will make separate legislation.

## **3. Consultation**

### Public Consultation

- 3.1 The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 Stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

### Within Government

- 3.2 Scottish Government officials from the Rural and Environment Directorate Animal Health and Welfare Division were consulted as part of the above-mentioned public consultation as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

### With Business

- 3.3 This assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. Face to face engagement with Scottish business was therefore not carried out during the development process. However, 255 Stakeholders including Scottish small to medium enterprises were consulted on the proposed enforcement measures. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

## 4. Options

4.1 The options considered to implement the hygiene requirements of Regulation (EC) No. 853/2004 in Scotland are:

- i. Option 1 - Do nothing;
- ii. Option 2 - Amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of this national measure concerning a special health and identification mark.

4.2 Option 2 is the preferred option.

### Sectors and Groups affected

4.3 Cattle are the most common species to be subject to emergency slaughter. It also occurs with other red meat species, such as sheep and pigs, but to a much lesser extent because of their lower individual value. The sectors of the meat industry that would be affected are red meat slaughterhouses, red meat cutting plants and meat processing plants producing meat products, meat preparations, minced meat and MSM.

### Benefits

#### **Option 1 – Do nothing**

4.4 Doing nothing maintains the current position and we are not aware of any benefits associated with Option 1.

#### **Option 2 - Amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of this national measure concerning a special health and identification mark.**

4.5 The application of the mark will lead to greater market transparency, as meat slaughtered outside of a slaughterhouse and derived products will be marked as such. It will also inform processors and consumers on the source of such meat, which may be perceived to be of lower quality, and restrict it to the national market.

4.6 We understand that a fairly significant proportion of the carcasses from emergency slaughtered animals are supplied directly to local (unapproved) butchers rather than to cutting plants, in which case no identification mark would need to be applied (as this is only a requirement for meat supplied from approved premises).

## Costs

- 4.7 Option 1 – Doing nothing maintains the current position and we are not aware of any benefits associated with Option 1.

## Option 2

- 4.8 There is likely to be minimal costs to the Food Standards Agency Operations Group (FSAOG)<sup>1</sup> providing new health stamps as they will already own such stamps (as they were required under the previous legislation). If new marks are required they can be ordered at a cost of approximately £33 each. For illustration, the total costs that would be faced by FSAOG if half of the 38 affected plants were to require a new stamp (at the price of £33 each) would be £627.
- 4.9 Specially marked carcasses that are supplied to small and medium sized cutting plants would require those businesses to place the special mark on the outside of packaged meat. The special identification mark would also need to be applied to the labelling of meat products, meat preparations, minced meat and mechanically separated meat (MRM) when these are derived from specially marked carcasses or packaged meat.
- 4.10 These requirements are likely to impose some costs to businesses of re-printing packaging and labelling, but they should be minimal given the small number of affected carcasses (311 carcasses between January 2006 and September 2007). Some cutting plants may already have supplies of packaging containing the special mark, as this was also required under previous legislation.
- 4.11 The identification of meat from emergency slaughter animals and the restrictions on its use may result in a decrease in its value and may result in fewer slaughterhouses being ready to accept such animals and fewer businesses being willing to process such meat.
- 4.12 We understand that a number of slaughterhouses do not take the carcasses of animals that have been subject to emergency slaughter outside the slaughterhouse, particularly the larger businesses, as they are geared up to handle large numbers of live animals. This is usually for commercial reasons.
- 4.13 The Agency sought information on costs, arising from option 2, from stakeholders as part of the full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. However, no responses were received indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

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<sup>1</sup> The executive agency status of the MHS was dissolved on 31 March 2010 and, as of 1 April 2010, its functions and staff were formally integrated into the FSA.

## **5. Scottish Firms Impact Test**

- 5.1 Slaughterhouses in rural areas are integral to the rural economy. Farmers with a small number of animals to slaughter want to be able to take them to a local slaughterhouse, as it may not be economical to transport the animals further to a larger slaughterhouse. Given the relatively small number of emergency slaughtered animals in Scotland, many of which are sold direct to local butchers, and the fact that the proposed national measure is not a completely new requirement, the impact on rural slaughterhouses is expected to be minimal.
- 5.2 Face to face engagement with Scottish business was not carried out during the development process as this assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. However, as previously stated, 255 Stakeholders including Scottish small to medium enterprises were consulted on the proposed enforcement measures with no responses received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

### Competition Assessment

- 5.3 Using the Office of Fair Trading (OFT) competition assessment Framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

### Test Run of Business Forms

- 5.4 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

## **6. Legal Aid Impact Test**

- 6.1 The amending regulations do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

## **7. Enforcement, Sanctions and Monitoring**

- 7.1 The application of the health mark in slaughterhouses is an activity that must be supervised by an Official Veterinarian (OV) appointed by the

Food Standards Agency Operations Group (FSAOG).<sup>2</sup> The FSAOG will be responsible in Scotland and elsewhere in GB for enforcement; sanctions and monitoring for meat hygiene requirements set out in the Regulations. Local Authorities will also have a role in enforcing the special identification mark on relevant product labels further down the food chain in establishments engaged in further processing.

7.2 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006.

7.3 The effectiveness and impact of the 2012 amending regulations will be monitored via feedback from stakeholders, as part of the ongoing policy process.

## 8. Implementation and Delivery Plan

8.1 The coming into force of The Food Hygiene (Scotland) Amendment Regulations 2012 will be communicated to stakeholders by email, letter and via the Agency's website.

### Post-Implementation Review

8.2 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in October 2013.

8.3 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## 9. Summary and Recommendation

9.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of this national measure concerning a special health and identification mark.

### 9.2 Summary Costs and Benefits Table


Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social  - Policy and Administrative
1. Do Nothing	No benefits have been identified.	No costs have been identified.
2. Amend the Food Hygiene (Scotland) Regulations 2006 to provide for the	The application of the mark will lead to greater market transparency, as meat	Minimal costs to Enforcement providing new health stamps as they will already own such stamps.

<sup>2</sup> The executive agency status of the MHS will be dissolved on 31 March 2010 and, as of 1 April 2010, its functions and staff will be formally integrated into the FSA.

<p><b>enforcement of this national measure concerning a special health and identification mark.</b></p>	<p>slaughtered outside of a slaughterhouse and derived products will be marked as such. It will also inform processors and consumers on the source of such meat, which may be perceived to be of lower quality, and restrict it to the national market.</p>	<p>Some costs to industry of pre-packaging and labelling, but this should be minimal given the small number of affected carcasses.</p> <p>Economic/ social/ environmental cost- negligible.</p>
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**10. Declaration and publication**

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature..... 

Ministers Title..... Minister for Public Health

Date..... 29/2/12

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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

### **The Food Hygiene (Scotland) Amendment Regulations 2012**

**To provide for the enforcement, in Scotland, of Commission Regulation (EC) No. 1021/2008 amending Annex I to Regulation (EC) No. 854/2004 and Regulation (EC) No. 2076/2005**

<b>File No:</b>	SPARD/FSAS
<b>Date:</b>	February 2012
<b>Stage:</b>	Final
<b>Source of intervention:</b>	EU
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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### **1. Title of Proposal**

1.1 The Food Hygiene (Scotland) Amendment Regulations 2012.

### **2. Purpose and Intended Effect**

#### Objectives

- 2.1 To provide for the enforcement, in Scotland, of Regulation (EC) No. 1021/2008, amending Annexes I, II and III to Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, and Regulation (EC) No. 2076/2005 as regards live bivalve molluscs, certain fishery products and staff assisting with official controls in slaughterhouses. *This BRIA concerns only those amendments to Part A of Chapter III of Section III of Annex I to Regulation 854/2004 and Regulation 2076/2005 relating to staff assisting with official controls in poultry and rabbit slaughterhouses. Separate BRIAs have been prepared for the other amendments to Regulations 854/2004 and 2076/2005 resulting from Regulation 1021/2008.*
- 2.2 Regulation (EC) No. 1021/2008 makes permanent the exemption provided for by Regulation (EC) No. 2076/2005 which allows slaughterhouse staff to be trained to the satisfaction of the designated Competent Authority, (the Food Standards Agency (FSA)), to carry out official control duties in poultry and rabbit slaughterhouses without the requirement to pass the same examination as official auxiliaries.
- 2.3 The objective is to maintain sufficient official controls in slaughterhouses to ensure that public health is protected, while minimising the burden on food business operators (FBOs) and the FSA.

#### Background

- 2.4 Regulation (EC) No. 854/2004 applied on 1 January 2006 setting out specific rules for the organisation of official controls on products of animal origin intended for human consumption. Together with Regulation (EC) No. 852/2004 and Regulation (EC) No. 853/2004 (hygiene rules applicable to all foodstuffs and specific hygiene rules for food of animal origin respectively), these formed part of a new package of hygiene measures which consolidated the previous legislation.



- 2.5 Regulation (EC) No. 854/2004 made it the responsibility of the Competent Authority (in Scotland, the FSA) to ensure sufficient official controls are in place in slaughterhouses to protect public health.
- 2.6 An exemption in the EU Food Hygiene Regulations provided by Article 14 of Regulation (EC) No. 2076/2005 allowed slaughterhouse staff to carry out limited official control duties in poultry and rabbit slaughterhouses without the requirement to pass the same examination as official auxiliaries. This exemption allowed the continuation of the practice pre-2006 which had permitted slaughterhouse staff to carry out post-mortem checks of poultry and rabbit meat under the supervision of the Official Veterinarian (OV) on a voluntary basis, if they were of a standard acceptable to the FSA. This exemption was welcomed by businesses.
- 2.7 The four year exemption provided by Regulation (EC) No. 2076/2005 expired on 31 December 2009. However, agreement was reached in negotiations in Commission Working Groups that the use of PIAs to undertake certain official controls in poultry and rabbit slaughterhouses did not lead to a lowering of public health protection. Therefore, the introduction of EC Regulation No. 1021/2008 effectively makes the exemption permanent.
- 2.8 Before a slaughterhouse can use their own staff to carry out limited official controls, they must meet FSA requirements in the following areas:
- a) Production and inspection records;
  - b) Type of activities undertaken in the establishment which includes livestock production, HACCP procedures, animal welfare and legislation;
  - c) History of compliance with the rules; and,
  - d) Expertise, professional attitude and sense of responsibility of the slaughterhouse staff with regard to food safety.

### Rationale for Government intervention

- 2.9 Consumers and food manufacturers need to be confident that meat is of the nature, substance and quality that they wish to buy, but they cannot assess this fully from its appearance when it is offered for sale. Government intervention is needed to ensure that meat is of the standard necessary, to ensure that a good level of confidence is maintained, and that the risk of meat-borne disease is managed appropriately. Meat official controls are carried out in order for the Government to achieve these objectives. However, to be efficient, these controls need to be proportionate to the risk with all the costs of compliance fully justified by the benefits.

- 2.10 This is in accordance with the Scottish Government's national performance framework target to increase economic sustainable growth in Scotland and that we live longer and healthier lives.

### Devolution

- 2.11 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

## **3. Consultation**

### Public Consultation

- 3.1 FSA Scotland initially wrote to all operators of licensed poultry meat and wild game meat establishments in November 2004 informing them that the new food hygiene regulations on the future of meat inspection and PIAs at poultry meat slaughterhouses would be applied from 1 January 2006. The letter asked the FBOs of these small businesses to complete a short questionnaire for poultry meat slaughterhouses about the current arrangements for meat inspection by company staff and their thoughts on future plans on the basis of present knowledge.
- 3.2 The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 Stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

### Within Government

- 3.3 Scottish Government officials from the Rural and Environment Directorate were consulted as part of the above-mentioned public consultation as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

### With Business

- 3.4 Informal consultation took place with the British Poultry Council (BPC), the Royal Society for the Promotion of Health (RSPH) and the Meat Training Council regarding the proposal to make the exemption, provided by Regulation (EC) No. 2076/2005, permanent. No objections were raised. The BPC fully supports the move to make permanent the need for PIAs to be trained only for the specific tasks they perform, and to the satisfaction of the competent authority.
- 3.5 Small businesses such as the operators of licensed poultry meat and wild game meat plants were also formally consulted (as stated in paragraph 3.2).

## 4. Options

4.1 The options considered were:

Option 1 - Do nothing; Doing nothing would mean that enforcement of Regulation (EC) 1020/2008 would not be provided for in Scotland and the UK would be in breach of its EU Treaty obligations. This could leave the UK Government open to infraction proceedings by the European Commission, for which Scottish Ministers would be accountable.

Option 2 - Provide for the enforcement in Scottish law of Regulation (EC) No. 1021/2008, which makes the exemption permanent, allowing slaughterhouses to train their own staff to carry out official controls in meat plants under supervision of the Official Veterinarian.

4.2 Option 2 is the preferred option. This would largely maintain the current costs for FBOs compared to option 1 while maintaining public health protection.

### Sectors and Groups Affected

4.3 FBOs of poultry and rabbit meat slaughterhouses would be directly affected.

### Costs and Benefits

#### BENEFITS

4.4 Option 1 involves a change from the current position (as described above), but provides no incremental benefits since this is what will occur if no action is taken. It is the baseline from which Option 2 is measured.

4.5 There are considerable benefits to industry and the FSA by adopting option 2 as this would allow FBOs, of poultry and rabbit slaughterhouses, to continue to use PIAs instead of MHIs where they choose to, which is a more efficient way of carrying out official controls, while maintaining a high standard of public health protection (as described above). The cost of an MHI is approximately £30.70/hour<sup>1</sup>, whereas the cost of a PIA is around £11/hour<sup>2</sup>. The savings through using a PIA (rather than an MHI) are estimated at about £19.70 per hour (£30.70 - £11 = £19.70). It is estimated that in

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<sup>1</sup> 2009/10 standard full cost rate for MHI. Not adjusted for any higher rate hours or chargeable allowances for unsocial hours etc.

<sup>2</sup> 2009/10 average for poultry slaughterhouses using PIAs, weighted by number of PIA hours, based on planned rates and hours from Business Agreements (BAs) where available, and 2008/09 data where a BA is not available.

2009/10 approximately 4,626<sup>3</sup> PIA hours were used in Scotland. This suggests a saving in the cost of official controls in the region of £911,000 per year, compared to letting the derogation lapse, assuming the cost differential, and the number of hours remains constant. There would also be some one-off savings from avoiding the costs of transition from PIAs to MHIs, i.e. the training costs of the MHIs needed to replace current PIAs, the costs of understanding the change and reorganising operations, and the costs of briefing the PIAs.

- 4.6 There will also be a benefit for other slaughterhouses and government if they decide to start using PIAs instead of MHIs (currently 2 of the 5 poultry slaughterhouses in Scotland use PIAs). Under option 2, they would be able to replace more expensive MHIs with PIAs, saving the ongoing cost of official controls. Since this would be a business decision for each individual slaughterhouse, we cannot predict how many might move to using PIAs in future and, therefore, this benefit cannot be quantified.
- 4.7 There would also be some one-off savings from avoiding the costs of transition from PIAs to MHIs, i.e. the training costs of the MHIs needed to replace current PIAs, the costs of understanding the change and reorganising operations, and the costs of briefing the PIAs. As described above, these are estimated at £4.05 million in total, over a two-year transition period. As also described above, these savings would be shared across the MHS and industry. It is not possible to estimate precisely how the benefits would be shared, but the majority are likely to accrue to the MHS.

## COSTS

- 4.8 Doing nothing would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. This would leave the UK Government open to monetary sanctions by the European Commission. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>4</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.
- 4.9 Under Option 2 there may be costs associated with letting PIAs know that the derogation will no longer cease, and that it will be adapted into law. Since this would merely be a continuation of the current practice with no further changes, it should be quite easy to convey this information to both plant and PIAs. Therefore, it is assumed that it

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<sup>3</sup> Based on planned hours from Business Agreements (BAs) where available, and 2008/09 data where a BA is not available.

<sup>4</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

would take a maximum of 1 hour for managers to understand and brief their PIAs, and 15 minutes for PIAs to understand this. This equates to a total one-off cost to industry of approximately £1,400, comprising £840 (40 slaughterhouses \* 1 hours \* £21 pay per hour<sup>8</sup>) for poultry plant managers, and £525 to PIAs (193 PIAs \* 0.25 hours \* £11 pay per hour).

## **5. Scottish Firms Impact Test**

- 5.1 FSA Scotland formally consulted 24 small businesses, such as operators of licensed poultry meat and wild game meat establishments in November 2004, informing them that the new food hygiene regulations on the future of meat inspection and PIAs at poultry meat slaughterhouses would be applied from 1 January 2006. Within this consultation small and medium sized poultry meat slaughterhouses were asked to complete a short questionnaire about the current arrangements for meat inspection by company staff, and their thoughts on future plans on the basis of present knowledge. From their responses, small and medium sized businesses fully supported the decision that would allow PIAs to be trained and qualified to the satisfaction of the Competent Authority to carry out official control duties in poultry and rabbit slaughterhouses.
- 5.2 The Agency then conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 Stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

### Competition Assessment

- 5.3 Using the Office of Fair Trading (OFT) competition assessment Framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. It should not limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously.
- 5.4 The use of PIAs may actually open the market and encourage competition. It encourages efficiency in official controls in the poultry sector. There is obviously a limited number of PIAs needed in the industry, but there will be an ongoing level of turnover that will support a small market for training and/or contracting. That market will be open to all interested parties.

