EXECUTIVE NOTE

THE FOOD HYGIENE (SCOTLAND) AMENDMENT REGULATIONS 2010 (SSI 2010/69)

These Regulations amend the Food Hygiene (Scotland) Regulations 2006 (SSI No. 3) by providing for the execution and enforcement in Scotland of a suite of transitional and implementing measures for the EU Food Hygiene Regulations. It will also provide for the application of two national measures. The Regulations will also revoke the Food Hygiene (Scotland) Amendment Regulations 2007 (SSI No.11) (regulation 3). The instrument is subject to negative resolution procedure, and does not amend primary legislation.

Policy Objectives

Since the I January 2006, the European Commission has adopted a number of implementing and transitional regulations for which provision must also be made in national legislation. This instrument provides for the execution and enforcement on transitional and implementing measures in respect of the EU Food Hygiene Regulations. It also provides for the application of two national measures that exempt (former) low throughput slaughterhouses from certain hygiene requirements. This instrument will come into force across the United Kingdom on the 13 April 2010.

Background

The EU Hygiene Regulations have as a main priority the optimisation of public health protection, and are directly applicable in EU Member States. The transitional measures which are the subject of this SSI will either amend or apply transitional measures to the following policy areas:

- record keeping for small fishing vessels (Regulation) (EC) 1243/2007);
- the production of gelatine (Regulation (EC) 1243/2007);
- the criteria for competent authorities to apply when determining Official Veterinarian attendance during post-mortem inspection (Regulation (EC) 1244/2007);
- the criteria for the "visual only" inspection post-mortem of young animals (Regulation (EC) 1244/2007);
- the use of an alternative form of pepsin for the detection of Trichinella (Regulation (EC)1245/2007);
- microbiological criteria (Regulation (EC) 1441/2007); and
- the screening of live bivalve molluscs for Amnesic Shellfish Poisoning (Regulation (EC) 1244/2007).

These Regulations also