### Test Run of Business Forms

- 5.5 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

## **6. Legal Aid Impact Test**

- 6.1 The amendments to the Regulations do not introduce new criminal sanctions or civil penalties; therefore, there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

## **7. Enforcement, Sanctions, and Monitoring**

- 7.1 The FSA must remain responsible for enforcement of official controls. FBOs performing official control duties will do so subject to the FBO or their slaughterer having had appropriate training and the FBO or those that slaughter and bleed the animals being subject to regular verification checks by the OV or AV.
- 7.2 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006.
- 7.3 The effectiveness and impact of the 2012 amending regulations will be monitored via feedback from stakeholders, as part of the ongoing policy process.

## **8. Implementation and Delivery Plan**

- 8.1 Regulation (EC) No. 1021/2008 applied directly in the UK from 28 October 2008 (i.e. 10 days after being published in the EU Official Journal on 18 October 2008).
- 8.2 The coming into force of The Food Hygiene (Scotland) Amendment Regulations 2012 will be communicated to stakeholders by email, letter and via the Agency's website.

### Post-Implementation Review

- 8.3 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in October 2013 (i.e. 5 years from the direct application of Regulation (EC) No. 1021/2008 in the UK).
- 8.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## **9. Summary and Recommendation**

- 9.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EC) 1020/2008.
- 9.2 Taking this option allows the Government to fulfil its obligations to implement EU law.

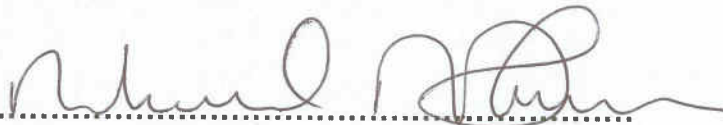
### 9.3 Summary Costs and Benefits Table

Option	Total Benefit per annum: <b>-Economic, environmental, social</b>	Total Cost per annum: <b>-Economic, environmental, social</b>  <b>- Policy and Administrative</b>
<b>1. Do Nothing</b>	No benefits since this is what will occur if no action is taken.	Risk of infraction proceedings for failure to implement (EC) 1020/2008. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day <sup>5</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.
<b>2. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</b>	<p>This would allow the industry to continue to use PIAs instead of MHIs where they choose to, which is a more efficient way of carrying out official controls, while maintaining a high standard of public health protection.</p> <p>There would also be some one-off savings from avoiding the costs of transition from PIAs to MHIs, i.e. the training costs of the MHIs needed to replace current PIAs, the costs of understanding the change and reorganising operations, and the costs of briefing the PIAs.</p>	There may be costs associated with letting PIAs know that the derogation will no longer cease, and that it will be adapted into law. Since this would merely be a continuation of the current practice with no further changes, it should be quite easy to convey this information to both plant and PIAs.

<sup>5</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

## 10. Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature.....

Ministers Title ..... Minister for Public Health

Date..... 29/2/12

### **Contact point**

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## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

### The Food Hygiene (Scotland) Amendment Regulations 2012

To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1021/2008 amending Regulation (EC) 854/2004 and (EC) 2076/2005

<b>BRIA No:</b>	FSMP/SHU/0028
<b>Date:</b>	February 2012
<b>Stage:</b>	Final
<b>Source of intervention:</b>	EU
<b>Type of measure:</b>	Other
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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### **1. Title of Proposal**

1.1 The Food Hygiene (Scotland) Amendment Regulations 2012.

### **2. Purpose and Intended Effect**

#### Objective

2.1 To provide for the enforcement, in Scotland, of Regulation (EC) 1021/2008, amending Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, and Regulation (EC) 2076/2005 as regards live bivalve molluscs, certain fishery products and staff assisting with controls in slaughterhouses. *This BRIA concerns only those amendments to Regulation (EC) 854/2004 and Regulation (EC) 2076/2005 concerning live bivalve molluscs and certain fishery products. Separate BRIAs have been prepared for the other amendments resulting from Regulation (EC) 1021/2008.*

2.2 The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulation (EC) 854/2004 and Regulation (EC) 2076/2005. There is a need, therefore, to amend the Food Hygiene (Scotland) Regulations 2006 (as amended) in order to provide for the enforcement, in Scotland, of Regulation (EC) 1021/2008. However, the amendment will have no effect in itself, and any costs or benefits which may arise will result purely from the provisions of the Regulation.

2.3 Regulation (EC) 1021/2008 introduces measures which lower the risk of gastrointestinal illness from the consumption of bivalve molluscs. These measures improve the protection of public health whilst continuing to provide flexibility and proportionality in the classification of live bivalve molluscs (LBM) production areas as follows:

- By modifying Annex II and Annex III of Regulation (EC) 854/2004 on the organisation of official controls on products of animal origin intended for human consumption, to make official the criteria for Class B LBM production areas. This criterion means that in order to classify areas as being of class B, samples from the area must not exceed 4 600 *E. coli* per 100 g of flesh and intra-valvular liquid in 90 % of the samples. In the remaining 10 % of samples, live bivalve

molluscs must not exceed 46 000 *E. coli* per 100 g of flesh and intra-valvular liquid. This flexibility did not exist in regulation previously.

- 2.4 Regulation (EC) 1021/2008 also introduces new requirements for competent authorities to carry out checks on frozen fishery products belonging to the *Gempylidae* family by amending Annex III of Regulation (EC) 854/2004.

## Background

### *Classification System*

- 2.5 Regulation (EC) 854/2004 (laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption) applied with effect from 1 January 2006.

- 2.6 The requirement for EU Member States to implement an LBM monitoring programme for classified production areas was carried over from the previous legislation, along with associated microbiological standards for Class A, B and C production areas. Harvesting areas are classified according to the level of *E. Coli* contamination found in shellfish sampled from an area. These areas are classified as follows:

Class A – shellfish must contain an amount of *E. Coli* less than 230 /100g of flesh, and can be placed on the market for direct human consumption

Class B – 90% of shellfish must contain an amount of *E. Coli* less than 4600/100g of flesh, and must be purified or relayed before being placed on the market for direct human consumption

Class C - shellfish must contain an amount of *E. Coli* less than 46,000/100g flesh, and must be heat treated using a permitted method or relayed for a longer period before being placed on the market for direct human consumption

- 2.7 Harvesting is prohibited from production areas exhibiting *E. Coli* levels above those specified for Class C.
- 2.8 After seeking agreement from the European Commission, the Food Standards Agency, on behalf of the UK, adopted the policy of continuing with the 90% provision for all Class B production areas under the transitional arrangements. The introduction of Regulation (EC) 1021/2008 permanently establishes the 90% provision for Class B production areas in the legislative requirements.
- 2.9 There are currently 168 classified beds in Scotland, and of these, 87 are Class B status for all or part of the year (52%). The current classification listing can be viewed on the Agency's website via the following link:

<http://www.food.gov.uk/scotland/safetyhygienescot/shellmonitorscot/shellclasssscot/shellclassscot1112>

### *Poisonous Fishery Products*

2.10 An opinion of the European Food Safety Authority (EFSA) adopted 30 Aug 2004 on contaminants in the food chain related to the toxicity of fishery products belonging to the family of *Gempylidae*, has demonstrated that fishery products belonging to that family, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may have adverse gastrointestinal effects if not consumed under certain conditions. Regulation (EC) 854/2004 requires competent authorities in the Member States to carry out checks regarding the marketing conditions that food business operators (FBOs) must comply with in relation to fishery products belonging to the family of *Gempylidae*.

2.11 Those conditions apply to fresh, prepared and processed fishery products derived from those species. However, similar risks for the consumer may be encountered with frozen fishery products derived from the family of *Gempylidae*. It is therefore appropriate to require competent authorities to carry out checks also for frozen fishery products belonging to that family.

### *History of the amendment*

2.12 The amendment was originally issued in draft form on 8 Jan 2008 as SANCO/44/2008, and underwent several amendments before publication in the EU Official Journal 18 October 2008 as Regulation (EC) 1021/2008. Details of the negotiations on the legislation can be found at:

<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/hist/eu/>

### Devolution

2.13 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made to provide for the enforcement of Regulation (EC) 1021/2008 in England, Wales and Northern Ireland.

### Rationale for government intervention

2.14 Failure to provide enforcement provisions for Regulation (EC) 1021/2008 may leave the UK open to monetary sanctions from the European Commission, for which Scottish Ministers would be accountable.

- 2.15 The Class B LBM production area standard has been applied continuously since the introduction of the EU hygiene legislation in 2006, even when it became apparent that the 90% provision had been omitted. The Regulation rectifies the omission and provides an additional regulatory measure establishing an upper limit of 46000 *E. coli*/100g on non-compliant samples. Ensuring compliance with Regulation (EC) 1021/2008 is in accordance with the Scottish Government's National Performance Framework target to ensure that we live longer, healthier lives.
- 2.16 Regulation (EC) 854/2004 requires competent authorities in the Member States to carry out checks regarding the marketing conditions that FBOs must comply with in relation to fishery products belonging to the family of *Gempylidae*.
- 2.17 The health risks which can arise from the consumption of fresh, prepared and processed fishery products derived from the *Gempylidae* species may also be encountered with frozen fishery products derived from this family... It is therefore appropriate to require competent authorities to carry out checks also for frozen fishery products belonging to that family in order to protect public health.

### **3. Consultation**

#### Public Consultation

- 3.1 All relevant stakeholders, including the shellfish industry, local enforcement bodies and the Small Business Federation, were consulted informally on these proposals in 2008 and are aware of the implications of the changes that were proposed. No objections to the proposals were received from stakeholders in Scotland.
- 3.2 The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 Stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

#### Within Government

- 3.3 Scottish Government officials from the Rural Directorate and Food & Drink Industry Division were consulted as part of the above-mentioned public consultation as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

#### With Business

- 3.4 255 Stakeholders including Scottish small to medium enterprises were consulted on the proposed enforcement measures. No responses were

received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

3.5 Since the proposals have no effect on business it was considered not proportionate to carry out additional face-to-face interviews with individual businesses.

#### **4. Options**

Two options have been identified as follows:

##### **Option 1: Do Nothing**

4.1 Doing nothing would mean that enforcement of Regulation (EC) 1021/2008 would not be provided for in Scotland and the UK would be in breach of its EU Treaty obligations. This could leave the UK Government open to monetary sanctions by the European Commission, for which Scottish Ministers would be accountable.

##### **Option 2: Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended)**

4.2 This option fully meets the UK Government's commitment to fulfill its EU Treaty obligations. Under these obligations we are required to give effect, in Scotland, to the enforcement provisions of the Regulation. The UK was involved with the Commission and other Member States throughout the negotiations that developed the Regulation and we supported its adoption.

#### **Costs and Benefits**

##### **Sectors and groups affected**

4.3 Food Standards Agency will be affected as it administers the shellfish classifications system in Scotland.

4.4 Local Authorities will be affected as they are responsible for enforcing the legislation with respect to food safety.

4.5 Consumers will be affected in that public health protection will improve.

4.6 These measures improve the protection of public health whilst continuing to provide flexibility and proportionality in the classification of LBM production areas as follows:

## Benefits

### **Option 1: Do nothing**

4.7 Enforcement authorities will not face increased costs for checks on the marketing conditions applied to *Gempylidae* species products.

### **Option 2: Support the Regulation's application and provide for its enforcement in Scotland by amending the Food Hygiene (Scotland) Regulations 2006(as amended)**

4.8 Providing for the enforcement, in Scotland, of Regulation (EC) 1021/2008 avoids any risk of the UK failing its Treaty obligations, with the consequence of monetary sanctions by the European Commission.

4.9 Option 2 explicitly improves the protection of public health in the UK by setting upper limits of *E. coli* in Class B areas. The benefits are that the standard for classification is now clearly set out in law which will provide added reassurance and protection to the public.

4.10 Although data is limited, indications are that in Scotland, the potential benefits of increased consumer protection would justify any costs.

4.11 An extension of checks to frozen fishery products belonging to the family of *Gempylidae* will reduce the risk to consumers of adverse gastrointestinal effects from consuming such fishery products.

## Costs

### **Option 1: Do nothing**

4.12 Doing nothing would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. This would leave the UK Government open to monetary sanctions by the European Commission. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.

4.13 Doing nothing would also mean that the derogation provided for by Regulation (EC) 2076/2008 could not be made permanent. Unless the provisions of the derogation were made permanent, this would have a significant impact on the enforcement of the classification monitoring

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

system from that date as the relevant rules<sup>2</sup> would have required 100% compliance for all Class B areas.

- 4.14 Doing nothing would mean that relevant checks would not be carried out on frozen fishery products belonging to the family of *Gempylidae*, thus exposing consumers to a potential health risk.

**Option 2: Support the Regulation's application and provide for its enforcement in Scotland by amending the Food Hygiene (Scotland) Regulations 2006(as amended)**

- 4.15 The provision for 90% compliance for Class B production areas and the upper limit for non-compliant samples will not add any administrative burdens or costs for stakeholders in Scotland. All samples taken from classified sites are considered when making classification decisions in accordance with the regulations and the Community Reference Laboratory Good Practice Guide for the Microbiological Assessment of Shellfisheries.

- 4.16 Additional costs will be incurred by competent authorities carrying out checks on frozen fishery products belonging to the family of *Gempylidae*. Local Authorities were unable to quantify these costs during the public consultation.

**5. Scottish Firms Impact Test**

- 5.1 Informal consultation with the Federation of Small Business during the development of Regulation (EC) 1021/2008 generated no comments. No comments were received from the 2010 public consultation.

- 5.2 Since the proposals have no effect on business it was considered not proportionate to carry out additional face-to-face interviews with individual businesses.

**Competition Assessment**

- 5.3 Using the Office of Fair Trading (OFT) competition assessment Framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

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<sup>2</sup> Regulation (EC) 854/2004, Annex II, Chapter I, A, point 5



## **Test Run of Business Forms**

- 5.4 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

## **6. Legal Aid Impact Test**

- 6.1 The amending regulations do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This draft BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

## **7. Enforcement, Sanctions and Monitoring**

- 7.1 Enforcement of the Regulation will be the responsibility of Local Authority Environmental Health Departments.
- 7.2 The effectiveness and impact of the Regulation will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys, and general enquiries from the public.
- 7.3 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

## **8. Implementation and Delivery Plan**

- 8.1 Regulation (EC) 1021/2008 applied directly in the UK from 28 October 2008 (i.e. 10 days after being published in the EU Official Journal 18 October 2008).
- 8.2 The coming into force of The Food Hygiene (Scotland) Amendment Regulations 2012 will be communicated to stakeholders by email, letter and via the Agency's website etc.

## **9. Post-implementation Review**

- 9.1 A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulations, will take place in November 2013 (i.e. 5 years from the direct application in the UK of Regulation (EC) 1021/2008).
- 9.2 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## 10. Summary and Recommendation

- 10.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EC) 1021/2008.
- 10.2 Taking this option allows the Government to fulfil its obligations to implement EU law.
- 10.3 Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

## 11. Summary Costs and Benefits Table

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social  - Policy and Administrative
<b>1. Do Nothing</b>	Local Authorities will not face increased costs for checks on marketing conditions of <i>Gempylidae</i> species fish	Risk of infraction proceedings for failure to implement (EC) 1019/2008. Possible fines of up to €703000 per day.  Increased burden on LAs to enforce the 100% compliance of class B LBMs.  Increased risk to public health and potential for gastrointestinal illness from consumption of <i>Gempylidae</i> species fish
<b>2. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</b>	Allows the Government to meet its commitment to fulfil its EU obligations.  Consumers will benefit from increased consumer protection by setting upper limits of <i>E. coli</i> in Class B shellfish harvesting areas  Improved public health protection from the risk of gastrointestinal illness from consuming <i>Gempylidae</i> species fish	Unquantified enforcement costs for LAs in the checking of marketing conditions of <i>Gempylidae</i> species fish.

## 12. Declaration

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature.....

Ministers Title ..... Minister for Public Health

Date..... 29/2/12

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## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

### The Food Hygiene (Scotland) Amendment Regulations 2012

To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1020/2008 amending Annex III of Regulation (EC) 853/2004, (EC) 1022/2008 amending (EC) 2074/2005 and (EC) 1023/2008 amending (EC) 2076/2005

**File No:** SPARD/FSAS  
**Date:** February 2012  
**Stage:** Final  
**Source of intervention:** EU  
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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### **1. Title of Proposal**

1.1 The Food Hygiene (Scotland) Amendment Regulations 2012.

### **2. Purpose and Intended Effect**

#### Objective

2.1 To provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008, amending Annexes II and III of Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin, and Regulation (EC) 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products. *This BRIA concerns only those amendments to Regulation (EC) 853/2004 and Regulation (EC) 2076/2005 relating to fish oil. Separate BRIAs have been prepared for the other amendments to Regulations 853/2004 and 2076/2005 resulting from Regulation 1020/2008.*

2.2 To provide for the enforcement, in Scotland, of Regulation (EC) 1022/2008 amending Regulation (EC) 2074/2005 as regards the total volatile basic nitrogen (TVB-N) limits.

2.3 This BRIA also makes reference to Regulation 1023/2008 amending Regulation (EC) 2076/2005 as regards the extension of the transitional period granted to food business operators importing fish oil intended for human consumption.

2.4 *Regulation (EC) 1020/2008 amends Annex III of Regulation (EC) 853/2004 to set out new hygiene requirements for fish oil intended for human consumption. It states that:*

1. *'Raw materials used in the preparation of fish oils for human consumption must:*
  - a. *Come from establishments, including vessels, registered or approved pursuant to Regulation (EC) 852/2004 or in accordance with Regulation (EC) 1020/2008;*
  - b. *Derive from fishery products which are fit for human consumption and which comply with the provisions set out in Regulation (EC) 1020/2008;*
  - c. *Be transported and stored in hygienic conditions; and*

- d. *Be chilled as soon as possible and remain at the temperature set out in Chapter VII of Annex III of Regulation (EC) 853/2004*

*By way of derogation from point (d) above, the food business operator may refrain from chilling the fishery products when whole fishery products are used directly in the preparation of fish oil for human consumption, and the raw material is processed within 36 hrs after loading, provided that the freshness criteria are met and the total volatile basic nitrogen (TVB-N) value of the unprocessed fishery products do not exceed the limits set out in point 1 of Chapter 1 of Section II of Annex II to Regulation (EC) 2074/2005.*

2. *The production process for fish oil must ensure that all raw material intended for the production of crude fish oil is subject to a treatment including, where relevant, heating, pressing, separation, centrifugation, processing, refining and purification steps before being placed on the market for the final consumer.*
3. *Provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption, a food business operator may produce and store both fish oil for human consumption and fish oil and fish meal not intended for human consumption in the same establishment.*
4. *Pending the establishment of specific Community legislation, food business operators must ensure compliance with national rules for fish oil being placed on the market for the final consumer.'*

2.5 Regulation (EC) 1022/2008 amends Annex II of Regulation (EC) 2074/2005 as regards the total volatile basic nitrogen (TVB-N) limits. Specifically, Regulation (EC) 1022/2008 amends Annex II of Regulation (EC) 2074/2005 by setting new limits for the TVB-N content for all fishery products used directly in the preparation of fish oil intended for human consumption. This requirement was deemed necessary in order to ensure the continued protection of public health.

2.6 Regulation (EC) 1023/2008 extended to 30 April 2009 the derogation from the hygiene requirements that was previously in place. This was necessary to allow third country (i.e. non-EU countries) fish oil manufacturers time to comply with the new hygiene requirements mentioned above, and it ensured the continued supply to the EU of fish oil.

## Background

### 2.7 Food Hygiene Regulations

Regulations (EC) 852/2004 and (EC) 853/2004 ('the food hygiene regulations') were introduced on 1 January 2006, consolidating and replacing the existing EC food hygiene legislation that laid down the hygiene rules for food of animal origin traded within the Community. The consolidation exercise

included Council Directive 91/493/EEC on the hygiene standards for fishery products.

2.8 Article 10 of Regulation (EC) 852/2004 required that the hygiene of foodstuffs imported into EU Member States from establishments in third countries, must comply with the requirements set out in Articles 3 to 6 of the Regulation (broadly covering general obligations, general and specific hygiene requirements, food safety procedures based on HACCP principles, and official controls, registration and approval).

### *2.9 Derogation*

Regulation 853/2004 lays down specific rules for food businesses handling products of animal origin, including those producing fish oil intended for human consumption. It was recognised that some businesses in approved third countries producing fish oil for export to EU Member States did not meet the requirements set out in the hygiene regulations, therefore, a derogation from full compliance with the hygiene regulations was put in place (from January 2006 until April 2009) to ensure that the supply of fish oil to the EU was not compromised. However, there was still a need to ensure the continued protection of public health as provided for by the hygiene regulations. In light of this, it was agreed that it was necessary to take a proportionate approach that balanced the need to ensure the continued supply of fish oil with the need to maintain food safety.

2.10 In light of the risk to supply, a derogation was put in place that allowed food business operators (mainly in third countries) time to make adjustments in order to achieve compliance with the new rules as regards fish oil production. This derogation meant that imports into EU Member States were not reduced during this period.

### *2.11 Total volatile basic nitrogen (TVB-N) content*

The previous derogation from full hygiene compliance set out for fish oils expired at the end of October 2008, therefore, it was necessary to extend this. Extending this derogation ensured that a number of approved third countries could continue to supply fish oil to the EU. However, in order to ensure the continued protection of public health, it was also necessary to set a limit for the total volatile basic nitrogen (TVB-N) content. This is now a requirement for all fishery products used directly in the preparation of fish oil.

### *2.12 Fish oil supply*

Due to the lack of marine resources in Europe, the regular supply of fish oil is almost exclusively dependent upon imports from third countries. A breakdown of the sources is shown in Table 1 in the costs and benefits section below.

2.13 Fish oils are mainly imported as crude or semi refined oils that are then refined for human consumption. Fish oils for human consumption contain Omega 3 and are used mainly in infant food products, food for particular nutritional uses, and animal feed.

#### *2.14 Additional hygiene requirements and extension of the transitional period*

Prior to 1 Jan 2006, fish oil was not covered by EU hygiene legislation as it was not included in the definition of 'fishery products'. However, in November 2006 Regulation (EC) 1662/2006 introduced specific hygiene requirements regarding the raw materials used in the preparation of fish oils for human consumption (by amending Regulation 853/2004).

2.15 In October 2008, Regulation 1020/2008 (also amending Regulation 853/2004), introduced further specific hygiene measures as regards the raw materials used in the preparation of fish oils for human consumption (Quality Control paragraph below refers). Regulation 1023/2008 extended to 30 April 2009, the transitional period granted to food business operators importing fish oil, in order to allow third country establishments time to comply with the new measures, and ensured the continued supply of fish oil to the EU.

2.16 Amendments to the food hygiene legislation means there are now further specific requirements in place for the production of fish oil. The aforementioned derogation from these requirements for third country establishments expired 30 April 2009 therefore full compliance with the relevant parts of Regulation 853/2004 is now required.

2.17 It was assumed at the time that third country producers would be able to meet the new hygiene requirements by 30 April 2009 so that imports of fish oil would not be compromised.

#### *2.18 Discussions with the Commission*

The Commission established a Restricted Working Group (RWG), involving a few Member States and certain non-EU countries with an interest. Membership of the RWG comprised UK, Spain, Ireland, Lithuania, Denmark, France, Norway and Iceland, and the first meeting was held 10 Dec 2007.

2.19 The RWG noted that fish oil is different from other fishery products in that the oil is not susceptible to microbiological deterioration. It does not require refrigerated storage or transport, and crude oils are always refined and purified before they are sold to consumers.

2.20 The Agency sent a letter to interested parties in December 2007 outlining the situation. Subsequently, the Agency held meetings with several industry representatives and arrangements were made for those representatives to attend a RWG meeting, where they were able to raise their concerns directly. Following on from this meeting, the Agency issued a further two letters to interested parties in Feb 2008 advising them of the draft proposals and asking for views/comments.

2.21 The RWG met again 6 March 2008 and discussed an updated draft proposal on fish oil for human consumption and, following the Commission tabling further documents, a further update letter was issued to interested parties in May 2008.



2.22 At the RWG meetings, arguments were raised in favour of certain parameters which the UK considered went beyond that necessary for the proportionate protection of public health, and which would have effectively established 'quality parameters' rather than 'hygiene parameters'. This was deemed to be disproportionate on the grounds that contaminants are regulated by other legislation, and other risks are managed by proper processing.

2.23 The issue was raised at a meeting of the Commission Working Group on Hygiene Legislation 19 May 2008, and at the Standing Committee on Food Chain and Animal Health (SCoFCAH) meeting 15 July 2008.

#### *2.24 Quality control*

At the above mentioned SCoFCAH meeting, unanimous approval was given to amending Regulation 2074/2005 with regards to the total volatile basic nitrogen (TVB-N) limits for fish oil. The TVB-N parameter is an indicator of protein quality and it was agreed to set the limit to 60mg of nitrogen/100g of whole fishery products, used directly for the preparation of fish oil for human consumption. Regulation 1022/2008 amends Regulation 2074/2005 to this effect as regards the TVB-N limits.

2.25 In addition, unanimous approval was also given at the SCoFCAH meeting to amending Regulation (EC) 2076/2005 as regards extending the transitional period granted to food business operators importing fish oil intended for human consumption. It was agreed this extended derogation would run until 30 April 2009. Moreover, where fish oil for which a duly completed and signed certificate has been issued prior to 30 April 2009 (in accordance with national rules and before the entry into force of Regulations (EC) 1020/2008 and 1022/2008, such fish oil could be imported into the EU until 30 June 2009.

2.26 Regulation 1020/2008, which was published in the EU journal 20 October 2008, amends Regulation 853/2004 in that it provides hygiene rules for businesses handling fish products from which fish oil for human consumption is derived. As far as the Agency is aware there is negligible or no industry in Scotland handling such fish products. Such businesses would appear to be largely confined to third countries or other EU Member States. Therefore, the Agency's considered view is that there will be no, or negligible, impact on Scottish industry.

#### *2.27 History of the proposals*

The proposed amendments were originally issued 9 June 2008 as SANCO/1729/2008 and SANCO/1730/2008, and underwent several amendments before publication in the EU Official Journal 20 October 2008 as Commission Regulation (EC) 1022/2008 and Commission Regulation (EC) 1023/2008. Details of the negotiations on the legislation can be found at:

<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu/>

## Rationale for government intervention

2.28 Failure to provide enforcement provisions for Regulations (EC) 1020/2008 and (EC) 1022/2008 (“the Regulations”) may leave the UK open to monetary sanctions from the European Commission, for which Scottish Ministers would be accountable.

2.29 There is potential for the emergence of unregulated fish oils being imported into the EU and potential food quality issues indicated by high TVB-N levels, with a subsequent negative impact on public health. Providing regulation to prevent this is in accordance with the Scottish Government’s national performance framework target to ensure that we live longer, healthier lives.

2.30 These measures ensure a consistent regulatory approach across the EU, thus facilitating trade in fish oil. Specifically, the measures will help ensure that all Member States throughout the EU are subject to the same TVB-N limits. This helps facilitate trade from third countries to the EU, rather than different rules applying on a country-by-country basis.

## Devolution

2.31 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

## **3. Consultation**

### *Public Consultation*

3.1 The Commission established a Restricted Working Group (RWG), involving a few Member States and certain non-EU countries with an interest. Membership of the RWG comprised UK, Spain, Ireland, Lithuania, Denmark, France, Norway and Iceland, and the first meeting was held 10 Dec 2007. As outlined in the paragraphs above, there has been some informal consultation in so far as the Agency kept interested parties informed about these discussions and asked for comments. Written concerns from industry were received and taken forward, and industry representations were made directly to SCoFCAH. Arrangements were also made for industry representatives to attend the RWG meeting to participate in the discussions and put their views forward.

3.2 The Agency carried out a full public consultation which ran for 12 weeks from 26 March 2010 until 1 April 2010. 255 Stakeholders were consulted. Separate but parallel consultations were carried out simultaneously in England, Wales and Northern Ireland. No responses were received in Scotland.

### *Within Government*

3.3 Scottish Government officials from the Rural Directorate and Food & Drink Industry Division were consulted as part of the above-mentioned public

consultation as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

#### *With Business*

3.4 This impact assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. Face to face engagement with Scottish business was therefore not carried out during the development process. However, UK businesses were involved in discussions as part of the RWG and stakeholders were kept informed of the progress of the RWG and their input and comments were requested and fed into these discussions. In addition, 255 Stakeholders including Scottish small to medium enterprises were consulted on the proposed enforcement measures in the period April to June 2010. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

## **4. Options**

Two options have been identified, the details of which are set out below:

### **Option 1:** Do nothing

4.1 Doing nothing would mean that enforcement of the Regulations would not be provided for in Scotland and the UK would be in breach of its EU Treaty obligations. This could leave the UK Government open to infraction proceedings by the European Commission, for which Scottish Ministers would be accountable.

**Option 2:** Support the Regulation's application and provide for their enforcement, in Scotland, by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).

4.2 Both of these Regulations are directly applicable in all Member States.

4.3 This option fully meets the UK Government's commitment to fulfill its EU Treaty obligations. Under these obligations we are required to give effect in the UK to the enforcement provisions of the Regulations. The UK was involved with the Commission and other Member States throughout the negotiations that developed the Regulation.

#### *4.4 Sectors and groups affected*

- Local Authorities are responsible for enforcing food hygiene legislation and will therefore be affected, although no significant impact is expected
- Consumers will be affected in that food safety will be maintained

- Manufacturers of fish oil will be affected by the additional hygiene requirements

## Costs

### **Option 1: Do nothing**

4.5 Doing nothing would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. This would leave the UK Government open to monetary sanctions by the European Commission. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.

4.6 Prior to the introduction of Regulation 1023/2008 on 28 October 2008, a derogation was in place which permitted certain producers of fish oil in third countries to export to EU Member States oil that did not fully meet the relevant food hygiene requirements. This derogation was due to expire at the end of October 2008. Regulation 1023/2008 extended this derogation to 30 April 2009, thus granting food business operators importing fish oil a transitional period in order to allow third country establishments time to comply with the new measures. Without this extended derogation, these third country producers would have been unable to continue exporting fish oil to the EU as of 1 November 2008.

4.7 Without the appropriate derogation there would have been a significant impact on the supply of fish oil into the EU. This would have resulted in a severe reduction in supply, resulting in price increases and a subsequent impact on Omega 3 consumption levels. An inadequate supply of fish oils would potentially have detrimental health consequences for consumers, for example for people taking fish oils at maximum levels in order to prevent heart disease.

4.8 Prior to the introduction of Regulation 1022/2008 on 28 October 2008, there was insufficient protection of public health with regards to the permitted limit of TVB-N in some fish species.

4.9 There was also potential for the emergence of unregulated fish oils being imported into the EU and potential food quality issues indicated by high TVB-N levels, with a subsequent negative impact on public health.

### **Option 2: Support the application of the Regulations and provide for their enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).**

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

4.10 There is a theoretical additional cost to enforcement authorities from having to test fish oils with respect to TVB-N limits to ensure acceptable quality, although this is likely to be negligible as this will fall entirely on competent authorities in third countries. Enforcement authorities did not comment on this during the consultation and the Agency is therefore unable to quantify this theoretical cost.

4.11 **Table 1** below shows that, in the UK, a large share of fish oil comes from non- EU countries (including Norway). While the UK does export some fish oils, it is unclear whether this can be substituted for the domestic market. Therefore, without the derogation, UK consumers and industry would face either an increase in the price of fish oils and/or a reduction in supply. The changes to the TVB-N limits ensures that all firms throughout EU will be subject to same limits. This will help facilitate trade from third countries to all of EU, rather than on a country-by-country basis.

**Table 1: UK 2007, 1504: Fats and oils and their fractions of fish or marine animals, whether or not refined (excluding chemically modified)<sup>2</sup>**

Country	Total Imports (Tonnes)	Total Exports (Tonnes)
Total	22,679,337	3,178,189
European Union 27	4,189,098	2,675,772
W EUROPE (exc EU 27)	14,299,261	92,371
EASTERN EUROPE (exc EU 15)	-	70,372
EASTERN EUROPE (exc EU 27)	-	2,700
NORTH AMERICA	2,116,249	77,032
OTHER AMERICA	1,531,605	167,375
M EAST & N AFRICA (exc EU15)	-	3,269
M EAST & N AFRICA (exc EU27)	-	2,377
SUB SAHARAN AFRICA	-	2,160
ASIA & OCEANIA	543,124	158,402

## Benefits

### **Option 1 – Do nothing**

4.12 Doing nothing maintains the current position and we are not aware of any benefits associated with Option 1.

### **Option 2 - Support the application of the Regulations and provide for their enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).**

#### *4.13 Industry benefits*

Option 2 ensures a consistent regulatory approach across the EU, thus facilitating trade in fish oil. Specifically, the changes to the TVB-N limits ensures that all Member States throughout the EU are subject to the same

<sup>2</sup> HM Revenue and Customs UKTradeInfo service, [www.uktradeinfo.com](http://www.uktradeinfo.com)

limits. This helps facilitate trade from third countries to the EU, rather than different rules applying on a country-by-country basis.

4.14 The extension of the derogation gave third country producers notice of the intention to remove the derogation and allowed them time to fully comply with the EU hygiene requirements.

#### 4.15 *Consumer benefits*

Option 2 also avoids a potential reduction in the supply of fish oil to the EU.

#### 4.16 *Industry/Public Health Benefits*

The extension of the derogation and the setting of TVB-N limits introduces an appropriate level of control. As a consequence, the regulatory burden on businesses will be kept to a minimum, whilst maintaining public health protection.

4.17 The costs and benefits highlighted above have not been monetised because the available methods would not yield acceptable estimates.

### **5. Scottish Firms Impact Test**

5.1 We are not aware of any adverse effect on Scottish businesses.

5.2 The Agency's understanding is that any manufacturing in Scotland using imported fish oil is undertaken exclusively by larger firms. As such, no new administrative burdens have been identified as a result of the introduction of these measures.

5.3 Please refer to the Consultation section in paragraph 3 above.

### **Competition Assessment**

5.4 Using the Office of Fair Trading (OFT) competition assessment framework<sup>3</sup>, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

### **Test Run of Business Forms**

5.5 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to the businesses that will be affected by the Regulations.

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<sup>3</sup> [http://www.offt.gov.uk/shared\\_oftr/reports/comp\\_policy/oft876.pdf](http://www.offt.gov.uk/shared_oftr/reports/comp_policy/oft876.pdf)

## **6. Legal Aid Impact Test**

6.1 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce new criminal sanctions or civil penalties therefore there are no legal aid implications. This has been confirmed by the Access to Justice Team of Scottish Government.

## **7. Enforcement Sanctions and Monitoring**

7.1 Enforcement of the Regulations will be the responsibility of Local Authority Environmental Health Departments. No additional costs are expected to be incurred as there will be no significant change to the current enforcement regime.

7.2 The effectiveness and impact of the Regulations will be monitored via feedback from stakeholders, as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys, and general enquiries from the public.

7.3 No changes are being proposed to the criminal sanctions contained in the original Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

## **8. Implementation and Delivery Plan**

8.1 Regulations (EC) 1020/2008, (EC) 1022/2008 and (EC) 1023/2008 applied directly in the UK from 28 October 2008 (i.e. 10 days after being published in the EU Official Journal on 18 October 2008).

8.2 The publication of the Food Hygiene (Scotland) Amendment Regulations 2012 will be communicated to stakeholders through the Agency's website and FSA News.

### **Post-implementation Review**

8.3 A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulations, will take place in November 2013 (i.e. 5 years from the direct application in the UK of Regulations (EC) 1020/2008 and 1022/2008).

8.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

8.5 Manufacturers of fish oil for human consumption have had to fully comply with the processing requirements of Annex III of Regulation 853/2004 (as amended) with effect from 1 May 2009. If this proves too burdensome, the

Commission may have to revisit this issue. The Agency will also review the situation at this point.

## 9. Summary and Recommendation

9.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulations (EC) 1020/2008, (EC) 1022/2008 and (EC) 1023/2008.

9.2 Taking this option allows the Government to fulfil its obligations to implement EU law. It also ensures that Enforcement Authorities can fulfil the requirements placed on them and the Courts can impose penalties consistent with those elsewhere in Food Law.

9.3 Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

### 9.4 Summary Costs and Benefits Table

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social  - Policy and Administrative
<b>1. Do Nothing</b>	No benefits have been identified.	<p>Risk of infraction proceedings for failure to implement (EC) 1020/2008, (EC) 1022/2008 &amp; (EC) 1023/2008. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>4</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.</p> <p>Detrimental effect on the health of consumers due to shortage of fish oil</p> <p>Insufficient protection of public health due to high TVB-N in some fish species</p> <p>Potential for the emergence of unregulated fish oils with a subsequent effect on public health</p>
<b>2. Support the Regulation's</b>	Allows the Government to meet its commitment to fulfil	Theoretical cost to enforcement authorities from testing fish oils is

<sup>4</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>




<p><b>application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</b></p>	<p>its EU obligations.</p> <p>Avoids potential reduction in fish oil imports to the UK.</p> <p>Introduces an appropriate level of control, reducing regulatory burden on businesses whilst maintaining public health protection</p> <p>Harmonises standards across Member States &amp; removes barriers to trade</p>	<p>likely to be negligible as this will fall entirely on competent authorities in 3<sup>rd</sup> countries.</p> <p>Increased cost and decreased availability of fish oils for consumers</p>
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## 10. Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature .....



Ministers Title .....

Minister of Public Health

Date .....

29/2/12

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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

**The Food Hygiene (Scotland) Amendment Regulations 2012**

**To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1020/2008 amending Annex III to Regulation (EC) 853/2004**

<b>File No:</b>	SPARD/FSAS
<b>Date:</b>	February 2012
<b>Stage:</b>	Final
<b>Source of intervention:</b>	EU
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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### **1. Title of Proposal**

1.1 The Food Hygiene (Scotland) Amendment Regulations 2012.

### **2. Purpose and Intended Effect**

#### Objectives

- 2.1 To provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008 ('the Regulation') amending Annexes II and III of Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin, and Regulation (EC) 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products. *This BRIA concerns only those amendments to Annex III of Regulation (EC) 853/2004 relating to the use of clean water when handling fishery products and other minor amendments. Separate BRIAs have been prepared for the other amendments to Regulations 853/2004 and 2076/2005 resulting from Regulation 1020/2008.*
- 2.2 The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulations (EC) 853/2004 and (EC) 2076/2005. There is a need, therefore, to amend the Food Hygiene (Scotland) Regulations 2006 (as amended) in order to provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008.
- 2.3 Regulation (EC) 1020/2008 amends Annex III of Regulation (EC) 853/2004 to say that:
- (i) clean seawater may be used for the handling and washing of fishery products, the production of ice used to chill fishery products, and the rapid cooling of crustaceans and molluscs after their cooking.
  - (ii) where fish are headed and/or gutted on board vessels, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly after these operations.
  - (iii) operations such as heading and gutting must be carried out hygienically, and as quickly as possible after the products have been caught or landed, and the products must be washed immediately and thoroughly after these operations.

- 2.4 Regulation (EC) 1020/2008 also amends Annex III of Regulation (EC) 853/2004 regarding the requirements for cooking crustaceans and molluscs.

## Background

### *Food Hygiene Regulations*

- 2.5 Regulations (EC) 852/2004 and (EC) 853/2004 ('the Food Hygiene Regulations') were introduced on 1 January 2006, consolidating the existing EC food hygiene legislation that laid down the hygiene rules for food of animal origin traded within the Community. The consolidation exercise included Council Directive 91/493/EEC on the hygiene standards for fishery products.

- 2.6 The Food Hygiene Regulations also introduced the requirement for food businesses using clean water (as defined below) when handling fishery products, to have in place measures to ensure the water is not a source of food contamination. They also made permanent the transitional measure allowing land-based establishments to use clean water on fishery products. Specifically, Annex II, Chapter VII, 1(b) of Regulation (EC) 852/2004 provides for food business operators to use 'clean water' with whole fishery products, provided that adequate facilities are available for its supply.

### *Definition of clean water*

- 2.7 Clean water is currently defined in Regulation (EC) 852/2004 as including clean seawater and fresh water of a similar quality. As the quality of clean sea water (and by definition therefore, clean water) can vary along the coastline, and can vary significantly between coastal and offshore waters, it is recognised that those food business operators using clean water when handling fishery products should ensure that appropriate risk factors are considered so that the water does not detrimentally affect the safety or quality of the foodstuff. Regulation (EC) 1019/2008 amends Regulation (EC) 852/2004 by introducing this requirement, thereby ensuring the protection of public health.

### *Transitional arrangements*

- 2.8 The use of clean water (the definition of which includes clean seawater) on fishery products has been permitted on fishing vessels since the implementation of the consolidated hygiene legislation. It has also been permitted in land-based establishments under the transitional arrangements of Regulation 2076/2005, in order to allow these establishments to adapt progressively. This provision expired 31 December 2009.
- 2.9 Regulation (EC) 1020/2008 amends Regulation (EC) 853/2004 to make permanent the temporary transitional measure allowing land-based establishments to use clean water when handling fishery products. As this transitional measure expired 31 December 2009, making this provision permanent ensures that food business operators handling

fishery products (e.g. preparation and processing establishments) will be able to continue to use 'clean water' (clean sea/fresh water) when handling fishery products after the end of the transitional period.

- 2.10 This will continue the current regime, thus minimising the burden on business and giving legislative certainty to all stakeholders. This will also prevent increased costs to industry by allowing the continued use of clean water (as opposed to potable water) when handling fishery products after 31 December 2009, whilst improving the level of public health protection by introducing a risk-based control procedure. However, when using 'clean water' in this way, these businesses will still be required to apply adequate control procedures to ensure that water does not contaminate foodstuffs, thus ensuring food safety for consumers is maintained.

#### *HACCP*

- 2.11 During discussions to make the transitional measure permanent it was agreed that, whilst the quality of clean water can vary along different stretches of coastline, it would not represent a risk to public health if control procedures (for example those based on the Hazard Analysis and Critical Control Point (HACCP) principles as specified in Regulation (EC) 852/2004) are put into place by businesses to ensure that the use of such water in these establishments is not a source of contamination.
- 2.12 The use of clean seawater for the handling and washing of fishery products does not represent a risk for public health as long as control procedures based, in particular, on the Hazard Analysis and Critical Control points (HACCP) principles have been developed and put in place by food business operators to ensure that it complies with the definition of clean seawater set out in Regulation (EC) 852/2004. It was therefore necessary to delete Article 11 of Regulation (EC) 2076/2005 and to make permanent the transitional arrangement provided for in that Regulation as regards the use of clean seawater. Section VIII of Annex III to Regulation (EC) 853/2004 is also amended accordingly.
- 2.13 With regard to water supply, Chapter VII of Annex II of Regulation (EC) 852/2004 provides that potable water is to be used, whenever necessary, to ensure that foodstuffs are not contaminated, and that clean water may be used with whole fishery products. It also provides that clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods, and that clean water may be used for their external washing.
- 2.14 The use of clean water with whole fishery products and for external washing of live bivalve molluscs, echinoderms, tunicates and marine gastropods, does not represent a risk for public health as long as control procedures, based in particular on the Hazard Analysis and Critical Control Point (HACCP) principles, have been developed and

put in place by food business operators to ensure that it is not a source of contamination.

#### *Amendments to 852 and 853*

- 2.15 The above mentioned requirements are achieved by amending Annex II, Section VII of Regulation (EC) 852/2004 and Annex III, Section VIII of Regulation (EC) 853/2004.
- 2.16 Regulation (EC) 1019/2008 amends Regulation (EC) 852/2004 (see separate BRIA) and Regulation (EC) 1020/2008 amends Regulation (EC) 853/2004 respectively.

#### Rationale for government intervention

- 2.17 Failure to provide enforcement provisions for Regulation (EC) 1020/2008 may leave the UK open to monetary sanctions from the European Commission.
- 2.18 Together, Regulations (EC) 1019/2008 and (EC) 1020/2008 ensure that food business operators handling fishery products (e.g. preparation and processing establishments) will be able to continue to use 'clean' water (clean sea/fresh water) when handling fishery products after the end of the transitional period on 31 December 2009. However, when using 'clean' water in this way, these businesses will be required to apply adequate control procedures to ensure that water does not contaminate foodstuffs, thus ensuring food safety for consumers is maintained. This is in accordance with the Scottish Government's national performance framework target to ensure that we live longer, healthier lives.
- 2.19 Intervention is required to apply clear consumer health standards, limit industry costs arising from potential contamination outbreaks and reduce industry costs that would have arisen from having to use potable water from January 2010.

#### Devolution

- 2.20 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

### **3. Consultation**

#### Public Consultation

- 3.1 Stakeholders have been kept informed of the developments of these proposals via notifications on the Agency's website since European negotiations began. In August 2008, an informal consultation letter was issued to a range of stakeholders, including Seafood Scotland and the Seafish Industries Authority (Seafish) which represents a large

proportion of the UK fishing sector. No objections to the proposals were received. The Federation of Small Businesses was also consulted and again, no comments were received.

- 3.2 The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 Stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

#### Within Government

- 3.3 Scottish Government officials from the Rural Directorate and Food & Drink Industry Division were consulted as part of the above-mentioned public consultation as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

#### With Business

- 3.4 This impact assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. Face to face engagement with Scottish business was therefore not carried out during the development process. However, 255 Stakeholders including Scottish small to medium enterprises were consulted on the proposed enforcement measures. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

### **4. Options**

- 4.1 Two options have been identified as follows:

#### **Option 1: Do nothing**

- 4.2 Doing nothing would mean that enforcement of Regulation (EC) 1020/2008 would not be provided for in Scotland and the UK would be in breach of its EU Treaty obligations. This would leave the UK Government open to infraction proceedings by the European Commission, for which Scottish Ministers would be accountable.

#### **Option 2: Support the Regulation's application and provide for its enforcement in Scotland by amending the Food Hygiene (Scotland) Regulations 2006 (as amended).**

- 4.3 This option fully meets the UK Government's commitment to fulfill its EU Treaty obligations. Under these obligations we are required to give effect, in Scotland, to the enforcement provisions of the Regulation. The UK was involved with the Commission and other Member States

throughout the negotiations that developed the Regulation and we supported its adoption.

#### Sectors and Groups affected

- 4.4 Local Authorities are responsible for enforcing the legislation with respect to food safety and will therefore be affected.
- 4.5 Consumers will be affected in that food safety will be maintained.
- 4.6 Land-based establishments using clean water to wash fishery products will be affected. The Agency is not aware of any land-based establishments in Scotland using clean water to wash fishery products at the present time.
- 4.7 However, establishments may wish to do so in the future, and if so, will be required to have in place adequate procedures to ensure the water is not a source of contamination. As all businesses (except primary producers) are currently required to implement and maintain procedures based on the HACCP principles specified in Regulation (EC) 852/2004, the clean water requirement can be incorporated into existing HACCP plans. As such no new administrative burdens have been identified as a result of the introduction of these measures.

#### Benefits

##### **Option 1: Do nothing**

- 4.8 Doing nothing maintains the current position and we are not aware of any benefits associated with Option 1.

##### **Option 2: Support the Regulation's application and provide for its enforcement by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended)**

- 4.9 Providing for the enforcement, in Scotland, of Regulation (EC) 1020/2008 avoids any risk of the UK failing its Treaty obligations, with the consequence of monetary sanctions by the European Commission.
- 4.10 Consumers will benefit from increased consumer protection by ensuring clear food safety standards in sourcing clean water.
- 4.11 Industry will benefit financially from the requirement to use clean rather than potable water when handling fishery products after 31 December 2009. Industry was unable to quantify the possible savings during the consultation.
- 4.12 Industry will also benefit from a consistent EU approach to facilitate trade.



## Costs

### **Option 1: Do nothing**

- 4.13 Doing nothing would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. This would leave the UK Government open to monetary sanctions by the European Commission. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.
- 4.14 Consumer protection may be affected by a lack of clear food safety standards in sourcing clean water.
- 4.15 Industry may be affected by increased costs as a result of having to use potable water in land-based establishments when handling fishery products after 31 December 2009. Industry stakeholders were unable to quantify these costs during the consultation.
- 4.16 Industry may be affected by the lack of a consistent EU approach to facilitate trade.

### **Option 2: Amend the Food Hygiene (Scotland) Regulations 2006**

- 4.17 There may be possible reading and understanding costs, although these are expected to be minimal as we are not aware of any land-based establishments using clean water when handling whole or prepared fishery products.
- 4.18 There may be further possible costs for businesses through the need to implement and maintain procedures based on the HACCP principles (if their current system does not sufficiently assess the water quality). However, as most businesses (except primary producers) are already required to have a HACCP system to manage food safety, it is not expected that these requirements will cause a considerable extra burden.
- 4.19 No additional costs are expected to be incurred as there will be no change to the enforcement regime. Local enforcement authorities will continue to enforce the HACCP requirements as they have done for many years. The required HACCP regime is as specified in Regulation (EC) 852/2004.

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

## **5. Scottish Firms Impact Test**

- 5.1 We are not aware of any adverse effect or any new administrative burdens on Scottish businesses as a result of the introduction of these measures. Informal consultation with the Federation of Small Business during the development of Regulation (EC) 1019/2008 generated no comments.
- 5.2 Please refer to the Consultation section in paragraph 3 above.

## **Competition Assessment**

- 5.3 Using the Office of Fair Trading (OFT) competition assessment Framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

## **Test Run of Business Forms**

- 5.4 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

## **6. Legal Aid Impact Test**

- 6.1 The amending regulations do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

## **7. Enforcement, Sanctions and Monitoring**

- 7.1 Enforcement of the Regulation will be the responsibility of Local Authority Environmental Health Departments.
- 7.2 The effectiveness and impact of the Regulation will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys, and general enquiries from the public.
- 7.3 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

## 8. Implementation and Delivery Plan

- 8.1 Regulation (EC) No. 1020/2008 applied directly in the UK from 28 October 2008 (i.e. 10 days after being published in the EU Official Journal on 18 October 2008).
- 8.2 The publication of the Food Hygiene (Scotland) Amendment Regulations 2012, providing for the enforcement in Scotland of Regulation (EC) 1020/2008, will be communicated to stakeholders by email, letter and via the Agency's website.

### Post-Implementation Review

- 8.3 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in October 2013 (i.e. 5 years from the direct application of Regulation (EC) No. 1020/2008 in the UK).
- 8.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## 9. Summary and Recommendation

- 9.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EC) 1020/2008.
- 9.2 Taking this option allows the Government to fulfil its obligations to implement EU law.
- 9.3 Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.
- 9.4 Summary Costs and Benefits Table

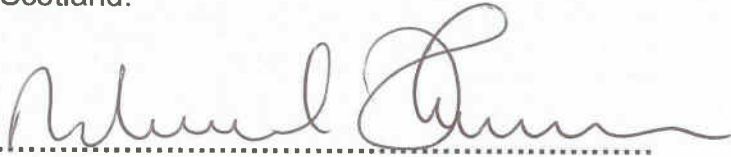
<b>Option</b>	<b>Total Benefit per annum: -Economic, environmental, social</b>	<b>Total Cost per annum: -Economic, environmental, social  - Policy and Administrative</b>
<b>1. Do Nothing</b>	No benefits have been identified.	Risk of infraction proceedings for failure to implement (EC) 1020/2008. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day <sup>2</sup> or some €250

<sup>2</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

		<p>million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.</p> <p>Consumers may be affected by a lack of clear food safety standards in sourcing clean water.</p> <p>Industry may be affected by increased costs as a result of having to use potable water in land-based establishments when handling fishery products.</p> <p>Industry may be affected by the lack of a consistent EU approach to facilitate trade.</p>
<p><b>2. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended)</b></p>	<p>Allows the Government to meet its commitment to fulfil its EU obligations.</p> <p>Consumers will benefit from increased consumer protection by ensuring clear food safety standards in sourcing clean water.</p> <p>Industry will benefit financially from decreased costs as a result of not having to use potable water in land-based establishments when handling fishery products.</p> <p>Harmonises standards across Member States &amp; removes barriers to trade.</p>	<p>One-off financial cost to industry for familiarisation and dissemination is estimated to be minimal.</p> <p>Costs to industry to update their food safety management system are estimated to be minimal.</p> <p>Administrative burdens/ costs- no new or additional costs have been identified.</p> <p>Economic/ social/ environmental cost- negligible.</p>

**10. Declaration and publication**

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature.....

Ministers Title.....*Minister for Public Health*

Date.....*29/2/12*

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## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

### The Food Hygiene (Scotland) Amendment Regulations 2012

To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1020/2008 amending Annex II to Regulation (EC) 853/2004

<b>File No:</b>	SPARD/FSAS
<b>Date:</b>	February 2012
<b>Stage:</b>	Final
<b>Source of intervention:</b>	EU
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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### **1. Title of Proposal**

1.1 The Food Hygiene (Scotland) Amendment Regulations 2012.

### **2. Purpose and Intended Effect**

#### Objectives

- 2.1 To provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008, amending Annexes II and III of Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin, and Regulation (EC) 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products. *This BRIA concerns only those amendments to Section III of Annex II to Regulation (EC) 853/2004 relating to food chain information. Separate BRIAs have been prepared for the other amendments to Regulations 853/2004 and 2076/2005 resulting from Regulation 1020/2008.*
- 2.2 The main policy objective is to provide clarification of the term “Food Chain Information” to ensure FCI terminology is commonly understood across the EU. A harmonised understanding of FCI terminology will help to ensure that information provided at each level of the food chain is consistent across all Member States, improving traceability and minimising any existing potential health risks.

#### Background

- 2.3 Regulation (EC) No. 853/2004 applied on 1 January 2006 setting out specific hygiene rules for food of animal origin. Together with Regulation (EC) No. 852/2004 and Regulation (EC) No. 854/2004 (hygiene rules applicable to all foodstuffs and specific rules for the organisation of official controls on products of animal origin respectively), these formed part of a new package of hygiene measures which consolidated the previous legislation.
- 2.4 Annex II, Section III of Regulation (EC) No. 853/2004, laying down specific rules for food of animal origin, requires slaughterhouse operators to ‘request, receive, check and act upon’ Food Chain Information for poultry, pigs, cattle, sheep, horses and calves sent to slaughterhouses.

- 2.5 This requirement forms part of the whole chain, farm-to-fork approach to food safety, introduced by the Hygiene Regulations from 1 January 2006. Implementation of FCI was initially required only for poultry, with a delayed, progressive implementation of FCI for other species: pigs from 1 January 2008; horse and veal calves from 1 January 2009; and cattle and sheep from 1 January 2010.
- 2.6 FCI contributes to slaughterhouse operators' HACCP-based food safety management systems by providing information about animals sent for slaughter.
- 2.7 The proposal will amend Annex II, Section III, Points 1 and 3 of Regulation (EC) No. 853/2004. It aims to replace the term "**Food Safety** Information" by "**Food Chain** Information". This does not introduce any new requirement.

#### Rationale for Government Intervention

- 2.8 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise, not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.
- 2.9 Slaughterhouse operators and official veterinarians cannot fully assess the health and welfare of animals when they arrive at slaughter, based only on observation of their appearance and behaviour. Government intervention is needed to ensure that information relevant to food safety is contained in the records kept at the holding of provenance, and passed along the food chain to ensure that appropriate actions to protect public health can be taken if necessary. It will also improve the traceability of the incidence of any animal disease, facilitating actions to minimise the risk to consumer health.
- 2.10 As part of a farm-to-fork approach to food safety FCI has been introduced progressively for different species of animals. It provides valuable information on the animals and their holding of origin. It informs slaughterhouse operators and official veterinarians on animal health and welfare, and on specific elements relevant to food safety. Animals presented for slaughter must be accompanied with FCI. The plant's operator evaluates FCI to determine their acceptance for slaughter and any special arrangements. The official veterinarian uses FCI to determine the need for any special ante- and post-mortem inspection or additional actions. There is, therefore, a need to ensure clarity around this information and its use.



2.11 This is in accordance with the Scottish Government's national performance framework target to increase economic sustainable growth in Scotland and that we live longer and healthier lives.

### Devolution

2.12 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

## **3. Consultation**

### Public Consultation

3.1 The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 Stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

### Within Government

3.2 Scottish Government officials from the Rural Directorate and Food & Drink Industry Division were consulted as part of the above-mentioned public consultation as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

### With Business

3.3 This impact assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. Face to face engagement with Scottish business was therefore not carried out during the development process. However, 255 Stakeholders including Scottish small to medium enterprises were consulted on the proposed enforcement measures. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

## **4. Options**

4.1 The options considered to implement the hygiene requirements of Regulation (EC) No. 853/2004 in Scotland are:

Option 1 - Do nothing.

Option 2 - Provide for enforcement of the amended EU hygiene legislation to clarify FCI terminology and provide for its execution and enforcement in Scottish law.

4.2 Sectors and Groups affected – keepers of animals intended for human consumption and slaughterhouse operators.

### Benefits

4.3 *Option 1* – If effect to Regulation (EC) No. 1020/2008 is not given in Scottish law the UK would be in breach of its Treaty obligations with the likely consequence of sanctions by the European Commission. Therefore doing nothing is not an option.

4.4 *Option 2* – The amended EU hygiene legislation will ensure a consistent definition and understanding of the term “Food Chain Information” and correct any existing misinterpretations of FCI across the EU, therefore minimising any existing associated health risks. The provision of enforcement powers in Scottish law will ensure these objectives are met in Scotland. Because the terms are used interchangeably in Scotland there are few direct benefits from the amendment. However, if FCI has been misinterpreted in other EU Member States, clarification of the regulatory requirements should correct this. Consistent use of FCI in the EU may result in smoother trade between businesses in Scotland and other EU Member States. There may also be an impact in minimising any existing associated health risks. The extent of these impacts is uncertain, and therefore these are not monetised.

### Costs

4.5 *Option 1* – Doing nothing would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. This would leave the UK Government open to monetary sanctions by the European Commission. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.

4.6 *Option 2* - There may be costs associated with reading and understanding the amended regulation, but these are expected to be negligible because the terms “Food Chain Information” and “Food Safety Information” are used interchangeably in Scotland. The amendment only clarifies FCI terminology and does not change the obligations on food businesses to request, receive, check and act upon

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

FCI. Both producers and slaughterhouse operators in Scotland are already compliant with the existing FCI requirements.

## **5. Scottish Firms Impact Test**

5.1 We are not aware of any adverse effect or any new administrative burdens on Scottish businesses as a result of the introduction of these measures. Informal consultation with the Federation of Small Business during the development of Regulation (EC) 1019/2008 generated no comments.

5.2 Please refer to the Consultation section in paragraph 3 above.

### Competition Assessment

5.3 Using the Office of Fair Trading (OFT) competition assessment Framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously. Since the terms “Food Safety Information” and “Food Chain Information” had been previously used interchangeably in Scotland, there are not thought to be any impact on firms, including those that are small in size.

### Test Run of Business Forms

5.4 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

## **6. Legal Aid Impact Test**

6.1 The amending regulations do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

## **7. Enforcement, Sanctions and Monitoring**

7.1 The Food Standards Agency Operations Group (FSAOG)<sup>2</sup> will be responsible in Scotland and elsewhere in GB for enforcement; sanctions and monitoring for meat hygiene requirements set out in the Regulations.

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<sup>2</sup> The executive agency status of the MHS was dissolved on 31 March 2010 and, as of 1 April 2010, its functions and staff were formally integrated into the FSA.

- 7.2 The effectiveness and impact of the Regulation will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys, and general enquiries from the public.
- 7.3 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

## **8. Implementation and Delivery Plan**

- 8.1 Regulation (EC) No. 1020/2008 applied directly in the UK from 28 October 2008 (i.e. 10 days after being published in the EU Official Journal on 18 October 2008).
- 8.2 The publication of the Food Hygiene (Scotland) Amendment Regulations 2012, providing for the enforcement in Scotland of Regulation (EC) 1020/2008, will be communicated to stakeholders by email, letter and via the Agency's website.

### Post-Implementation Review

- 8.3 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in October 2013 (i.e. 5 years from the direct application of Regulation (EC) No. 1020/2008 in the UK).
- 8.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## **9. Summary and Recommendation**

- 9.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EC) 1020/2008.
- 9.2 Taking this option allows the Government to fulfil its obligations to implement EU law.
- 9.3 Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

9.4 Summary Costs and Benefits Table

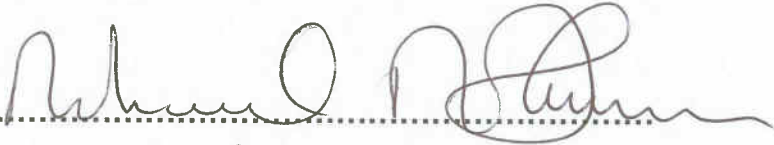
Option	Total Benefit per annum: <b>-Economic, environmental, social</b>	Total Cost per annum: <b>-Economic, environmental, social</b>  <b>- Policy and Administrative</b>
<b>1. Do Nothing</b>	No benefits have been identified.	<p>Risk of infraction proceedings for failure to implement (EC) 1020/2008. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>3</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.</p> <p>Industry may be affected by the lack of a consistent EU approach to facilitate trade.</p>
<b>2. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</b>	<p>Allows the Government to meet its commitment to fulfil its EU obligations.</p> <p>Will ensure a consistent definition and understanding of the term "Food Chain Information" and correct any existing misinterpretations of FCI across the EU, therefore minimising any existing associated health risks.</p> <p>Harmonises standards across Member States &amp; removes barriers to trade.</p>	<p>One-off financial cost to industry for familiarisation and dissemination is estimated to be minimal.</p> <p>Costs to industry to update their food safety management system are estimated to be minimal.</p> <p>Administrative burdens/ costs- no new or additional costs have been identified.</p> <p>Economic/ social/ environmental cost- negligible.</p>

<sup>3</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

## 10. Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature.....



Ministers Title .....

Minister for Public Health

Date.....

29/2/12

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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

**The Food Hygiene (Scotland) Amendment Regulations 2012.**

**To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1020/2008 amending Annex III of Regulation (EC) 853/2004**

<b>Ref No:</b>	SPARD/FSAS
<b>Date:</b>	February 2012
<b>Stage:</b>	Final
<b>Source of intervention:</b>	EU
<b>Contact for enquiries:</b>	Stewart Herd 01224 285154 <a href="mailto:Stewart.Herd@foodstandards.gsi.gov.uk">Stewart.Herd@foodstandards.gsi.gov.uk</a>

## 1. Title of Proposal

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### 1.1. The Food Hygiene (Scotland) Amendment Regulations 2012

## 2. Purpose and intended effect

### Objectives

- 2.1. To provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008 amending Annexes II and III of Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin and Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products. *This BRIA concerns only those amendments relating to those establishments that break out cracked eggs and freeze or refrigerate them before transport to another establishment for the production of liquid egg. Separate BRIAs have been prepared for the other amendments to Regulations (EC) 853/2004 and (EC) 2076/2005 resulting from Regulation 1020/2008.*
- 2.2. The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulations (EC) 852/2004 and (EC) 853/2004. There is a need, therefore, to amend the Food Hygiene (Scotland) Regulations 2006 (as amended) in order to provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008.
- 2.3. The intended effect is to prevent increased costs to industry and unnecessary waste of foodstuffs, whilst maintaining the same level of public health protection. The EC Regulation makes permanent a temporary measure allowing food businesses to be approved under food hygiene regulations to break out cracked eggs, and transport the frozen or refrigerated content for processing at an establishment approved for that purpose.

### Background

- 2.4. Regulation (EC) 853/2004, which applied from 1 January 2006, laid down special hygiene measures for food businesses handling products of animal origin, including, in Annex III, Section X, Chapter II, measures for eggs and egg products. Regulation (EC) 853/2004 also consolidated the previous EC food hygiene legislation that applied to establishments handling foods of animal origin, including EC Directive 89/437 on hygiene and health problems affecting the production and the placing on the market of egg products.
- 2.5. In summary, since 1 January 2006, the legal requirements for egg products have been that liquid egg and processed egg contents (e.g. pasteurised egg yolk) can only be produced by approved establishments. There are also a number of specific hygiene requirements, including requirements for raw materials, process criteria and end product testing requirements.



- 2.6. However, the effect of these provisions was to prohibit the breaking out (i.e. the removal of the white and yolk) of cracked eggs by producers and packers for heat treatment at another approved establishment, which was previously allowed. This practice had been used in Scotland for many years without any negative impact on human health. It is common practice in small and large businesses, because it is very simple to achieve and approval requirements are minimal.
- 2.7. Subsequently, in order that practices undertaken prior to 1 January 2006 could continue, EU Member States agreed that this provision should be reinstated temporarily while the issue was discussed further. The provision was therefore enacted for a transitional period until 31 December 2009 in Regulation (EC) 2076/2005. It has been agreed that the provision should remain permanently, which has been achieved by amending Regulation (EC) 853/2004 by Regulation (EC) 1020/2008, which applied from October 2008.

### **Rationale for Government intervention**

- 2.8 Failure to provide enforcement provisions for regulation (EC) 1020/2008 may leave the UK open to infraction proceedings from the European Commission for which Scottish Ministers would be accountable.
- 2.9 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.
- 2.10 In order to address this information asymmetry and protect human health, hygiene standards are set out in EU legislation. In this case, hygiene standards specify the treatment of eggs and egg products. However, to be efficient, these hygiene controls need to be proportionate to the risk with all the costs of compliance fully justified by the benefits so an amendment is needed to allow cracked eggs to be treated more appropriately.
- 2.11 This is in accordance with the Scottish Government's national performance framework to increase economic sustainable growth in Scotland and that we live longer and healthier lives

### **Devolution**

- 2.12 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

## **3. Consultation**

### **Within Government**

- 3.1 Scottish Government officials from the Rural Directorate and Food and Drink Industry Division were consulted as part of the public consultation mentioned below, as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

### **Public Consultation**

- 3.2 The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

### **Business**

- 3.3 This impact assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. Face to face engagement with Scottish business was therefore not carried out during the development process. Informal consultation took place with the British Egg Products Association, which represents the egg products industry in the UK, in 2006. There were no objections to the Regulation's application. 255 stakeholders, including Scottish small to medium enterprises, were consulted on the proposed enforcement measures. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders. The proposals are simply allowing current practices to continue and place no new criteria on business.

## **4. Options**

- 4.1. Two options have been identified, the details of which are set out below:
- 4.2. Option 1. Do nothing. If effect to Regulation (EC) No. 1020/2008 is not given in Scottish law, the UK would be in breach of its Treaty obligations with the likely consequence of sanctions by the European Commission. Resisting this amendment would increase the amount of eggs wasted by cracked eggs breaking in transit to processing establishments. It could also mean that producers and packers stop sending cracked eggs for processing, thereby increasing waste because of it being impractical or uneconomic.
- 4.3. Option 2. Provide for the enforcement in Scottish law of Regulation (EC) 1020/2008 which will permanently allow food businesses to be approved under food hygiene regulations to break out cracked eggs, and transport the frozen or refrigerated content for processing at an establishment approved for that purpose. This option fully meets the UK Government's commitment to fulfill its EU obligations. Under Treaty obligations we are required to give effect in the UK to the enforcement provisions of the Regulation. The UK was involved with the Commission and other Member States throughout the negotiations that developed the Regulation and we supported its adoption.

### **Sectors and groups affected**

- 4.4. The Egg Industry will be affected if the amendment is resisted as explained at para 4.2 above.
- 4.5. Local authorities are responsible for enforcing the legislation with respect to food safety but there will be no change to the enforcement regime and therefore no additional costs will be incurred.

## **Industry**

### **Benefits**

#### Option 1 – Do nothing

- 4.6. This option is considered to have no benefits

#### Option 2 - provide for the enforcement in Scottish law of Regulation (EC) 1020/2008.

- 4.7. This option prevents the approximately 7 egg industry establishments in Scotland from incurring the costs outlined below.

### **Costs**

#### Option 1 – Do nothing

- 4.8. If businesses cannot continue to break out cracked eggs and transport the contents for processing at an approved establishment, eggs may become broken in transit. Industry figures suggest this would result in average yearly costs in the order of £500; consequently, the option has estimated costs of £3,500 (7 times £500). Option 1 would also mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.

#### Option 2 – Provide for the enforcement in Scottish law of Regulation (EC) 1020/2008.

- 4.9. Provide for the enforcement of Regulation (EC) 1020/2008, which, by amending EC Regulation 853/2004, will allow practices to continue. The level of public health protection will be maintained at the same level as under the do nothing option.

## **5. Scottish Firms Impact Test**

- 5.1. As noted in the Consultation section above, the Agency undertook informal consultation with the British Egg Products Association, which represents the egg products industry (including SMEs) in the UK, during 2006. There were no

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

objections to the Regulation's application, which is considered to be cost beneficial to industry.

- 5.2. Small to medium enterprises were included in the formal consultation on the proposed enforcement measures.
- 5.3. The proposals are simply allowing current practices to continue and place no new criteria on business.

#### **Competition Assessment**

- 5.4 As this Regulation applies to all relevant businesses, there are not considered to be any issues for competition.
- 5.5 Using the Office of Fair Trading (OFT) competition assessment framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

#### **Test run of business forms**

- 5.6 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to businesses affected by the Regulation. The recommended option will maintain the status quo so there will be no additional administrative burdens created by the measure.

### **6. Legal Aid Impact Test**

- 6.1 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce new criminal sanctions or civil penalties, therefore there are no legal aid implications. This assumption has been confirmed by the Access to Justice Team of the Scottish Government.

### **7. Enforcement, sanctions and monitoring**

#### **Enforcement**

- 7.1 Local Authority Environmental Health Departments in Scotland will enforce the requirements as they have done for many years. There are only 7 establishments approved for the activity in Scotland who will just need the usual inspection and control activity they have received up to now. The approval regime is the existing one for Regulation (EC) 853/2004.

#### **Sanctions**

- 7.2 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

## Monitoring

- 7.3 The effectiveness and impact of the 2012 amending Regulations will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys and general enquiries from the public.

## 8. Implementation and delivery plan

- 8.1 Regulation (EC) 1020/2008 applied directly in the UK from 28<sup>th</sup> October 2008.
- 8.2 The publication of the Food Hygiene (Scotland) Amendment Regulations 2012, providing for the enforcement in Scotland of Regulation (EC) 1020/2008 will be communicated to stakeholders through the Agency's website and FSA News.

## 9. Post-implementation review

- 9.1 A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulation, will take place in October 2013 (i.e. 5 years from the direct application in the UK of Regulation (EC) 1020/2008).
- 9.2 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## 10. Summary and recommendation

- 10.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EC) 1020/2008. Taking this option allows the Government to fulfil its obligations to implement EU law. It also ensures that Enforcement Authorities can fulfil the requirements placed on them and the Courts can impose penalties consistent with those elsewhere in Food Law. Implementation of this legislation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

## 11. Summary costs and benefits table

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social - Policy and Administrative
1. Do Nothing	No benefits have been identified	Risk of infraction proceedings for failure to implement (EC) 1020/2008. Possible fines of up to €703,000 per day.  Industry may be affected by the lack of a consistent EU approach to facilitate trade.  Not to allow around 7 establishments in Scotland to break out cracked eggs and transport the contents for processing at an

		approved establishment would result in cracked eggs being broken in transit resulting in a cost to business from wasted eggs of seven times £500 - £3,500 a year. Producers and packers may also stop sending cracked eggs for processing, thereby increasing waste because of it being impractical or uneconomic.
<b>2. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</b>	<p>Allows the Government to meet its commitment to fulfil its EU obligations.</p> <p>Saves £3,500 to industry by preventing cracked eggs being broken in transit.</p> <p>Consumers will benefit from increased consumer protection by ensuring clear food safety standards</p>	No additional administrative burdens/costs or costs have been identified.

## 12. Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Ministers signature



Ministers title

Minister for Public Health

Date

29/12/12

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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

**The Food Hygiene (Scotland) Amendment Regulations 2012.**

**To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1020/2008 amending Annex III of Regulation (EC) 853/2004**

**Ref No:** SPARD/FSAS  
**Date:** February 2012  
**Stage:** Final  
**Source of intervention:** EU  
**Contact for enquiries:** Stewart Herd  
01224 285154  
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## 1. Title of Proposal

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAs developed after the new rules were in place.*

### 1.1. The Food Hygiene (Scotland) Amendment Regulations 2012

## 2. Purpose and intended effect

### Objectives

- 2.1. To provide for the enforcement, in Scotland, of Regulation (EC)1020/2008 amending Annexes II and III of Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin and Regulation (EC) 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products. *This BRIA concerns only those amendments relating to testing to ensure that raw cow's milk meets a limit criterion on bacteria content before processing, unless the processing is carried out within a set time limit. Separate BRIAs have been prepared for the other amendments to Regulations (EC) 853/2004 and (EC) 2076/2005 resulting from Regulation 1020/2008.*
- 2.2. The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulations (EC) 852/2004 and (EC) 853/2004. There is a need, therefore, to amend the Food Hygiene (Scotland) Regulations 2006 (as amended) in order to provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008.
- 2.3. The intention of enforcing this measure is to ensure that food business operators manufacturing dairy products from raw cows' milk will continue to not to have to carry out testing to establish the plate count levels of milk prior to processing, *as long as* that milk is processed within the time scales specified in the HACCP procedures. Extending the reliance on HACCP-based procedures should make it simpler for businesses to comply with the legislation.
- 2.4. Enforcement of this measure is intended to reduce and prevent increased costs to industry, whilst maintaining the existing satisfactory level of protection to public health. This will apply to manufacturers processing raw cows' milk and heat treated cows' milk.

### Background

- 2.5. Regulation (EC) 853/2004 applied in the UK from 1 January 2006 and sets out food hygiene requirements relating to products of animal origin. Annex III, Section IX, Chapter II, Part II, point 1 requires food business operators manufacturing dairy products to initiate procedures to ensure that, immediately prior to processing:
  - raw cows' milk used to prepare dairy products had a plate count at 30°C of less than 300,000 per ml



- processed cows' milk used to prepare dairy products has a plate count at 30°C of less than 100,000 per ml.
- 2.6. Regulation (EC) 2076/2005 introduced a number of transitional measures for the hygiene Regulations for a period of 4 years (i.e. up until 31 December 2009). This included a derogation that the plate count criteria for raw cows' milk intended for the manufacturing of dairy products should be required only where the milk had not been processed within the pre-defined time set out in the HACCP procedures.
- 2.7. Regulation (EC) 1020/2008 has been introduced to make the transitional arrangement for raw cows' milk described above permanent. In addition, the same principle applies to heat treated (processed) cows' milk intended for the manufacturing of dairy products (i.e. the plate count criteria should apply only where the milk had not been processed within the pre-defined time as set out in the HACCP procedures). This supports the principle (as previously provided by the derogation in Regulation (EC) 2076/2005) that it should be possible to ensure food safety within the provisions of the HACCP procedures providing the age of the milk is taken into account.
- 2.8. Enforcing EC Regulation 1020/2008 in Scotland will mean food business operators manufacturing dairy products from raw cow's milk will continue not to have to carry out testing to establish the plate count levels of milk prior to processing as long as that milk is processed within the time scales specified in the HACCP procedures. Evidence of the relevant testing would continue not be required for enforcement authority checks and occasional follow-up work. This will continue to provide savings for both businesses and enforcement agencies. This business and regulatory impact assessment has been calculated using the original provision (requiring plate count testing for cows' milk for processing) as its baseline.

#### **Rationale for Government intervention**

- 2.9. Failure to provide enforcement provisions for Regulation 1020/2008 may leave the UK open to infraction proceedings from the European Commission, for which Scottish Ministers would be accountable.
- 2.10. Food products can pose a potential risk to human health if pathogenic bacteria are present.
- 2.11. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.
- 2.12. In order to address this information asymmetry and protect human health, hygiene standards are set out in EU legislation. In this case, hygiene standards are set to ensure that raw cows' milk meets a limit criterion on bacteria plate count before processing. However, to be efficient these hygiene controls need

to be proportionate to the risk with all the costs of compliance fully justified by the benefits.

- 2.13 This is in accordance with the Scottish Government's national performance framework target to increase economic sustainable growth in Scotland and that we live longer and healthier lives.

### **Devolution**

- 2.14 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

## **3. Consultation**

### **Within Government**

- 3.1. Scottish Government officials from the Rural Directorate and Food and Drink Industry Division were consulted as part of the above-mentioned public consultation as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

### **Public Consultation**

- 3.2. The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

### **Business**

- 3.3 This impact assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. Face to Face engagement with Scottish business was therefore not carried out during the development process. Informal consultation took place with Dairy UK, which represents farming and processing in the dairy industry in the UK, during the negotiations leading up to the issue of Regulation (EC)1020/2008. There were no objections to what was proposed. 255 were consulted on the proposed enforcement measures. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by Stakeholders. The proposals are placing no new burdens on business.

## **4. Options**

- 4.1. Two options have been identified, the details of which are set out below:
- 4.2. Option 1. Doing nothing would mean that enforcement of the Regulation would not be provided for in Scotland and the UK would be in breach of its EU obligations. This option would require plate count testing to be carried out for all cow's milk intended for processing.
- 4.3. Option 2. Provide for the enforcement in Scotland of Regulation (EC) 1020/2008 which will enable food business operators manufacturing dairy

products from raw cow's milk to be able to continue not to have to carry out testing to establish the plate count levels of milk prior to processing as long as that milk is processed within the time scales specified in the HACCP procedures. This option fully meets the UK Government's commitment to fulfil its EU obligations. Under Treaty obligations we are required to give effect in the UK to the enforcement provisions of the Regulation. The UK was involved with the Commission and other Member States throughout the negotiations that developed the Regulation and we supported its adoption.

### **Sectors and groups affected**

- 4.4. Enforcing Regulation (EC) 1020/2008 will continue to reduce costs for those parts of the dairy industry processing cow's milk.
- 4.5. Local authorities are responsible for enforcing the legislation with respect to food safety but there will be no change to the existing enforcement regime..

### **Benefits**

#### Option 1 – Do nothing

- 4.6. This option is considered to have no benefits

#### Option 2 - provide for the enforcement in Scottish law of Regulation (EC) 1020/2008.

- 4.7. Enforcing regulation (EC) 1020/2008 will continue to reduce costs (and therefore has an implied benefit) for those parts of the dairy industry processing cows' milk. There is no reduction in the level of public health protection.
- 4.8. We are assuming that the cost for carrying out a plate count test is £5. Approximately 60 silos of raw cows' milk and 60 silos of heat treated milk would require testing on average 250 times pa under the current legislation. Under the proposal, no raw milk will be tested and the proportion of heat treated milk tested will decrease steadily from 100 % to 0% within 5 years, as processors adapt.
- 4.9. Option 2 will affect approximately 120 silos of milk in Scotland each year. If no amendments were made, platelet counts on raw cows' milk would be required, and so the benefit of an amendment in the raw cows' milk sector is the cost saving from not starting to carry out the platelet counts. Because businesses are not currently required to conduct platelet counts on raw cows' milk, we assume no platelet counts would be conducted and so the full saving would occur immediately. However, businesses producing heat treated (processed) cows' milk intended for the manufacturing of dairy products are currently required to conduct platelet counts. Therefore, we assume such businesses would not all immediately cease conducting platelet counts, but there would be a gradual decrease in testing with no platelet counts being conducted within five years.
- 4.10. By the fifth year we expect there would be an approximate saving to industry in Scotland of £150,000 per year from avoiding the costs of platelet counts. The cost of a platelet count test is approximately £5. It is estimated that approximately 60 silos of raw cows' milk and 60 silos of heat treated cows' milk would need to be tested, on average, 250 times per year. The annual total for

all milk is therefore £150,000 (£5x120x250). We assume the full benefit accrues to raw cows' milk producers from the first year, and for heat treated (processed) cows' milk producers there is a steady rate of progress from all milk needing to be tested at the start of the first year to no milk being tested by the fifth year. This means that 60% of the full benefit is felt in year 1, and this rises to 100% of the full benefit in year 5.

4.11. There is also expected to be a small saving to enforcement agencies, as they will not need to investigate historical test results or carry out occasional follow up work. The scale of this impact is uncertain and this saving is, therefore, not monetised.

Year	0	1	2	3	4	Average
Percentage of raw milk tested	0%	0%	0%	0%	0%	
Saving for raw milk (£m) 2008 terms	0.075	0.075	0.075	0.075	0.075	0.075
Percentage of heat treated milk tested	80%	60%	40%	20%	0%	
Saving for heat treated milk (£m) 2008 terms	0.015	0.030	0.045	0.060	0.075	0.045
Total saving (£m) 2008 terms	0.090	0.105	0.120	0.135	0.150	0.120
Discounted Total Saving (£m)	0.090	0.101	0.112	0.122	0.131	
Present value	0.556					

## Costs

### Option 1 – Do nothing

4.12. Plate count testing would be required to be carried out for all cow's milk intended for processing. The costs for option 1 would therefore equate to the benefits outlined in the Benefits section for Option 2, above. Option 1 would also mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine (potentially up to 100%) if the infraction related to devolved matters, depending on the extent of our involvement.

<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

Option 2 – Provide for the enforcement in Scottish law of Regulation (EC) 1020/2008.

- 4.13. Provide for the enforcement of Regulation (EC) 1020/2008, which, by amending 853/2004, will allow practices to continue. One-off financial cost to industry for familiarisation and dissemination is estimated to be minimal. Costs to industry to update their food safety management system are estimated to be minimal. The level of public health protection will be maintained at the same level as under the do nothing option.

**5. Scottish Firms Impact Test**

- 5.1. As noted in the Consultation section above, the Agency informally consulted with Dairy UK, during the negotiations leading up to the issue of Regulation (EC)1020/2008.
- 5.2. Small to medium enterprises were included in the formal consultation on the proposed enforcement measures.
- 5.3. The proposals are placing no new burden on business.

**Competition Assessment**

- 5.4. We do not expect this proposal to directly or indirectly limit the number or range of businesses, to limit the ability of businesses to compete, or to reduce the incentives to compete vigorously. The removal of the requirement to test will apply equally to all businesses and does not prevent each from implementing any testing regime they choose.
- 5.5. Using the Office of Fair Trading (OFT) competition assessment framework it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

**Test run of business forms**

- 5.6. The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to businesses affected by the Regulation

**Legal Aid Impact Test**

- 5.7. The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce new criminal sanctions or civil penalties, therefore there are no legal aid implications. This assumption has been confirmed by the Access to Justice Team of Scottish Government.

**6. Enforcement, sanctions and monitoring**

**Enforcement**

- 6.1. There will be no change to the existing enforcement regime. Local Authority Environmental Health Departments in Scotland will continue to enforce the

requirements relating to approval of dairy processors under Regulation (EC) 853/2004.

### **Sanctions**

- 6.2. No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

### **Monitoring**

- 6.3. The effectiveness and impact of the 2012 amending Regulations will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys and general enquiries from the public.

## **7. Implementation and delivery plan**

- 7.1. Regulation (EC) 1020/2008 applied directly in the UK from 28<sup>th</sup> October 2008.
- 7.2. The publication of the Food Hygiene (Scotland) Amendment Regulations 2012, providing for the enforcement in Scotland of Regulation (EC) 1020/2008 will be communicated to stakeholders through the Agency's website and FSA News.

## **8. Post-implementation review**

- 8.1. A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulation, will take place in October 2013 (i.e. 5 years from the direct application in the UK of Regulation (EC) 1020/2008).
- 8.2. A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## **9. Summary and recommendation**


- 9.1. The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EC) 1020/2008. Taking this option allows the Government to fulfil its obligations to implement EU law. It also ensures that Enforcement Authorities can fulfil the requirements placed on them and the Courts can impose penalties consistent with those elsewhere in Food Law. Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

## 10. Summary costs and benefits table

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social  - Policy and Administrative
1. Do Nothing	No benefits have been identified	Risk of infraction proceedings for failure to implement (EC) 1020/2008. Possible fines of up to €703,000 per day.
2. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).	<p>Allows the Government to meet its commitment to fulfil its EU obligations.</p> <p>Enforcing regulation (EC) 1020/2008 will continue to reduce costs for those parts of the dairy industry processing cows' milk as explained in paras 4.6 – 4.11..</p> <p>There is expected to be a small saving to enforcement agencies as they will not need to investigate historical test results or carry out occasional follow up work. The scale of this impact is uncertain and this saving is therefore not monetised.</p> <p>Extending the reliance on HACCP-based procedures should make it simpler for businesses to comply with the legislation.</p>	No changes to administrative burden costs to industry are expected.

## 11. Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Ministers signature   
Ministers title *Minister for Public Health*  
Date *29/2/12*

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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

**The Food Hygiene (Scotland) Amendment Regulations 2012.**

**To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1020/2008 amending Annex III of Regulation (EC) 853/2004**

**Ref No:** SPARD/FSAS  
**Date:** February 2012  
**Stage:** Final  
**Source of intervention:** EU  
**Contact for enquiries:** Stewart Herd  
01224 285154  
[Stewart.Herd@foodstandards.gsi.gov.uk](mailto:Stewart.Herd@foodstandards.gsi.gov.uk)

## 1. Title of Proposal

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### 1.1. The Food Hygiene (Scotland) Amendment Regulations 2012

## 2. Purpose and intended effect

### Objectives

- 2.1. To provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008 amending Annexes II and III of Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin and Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products. *This BRIA concerns only those amendments to Regulation (EC) 853/2004 and Regulation EC 2076/2005 relating to the temperature requirements for the storage and transportation of eggs. Separate BRIAS have been prepared for the other amendments to Regulations (EC) 853/2004 and (EC) 2076/2005 resulting from Regulation 1020/2008.*
- 2.2. The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulations (EC) 852/2004 and (EC) 853/2004. There is a need, therefore, to amend the Food Hygiene (Scotland) Regulations 2006 (as amended) in order to provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008.
- 2.3. Regulation (EC) 1020/2008 amends Regulation (EC) 853/2004, and has made permanent the arrangements whereby EU Member States have the flexibility to specify existing national temperature requirements for the storage and transportation of eggs. Enforcement of this Regulation will maintain good food hygiene with regard to the climatic conditions of each Member State and the same level of public health protection, without placing any new or additional requirements on industry.

### Background

- 2.4. EU food hygiene regulations (including Section X of Annex III of Regulation (EC) 853/2004) which applied from 1 January 2006, require eggs to be “stored and transported at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties”. However, those Member States which had, before 1 January 2006, preferred to transport eggs under temperature requirements laid down in their own national legislation could continue to do so under Regulation (EC) 2076/2005 which allowed this on a temporary and transitional basis until 31 December 2009.
- 2.5. Regulation (EC) 1020/2008 makes permanent the transitional arrangement that allows food businesses to store and transport eggs in accordance with nationally applied temperature requirements, and repeals the temporary arrangements as set out in Regulation (EC) 2076/2005.

- 2.6 Since the implementation of Regulation (EC) 2076/2005, the use of national temperature requirements for the storage and transport of eggs has been considered further and found not to interfere with the food safety objectives described in Regulation (EC) 853/2004. The transitional arrangements will, therefore be made permanent by amending Regulation (EC) 853/2004
- 2.7 The history of Regulation (EC) 1020/2008 is that the amendment was originally issued in draft form on 8 January 2008 as SANCO/43/2008 and underwent several amendments before publication in the EU Official Journal on 18 October 2008 as Commission Regulation (EC) 1020/2008, to come into force 10 days later. Details of the negotiations can be found at:  
<http://food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu>
- 2.8 No specific temperature requirements beyond the basic requirement stipulated in Regulation (EC) 853/2004 are in force in Scotland and the amendment does not impose any new requirements to be implemented for the storage and transportation of eggs.
- 2.9 It is possible that, if eggs are exported to other Member States, producers or wholesalers in Scotland might need to comply with national requirements that exist in other Member States.

### **Rationale for Government intervention**

- 2.10 Failure to provide enforcement provisions for Regulation 1020/2008 may leave the UK open to infraction proceedings from the European Commission for which Scottish Ministers would be accountable.
- 2.11 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.
- 2.12 In general, consumers cannot observe the production, manufacturing or handling process of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.
- 2.13 In order to address this information asymmetry and protect human health, hygiene standards are set out in EU legislation. In this case, hygiene standards specify the temperature at which eggs may be transported. However, to be efficient these hygiene controls need to be proportionate to the risk with all the costs of compliance fully justified by the benefits, so the flexibility is needed to set a temperature that is appropriate to the climate of each country.
- 2.14 This is in accordance with the Scottish Government's national performance framework target - that we live longer and healthier lives.

### **Devolution**

- 2.15 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

### **3. Consultation**

#### **Within Government**

- 3.1 Scottish Government officials from the Rural Directorate and Food and Drink Industry Division were consulted as part public consultation mentioned below, as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

#### **Public Consultation**

- 3.2 In 2008, informal consultations took place with the British Egg Industry Council (BEIC), British Free Range Egg Producers Association (BFREPA), which represents the egg products industry in the UK, and the Local Authorities Co-ordinating Organisation on Regulatory Standards (LACORS), which represents enforcement bodies in the UK. There were no objections.
- 3.3 The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 Stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

#### **Business**

- 3.4 This impact assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. Face to face engagement with Scottish business was therefore not carried out during the development process. As well as the informal consultation with the British Egg Industry Council detailed above, 255 stakeholders, including Scottish small to medium enterprises, were included in the public consultation on the proposed enforcement measures. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders. The proposals are simply allowing current practices to continue and place no new criteria on business.

### **4. Options**

- 4.1. Two options have been identified, the details of which are set out below:
- 4.2. Option 1. Do nothing. This would mean that enforcement of the Regulation would not be provided for in Scotland and the UK would be in breach of its EU Treaty obligations. Allowing the temporary arrangement to lapse would have prevented Member States from continuing to apply existing temperature requirements for the storage and transportation of eggs beyond December 2009. This could have adversely affected the hygienic condition of eggs that could be imported into Scotland.
- 4.3. Option 2 – Provide for the enforcement in Scottish law of Regulation (EC) 1020/2008. This will permit the continued use of existing national temperature controls, and enables Member States to apply such requirements that are considered appropriate, in that it allows Member States to conserve the hygienic properties of the eggs, and so maintain the current level of public health protection. Enforcing the EC Regulation fully meets the UK Government's commitment to fulfil its EU obligations. Under Treaty obligations

we are required to give effect in Scotland to the enforcement provisions of the Regulation. The UK was involved with the Commission and other Member States throughout the negotiations that developed the Regulation and we supported its adoption.

### **Sectors and groups affected**

- 4.4 The Egg Industry may be affected as it is possible that, if eggs are exported to other Member States, producers or wholesalers in Scotland might need to comply with national requirements that exist in other Member States.
- 4.5 Local authorities are responsible for enforcing the legislation with respect to food safety but there will be no change to the enforcement regime and therefore no additional costs will be incurred.

### **Benefits**

#### Option 1 – Do nothing

- 4.6 This option is considered to have no benefits.

#### Option 2 – Support the application of the Regulations and provide for the enforcement in Scottish law of Regulation (EC) 1020/2008.

- 4.7 This option offers a potential, though unquantifiable, benefit to consumers in Scotland by ensuring that eggs, imported from other Member States will, where appropriate, continue to be stored and transported at temperatures best suited to assure optimal conservation of their hygiene properties in the originating Member State.

### **Costs**

#### Option 1 – Do nothing

- 4.8 Option 1 would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine (potentially up to 100%) if the infraction related to devolved matters, depending on the extent of our involvement.

#### Option 2 – Provide for the enforcement in Scottish law of Regulation (EC) 1020/2008.

- 4.9 Option 2 is not considered to have any cost impact.

## **5. Scottish Firms Impact Test**

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

- 5.1. Informal consultation was undertaken with the British Egg Industry Council (BEIC) and British Free Range Egg Producers Association (BFREPA), whose members include SMEs.
- 5.2. Small to medium enterprises were included in the formal consultation on the proposed enforcement measures.
- 5.3 The proposals are simply allowing current practices to continue and place no new criteria on business

## **6. Competition Assessment**

- 6.1 The 2012 amending regulations should not have any implications for competition as they do not impose any new requirements on any businesses in Scotland.
- 6.2 Using the OFT competition assessment framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously

## **7. Test run of business forms**

- 7.1 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to businesses affected by the Regulation

## **8. Legal Aid Impact Test**

- 8.1 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce new criminal sanctions or civil penalties, therefore there are no legal aid implications. This assumption has been confirmed by the Access to Justice Team of Scottish Government.

## **9. Enforcement, sanctions and monitoring**

### **Enforcement**

- 9.1 Enforcement of the Regulations in Scotland will continue to be the responsibility of Local Authority Environmental Health Departments.

### **Sanctions**

- 9.2 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment, to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with the Food Safety Act 1990.

### **Monitoring**

- 9.3 The effectiveness and impact of the 2012 amending regulations will be monitored via feedback from stakeholders as part of the ongoing monitoring

process. Agency mechanisms for monitoring and review include: open for a, stakeholder meetings, surveys and general enquiries from the public.

## 10. Implementation and delivery plan

10.1 Regulation (EC) 1020/2008 applied directly in the UK from 28<sup>th</sup> October 2008.

10.2 The publication of the Food Hygiene (Scotland) Amendment Regulations 2012, providing for the enforcement in Scotland of Regulation (EC) 1020/2008 will be communicated to stakeholders through the Agency's website and FSA News.

## 11. Post-implementation review

11.1 A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulation, will take place in October 2013 (i.e. 5 years from the direct application in the UK of Regulation (EC) 1020/2008).

11.2 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## 12. Summary and recommendation

12.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EC) 1020/2008. Taking this option allows the Government to fulfil its obligations to implement EU law. It also ensures that Enforcement Authorities can fulfil the requirements placed on them and the Courts can impose penalties consistent with those elsewhere in Food Law. Implementation of this legislation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.


## 13. Summary costs and benefits table

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social - Policy and Administrative
1. Do Nothing	No benefits have been identified	Risk of infraction proceedings for failure to implement (EC) 1020/2008. Possible fines of up to €703,000 per day.
2. Support the Regulation's application and provide for its enforcement in	Allows the Government to meet its commitment to fulfil its EU obligations.	Administrative burdens/costs- no new or additional costs have been identified  The economic/social/environmental cost

<p><b>Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</b></p>	<p>Consumers will benefit from increased consumer protection by ensuring clear food safety standards</p> <p>This option offers a potential though unquantifiable benefit to consumers in Scotland by ensuring that eggs, imported from other Member States will, where appropriate, continue to be stored and transported at temperatures best suited to assure optimal conservation of their hygienic properties in the originating Member State</p>	<p>is considered to be negligible.</p>
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#### 14. Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Ministers signature 

Ministers title *Minister for Public Health*

Date *29/2/12*

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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

**The Food Hygiene (Scotland) Amendment Regulations 2012**

**To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1020/2008 amending Annex III to Regulation (EC) 853/2004**

<b>File No:</b>	SPARD/FSAS
<b>Date:</b>	February 2012
<b>Stage:</b>	Final
<b>Source of intervention:</b>	EU
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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### **1. Title of Proposal**

1.1 The Food Hygiene (Scotland) Amendment Regulations 2012.

### **2. Purpose and Intended Effect**

#### Objectives

- 2.1 To provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008 amending Annexes II and III of Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin, and Regulation (EC) 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products. *This BRIA concerns only those amendments to Annex III of Regulation (EC) 853/2004 relating to the placing on the market of fishery products derived from certain poisonous fish. Separate BRIAs are being prepared for the other amendments to Regulations 853/2004 and 2076/2005 resulting from Regulation 1020/2008.*
- 2.2 The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulation (EC) 853/2004. There is a need, therefore, to amend the Food Hygiene (Scotland) Regulations 2006 (as amended) in order to provide for the enforcement, in Scotland, of Regulation (EC) 1020/2008.
- 2.3 Regulation (EC) 1020/2008 amends Annex III of Regulation (EC) 853/2004 as follows:
  - (i) fishery products derived from poison fish of the following families must not be placed on the market: *Tetraodontidae, Molidae, Diodontidae* and *Canthigasteridae*.
  - (ii) fresh, prepared, frozen and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods, and on the risk relating to the presence of substances with adverse gastrointestinal effects.
  - (iii) the scientific name of the fishery product must accompany the common name on the label.

## Background

- 2.4 The opinion of the European Food Safety Authority (EFSA) adopted 30 Aug 2004 on contaminants in the food chain related to the toxicity of fishery products belonging to the family of *Gempylidae*, has demonstrated that fishery products belonging to that family, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may have adverse gastrointestinal effects if not consumed under certain conditions. Chapter V of Section VIII of Annex III to Regulation (EC) 853/2004 lays down specific marketing conditions for those fishery products.
- 2.5 Those conditions apply to fresh, prepared and processed fishery products derived from those species. However, similar risks for the consumer may be encountered with frozen fishery products derived from the family of *Gempylidae*. It is therefore appropriate to require similar protective informative conditions for those frozen fishery products. Section VIII of Annex III to Regulation (EC) 853/2004 is therefore amended accordingly.

## Rationale for government intervention

- 2.6 Failure to provide enforcement provisions for Regulation (EC) 1020/2008 may leave the UK open to monetary sanctions from the European Commission, for which Scottish Ministers would be accountable.
- 2.7 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Failure to set out the specific marketing conditions laid down in Regulation (EC) 1020/2008 may present a risk to public health. This is in accordance with the Scottish Government's national performance framework target to ensure that we live longer, healthier lives.

## Devolution

- 2.8 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made to provide for the enforcement of Regulation (EC) 1020/2008 in England, Wales and Northern Ireland.

## **3. Consultation**

### Public Consultation

- 3.1 Stakeholders have been kept informed of the developments of these proposals via notifications on the Agency's website since European negotiations began. In August 2008, an informal consultation letter was issued to a range of stakeholders, including Seafood Scotland and the Seafish Industries Authority (Seafish) which represents a large

proportion of the UK fishing sector. No objections to the proposals were received. The Federation of Small Businesses was also consulted and again, no comments were received.

- 3.2 The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 Stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

#### Within Government

- 3.3 Scottish Government officials from the Rural Directorate and Food & Drink Industry Division were consulted as part of the above-mentioned public consultation as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

#### With Business

- 3.4 This impact assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. Face to face engagement with Scottish business was therefore not carried out during the development process. However, 255 Stakeholders including Scottish small to medium enterprises were consulted on the proposed enforcement measures. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

### **4. Options**

- 4.1 Two options have been identified as follows:

#### **Option 1: Do nothing**

- 4.2 Doing nothing would mean that enforcement of Regulation (EC) 1020/2008 would not be provided for in Scotland and the UK would be in breach of its EU Treaty obligations. This could leave the UK Government open to infraction proceedings by the European Commission, for which Scottish Ministers would be accountable.

#### **Option 2: Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).**

- 4.3 This option fully meets the UK Government's commitment to fulfill its EU Treaty obligations. Under these obligations we are required to give effect, in Scotland, to the enforcement provisions of the Regulation. The UK was involved with the Commission and other Member States

throughout the negotiations that developed the Regulation and we supported its adoption.

#### Sectors and Groups affected

- 4.4 Local Authorities are responsible for enforcing the legislation with respect to food safety and will therefore be affected.
- 4.5 Consumers will be affected in that food safety will be maintained.
- 4.6 Land-based establishments using clean water to wash fishery products will be affected. The Agency is not aware of any land-based establishments in Scotland using clean water to wash fishery products at the present time.
- 4.7 However, establishments may wish to do so in the future, and if so, will be required to have in place adequate procedures to ensure the water is not a source of contamination. As all businesses (except primary producers) are currently required to implement and maintain procedures based on the HACCP principles specified in Regulation (EC) 852/2004, the clean water requirement can be incorporated into existing HACCP plans. As such no new administrative burdens have been identified as a result of the introduction of these measures.

#### Benefits

##### **Option 1: Do nothing**

- 4.8 Doing nothing maintains the current position and we are not aware of any benefits associated with Option 1.

##### **Option 2: Support the Regulation's application and provide for its enforcement by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended)**

- 4.9 Providing for the enforcement, in Scotland, of Regulation (EC) 1020/2008 avoids any risk of the UK failing its Treaty obligations, with the consequence of monetary sanctions by the European Commission.
- 4.10 Consumers will benefit in that appropriate marketing (e.g. wrapping, packaging, labelling) of these poisonous fish species will reduce the potential health risks for consumers.
- 4.11 An extension of checks to frozen fishery products belonging to the family of *Gempylidae* will also benefit consumers by reducing the risk of adverse gastrointestinal effects from consuming such fishery products.

## Costs

### **Option 1: Do nothing**

- 4.12 Doing nothing would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. This would leave the UK Government open to monetary sanctions by the European Commission. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.
- 4.13 It would also mean that these poisonous fish species may not be appropriately marketed, thus exposing consumers to potential health risks.

### **Option 2: Amend the Food Hygiene (Scotland) Regulations 2006**

- 4.14 Additional costs may be incurred by food business operators with regards to wrapping, packaging and labelling of these poisonous fish species.
- 4.15 Additional costs will be incurred by competent authorities carrying out checks on frozen fishery products belonging to the family of *Gempylidae*.

## **5. Scottish Firms Impact Test**

- 5.1 We are not aware of any adverse effect or any new administrative burdens on Scottish businesses as a result of the introduction of these measures. Informal consultation with the Federation of Small Business during the development of Regulation (EC) 1019/2008 generated no comments.
- 5.2 Please refer to the Consultation section in paragraph 3 above.

## **Competition Assessment**

- 5.3 Using the Office of Fair Trading (OFT) competition assessment Framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

## **Test Run of Business Forms**

- 5.4 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

## **6. Legal Aid Impact Test**

- 6.1 The amending regulations do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

## **7. Enforcement, Sanctions and Monitoring**

- 7.1 Enforcement of the Regulation will be the responsibility of Local Authority Environmental Health Departments.
- 7.2 The effectiveness and impact of the Regulation will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys, and general enquiries from the public.
- 7.3 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

## **8. Implementation and Delivery Plan**

- 8.1 Regulation (EC) No. 1020/2008 applied directly in the UK from 28 October 2008 (i.e. 10 days after being published in the EU Official Journal on 18 October 2008).
- 8.2 The coming into force of The Food Hygiene (Scotland) Amendment Regulations 2012 will be communicated to stakeholders by email, letter and via the Agency's website.

### Post-Implementation Review

- 8.3 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in October 2013 (i.e. 5 years from the direct application of Regulation (EC) No. 1020/2008 in the UK).

8.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## 9. Summary and Recommendation

9.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EC) 1020/2008.

9.2 Taking this option allows the Government to fulfil its obligations to implement EU law.

9.3 Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

### 9.4 Summary Costs and Benefits Table

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social  - Policy and Administrative
1. <b>Do Nothing</b>	No benefits have been identified.	The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day <sup>2</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.  Poisonous fish species may not be appropriately marketed, thus exposing consumers to potential health risks.
2. <b>Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).</b>	Allows the Government to meet its commitment to fulfil its EU obligations.  Consumers will benefit in that appropriate marketing (e.g. wrapping, packaging, labelling) of these poisonous fish species will reduce the	One-off financial cost to industry for familiarisation and dissemination is estimated to be minimal.  Additional costs may be incurred by food business operators with regards to wrapping, packaging and labelling of these poisonous


<sup>2</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>



	<p>potential health risks for consumers.</p> <p>An extension of checks to frozen fishery products belonging to the family of <i>Gempylidae</i> will also benefit consumers by reducing the risk of adverse gastrointestinal effects from consuming such fishery products.</p>	<p>fish species.</p> <p>Economic/ social/ environmental cost- negligible.</p> <p>Additional costs may be incurred by competent authorities carrying out checks on frozen fishery products belonging to the family of <i>Gempylidae</i>.</p>
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**10. Declaration and publication**

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature.....

Ministers Title ..... Minister for Public Health

Date..... 29/2/12

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## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

**The Food Hygiene (Scotland) Amendment Regulations 2012**

**To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1019/2008 amending Annex II of Regulation (EC) 852/2004.**

<b>File No:</b>	SPARD/FSAS
<b>Date:</b>	February 2012
<b>Stage:</b>	Final
<b>Source of intervention:</b>	EU
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## **FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

*Note: this impact assessment was developed in advance of the new BRIA requirements. It has been transposed as far as possible into BRIA format as part of this package for consistency of appearance with those BRIAS developed after the new rules were in place.*

### **1. Title of Proposal**

1.1 The Food Hygiene (Scotland) Amendment Regulations 2012.

### **2. Purpose and Intended Effect**

#### Objective

2.1 To provide for the enforcement, in Scotland, of Regulation (EC) 1019/2008 ('the Regulation'), which amends Annex II of Regulation (EC) 852/2004 on the hygiene of foodstuffs.

2.2 The Regulation:

(i) specifies that clean water may be used with whole fishery products, provided that adequate facilities and procedures are to be available for its supply to ensure that such use is not a source of contamination; and

(ii) specifies that clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods.

(ii) amends the text of Chapter VII of Annex II of Regulation (EC) 852/2004, point 1(b) by replacing it with the following:

'Clean water may be used with whole fishery products.

Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing.

When clean water is used, adequate facilities and procedures are to be available for its supply to ensure that such use is not a source of contamination for the foodstuff'

2.3 The intended effects are to allow Food Business Operators (FBOs) handling fishery products (e.g. preparation and processing establishments) to continue to use 'clean' water (clean fresh/sea water) when handling fishery products after the transitional period which ended 31 December 2009. However, when using 'clean' water in this way, FBOs are required to apply adequate risk-based control procedures to ensure that water does not contaminate foodstuffs, thus ensuring food safety for consumers is maintained.

2.4 The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulation (EC) 852/2004. There is a need, therefore,

to amend the Food Hygiene (Scotland) Regulations 2006 (as amended) in order to provide for the enforcement, in Scotland, of Regulation (EC) 1019/2008.

## Background

### *2.5 Food Hygiene Regulations*

Regulations (EC) 852/2004 and (EC) 853/2004 ('the Food Hygiene Regulations') were introduced on 1 January 2006, consolidating the existing EC food hygiene legislation that laid down the hygiene rules for food of animal origin traded within the Community. The consolidation exercise included Council Directive 91/493/EEC on the hygiene standards for fishery products.

2.6 The Food Hygiene Regulations also introduced the requirement for food businesses using clean water (as defined below) when handling fishery products, to have in place measures to ensure the water is not a source of food contamination. They also made permanent the transitional measure allowing land-based establishments to use clean water on fishery products. Specifically, Annex II, Chapter VII, 1(b) of Regulation (EC) 852/2004 provides for food business operators to use 'clean water' with whole fishery products, provided that adequate facilities are available for its supply.

### *2.7 Definition of clean water*

Clean water is currently defined in Regulation (EC) 852/2004 as including clean seawater and fresh water of a similar quality. As the quality of clean sea water (and by definition therefore, clean water) can vary along the coastline, and can vary significantly between coastal and offshore waters, it is recognised that those food business operators using clean water when handling fishery products should ensure that appropriate risk factors are considered so that the water does not detrimentally affect the safety or quality of the foodstuff. Regulation (EC) 1019/2008 amends Regulation (EC) 852/2004 by introducing this requirement, thereby ensuring the protection of public health.

2.8 The use of clean water (the definition of which includes clean seawater) on fishery products has been permitted on fishing vessels since the implementation of the consolidated hygiene legislation. It has also been permitted in land based establishments under the transitional arrangements of Regulation 2076/2005, in order to allow these establishments to adapt progressively. This provision expired 31 December 2009.

### *2.9 Transitional arrangements*

Regulation (EC) 1020/2008 (see separate BRIA) amends Regulation (EC) 853/2004 to make permanent the temporary transitional measure allowing land-based establishments to use clean water when handling fishery products. As this transitional measure expired 31 December 2009, making this provision permanent ensures that food business operators handling fishery products (e.g. preparation and processing establishments) will be able to continue to use 'clean water' (clean sea/fresh water) when handling fishery products after the end of the transitional period.

2.10 This will continue the current regime, thus minimising the burden on business and giving legislative certainty to all stakeholders. This will also prevent increased costs to industry by allowing the continued use of clean water (as opposed to potable water) when handling fishery products after 31 December 2009, whilst improving the level of public health protection by introducing a risk-based control procedure. However, when using 'clean water' in this way, these businesses will still be required to apply adequate control procedures to ensure that water does not contaminate foodstuffs, thus ensuring food safety for consumers is maintained.

#### 2.11 *HACCP*

During discussions to make the transitional measure permanent it was agreed that, whilst the quality of clean water can vary along different stretches of coastline, it would not represent a risk to public health if control procedures (for example those based on the Hazard Analysis and Critical Control Point (HACCP) principles as specified in Regulation (EC) 852/2004) are put into place by businesses to ensure that the use of such water in these establishments is not a source of contamination.

2.12 With regard to water supply, Chapter VII of Annex II of Regulation (EC) 852/2004 provides that potable water is to be used, whenever necessary, to ensure that foodstuffs are not contaminated, and that clean water may be used with whole fishery products. It also provides that clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods, and that clean water may be used for their external washing.

2.13 The use of clean water with whole fishery products and for external washing of live bivalve molluscs, echinoderms, tunicates and marine gastropods, does not represent a risk for public health as long as control procedures, based in particular on the Hazard Analysis and Critical Control Point (HACCP) principles, have been developed and put in place by food business operators to ensure that it is not a source of contamination.

#### 2.14 *Amendments to 852 and 853*

The above mentioned requirements are achieved by amending Annex II, Section VII of Regulation (EC) 852/2004 and Annex III, Section VIII of Regulation (EC) 853/2004.

2.15 Regulation (EC) 1019/2008 amends Regulation (EC) 852/2004 and Regulation (EC) 1020/2008 amends Regulation (EC) 853/2008 respectively.

#### Rationale for government intervention

2.16 Failure to provide enforcement provisions for Regulation (EC) 1019/2008 may leave the UK open to monetary sanctions from the European Commission.

2.17 Together, Regulations (EC) 1019/2008 and (EC) 1020/2008 ensure that food business operators handling fishery products (e.g. preparation and processing establishments) will be able to continue to use 'clean' water (clean sea/fresh water) when handling fishery products after the transitional period which ended 31 December 2009. However, when using 'clean' water in this way, these businesses will be required to apply adequate control procedures to ensure that water does not

contaminate foodstuffs, thus ensuring food safety for consumers is maintained. This is in accordance with the Scottish Government's national performance framework target to ensure that we live longer, healthier lives.

2.18 Intervention is required to apply clear consumer health standards, limit industry costs arising from potential contamination outbreaks and reduce industry costs that would have arisen from having to use potable water from 1 January 2010.

### Devolution

2.19 The Food Hygiene (Scotland) Amendment Regulations 2012 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

## **3. Consultation**

### Public Consultation

3.1 Stakeholders have been kept informed of the developments of these proposals via notifications on the Agency's website since European negotiations began. In August 2008, an informal consultation letter was issued to a range of stakeholders, including Seafood Scotland and the Seafish Industries Authority (Seafish) which represents a large proportion of the UK fishing sector. No objections to the proposals were received. The Federation of Small Businesses was also consulted and again, no comments were received.

3.2 The Agency conducted a full public consultation which ran for 12 weeks from 1 April 2010 until 24 June 2010. 255 Stakeholders were consulted. No responses were received. Separate but parallel consultations were issued in England, Wales and Northern Ireland.

### Within Government

3.3 Scottish Government officials from the Rural Directorate and Food & Drink Industry Division were consulted as part of the above-mentioned public consultation as were all 32 Scottish Local Authorities. No responses were received. The Scottish Government Legal Directorate was involved in the drafting of the Regulations as well as advising on legal aspects of the consultation process.

### With Business

3.4 This impact assessment was developed prior to the introduction of Scottish Government's enhanced Business and Regulatory Impact Assessment. Face to face engagement with Scottish business was therefore not carried out during the development process. However, 255 Stakeholders including Scottish small to medium enterprises were consulted on the proposed enforcement measures. No responses were received, indicating that the Agency's assessment of the impact is perceived to be accurate by stakeholders.

## **4. Options**

### **Option 1: Do nothing**

4.1 Doing nothing would mean that enforcement of the Regulation would not be provided for in Scotland and the UK would be in breach of its EU obligations. This would leave the UK Government open to monetary sanctions by the European Commission, for which Scottish Ministers would be accountable.

### **Option 2: Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).**

4.2 This option fully meets the UK Government's commitment to fulfill its EU Treaty obligations. Under these obligations we are required to give effect, in Scotland, to the enforcement provisions of the Regulation.

4.3 The UK was involved with the Commission and other Member States throughout the negotiations that developed the Regulation and we supported its adoption.

4.4 Option 2 allows FBOs to continue to use 'clean' water (clean fresh/sea water) when handling fishery products after the transitional period which ended 31 December 2009.

#### **4.5 Sectors and Groups affected**

- Local Authorities are responsible for enforcing the legislation with respect to food safety and will therefore be affected.
- Consumers will be affected in that food safety will be maintained.
- Land-based establishments using clean water to wash fishery products will be affected. The Agency is not aware of any land-based establishments in Scotland using clean water to wash fishery products at the present time.

4.6 However, establishments may wish to do so in the future, and if so, will be required to have in place adequate procedures to ensure the water is not a source of contamination. As all businesses (except primary producers) are currently required to implement and maintain procedures based on the HACCP principles specified in Regulation 852/2004, the clean water requirement can be incorporated into existing HACCP plans. As such no new administrative burdens have been identified as a result of the introduction of these measures.

### **Benefits**

#### **Option 1 – Do nothing**

4.7 Doing nothing maintains the current position and we are not aware of any benefits associated with Option 1.

## **Option 2 – Support the Regulation’s application and provide for its enforcement in Scotland by amending the Food Hygiene (Scotland) Regulations 2006 (as amended)**

4.8 Providing for the enforcement, in Scotland, of Regulation (EC) 1019/2008 avoids any risk of the UK failing its Treaty obligations, with the consequence of monetary sanctions by the European Commission.

4.9 Consumers will benefit from increased consumer protection by ensuring clear food safety standards in sourcing clean water.

4.10 Industry will benefit financially from the requirement to use clean rather than potable water when handling fishery products after 31 December 2009. Industry was unable to quantify the possible savings during the consultation.

4.11 Industry will also benefit from a consistent EU approach to facilitate trade.

### Costs

#### **Option 1 – Do nothing**

4.12 Doing nothing would mean that the Commission may impose monetary sanctions on the UK for failing to comply with its Treaty obligations. This would leave the UK Government open to monetary sanctions by the European Commission. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>1</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.

4.13 Consumer protection may be affected by a lack of clear food safety standards in sourcing clean water.

4.14 Industry may be affected by increased costs as a result of having to use potable water in land-based establishments when handling fishery products after 31 December 2009. Industry stakeholders were unable to quantify these costs during the consultation.

4.15 Industry may be affected by the lack of a consistent EU approach to facilitate trade.

## **Option 2 – Support the Regulation’s application and provide for its enforcement in Scotland by amending the Food Hygiene (Scotland) Regulations 2006(as amended)**

### *4.16 Industry Costs*

There may be possible reading and understanding costs, although these are expected to be minimal as we are not aware of any land-based establishments using clean water when handling whole or prepared fishery products.

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<sup>1</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>



4.17 There may be further possible costs for businesses through the need to implement and maintain procedures based on the HACCP principles (if their current system does not sufficiently assess the water quality). However, as most businesses (except primary producers) are already required to have a HACCP system to manage food safety, it is not expected that these requirements will cause a considerable extra burden.

#### 4.18 *Enforcement costs*

No additional costs are expected to be incurred as there will be no change to the enforcement regime. Local enforcement authorities will continue to enforce the HACCP requirements as they have done for many years. The required HACCP regime is as specified in Regulation (EC) 852/2004.

### **5. Scottish Firms Impact Test**

5.1 We are not aware of any adverse effect or any new administrative burdens on Scottish businesses as a result of the introduction of these measures. Informal consultation with the Federation of Small Business during the development of Regulation (EC) 1019/2008 generated no comments.

5.2 Please refer to the Consultation section in paragraph 3 above.

### **Competition Assessment**

5.3 Using the Office of Fair Trading (OFT) competition assessment framework<sup>2</sup>, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

### **Test Run of Business Forms**

5.4 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

### **6. Legal Aid Test**

6.1 The Food Hygiene (Scotland) Amendment Regulations 2012 will not introduce new criminal sanctions or civil penalties, therefore there are no legal aid implications. This assumption has been confirmed by the Access to Justice Team of Scottish Government.

### **7. Enforcement Sanctions and Monitoring**

7.1 Enforcement of the Regulation will be the responsibility of Local Authority Environmental Health Departments.

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<sup>2</sup> [http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft876.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf)

7.2 The effectiveness and impact of the Regulation will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys, and general enquiries from the public.

7.3 No changes are being proposed to the criminal sanctions contained in the Food Hygiene (Scotland) Regulations 2006. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

## **8. Implementation and Delivery Plan**

8.1 Regulation (EC) 1019/2008 applied directly in the UK from 28 October 2008 (i.e. 10 days after being published in the EU Official Journal)

8.2 The publication of the Food Hygiene (Scotland) Amendment Regulations 2012, providing for the enforcement in Scotland of Regulation (EC) 1019/2008 will be communicated to stakeholders through the Agency's website and FSA News.

### **Post- implementation Review**

8.3 A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulation, will take place in October 2013 (i.e. 5 years from the direct application in the UK of Regulation (EC) 1019/2008.

8.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

## **9. Summary and Recommendation**

9.1 The Agency recommends Option 2, to amend the Food Hygiene (Scotland) Regulations 2006 to provide for the enforcement of Regulation (EC) 1019/2008.

9.2 Taking this option allows the Government to fulfil its obligations to implement EU law. It also ensures that Enforcement Authorities can fulfil the requirements placed on them and the Courts can impose penalties consistent with those elsewhere in Food Law.

9.3 Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

## 9.4 Summary Costs and Benefits Table

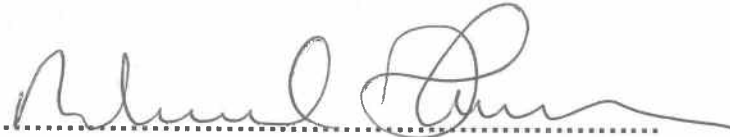
Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social  - Policy and Administrative
1. Do Nothing	No benefits have been identified.	<p>Risk of infraction proceedings for failure to implement (EC) 1019/2008. The maximum fine that could be imposed on the UK is currently some €703,000 (£594,000) per day<sup>3</sup> or some €250 million (£211 million) per year. Scotland would be required to pay a percentage of any UK fine, if the infraction related to devolved matters, depending on the extent of our involvement.</p> <p>Consumers may be affected by a lack of clear food safety standards in sourcing clean water.</p> <p>Industry may be affected by increased costs as a result of having to use potable water in land-based establishments when handling fishery products.</p> <p>Industry may be affected by the lack of a consistent EU approach to facilitate trade.</p>
2. Support the Regulation's application and provide for its enforcement in Scotland by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).	<p>Allows the Government to meet its commitment to fulfil its EU obligations.</p> <p>Consumers will benefit from increased consumer protection by ensuring clear food safety standards.</p> <p>Industry will benefit from decreased costs as a result of not having to use potable water in land-based establishments when handling fishery products. This cost was not quantified by industry.</p> <p>Harmonises standards across Member States &amp; removes</p>	<p>One-off financial cost to industry for familiarisation and dissemination is estimated to be minimal.</p> <p>Costs to industry to update their food safety management system are estimated to be minimal.</p> <p>Administrative burdens/ costs- no new or additional costs have been identified.</p> <p>Economic/ social/ environmental cost-negligible.</p>

<sup>3</sup> <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

## 10. Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's Signature.....



Ministers Title .....

Minister for Public Health

Date.....

29/2/12

### Contact point

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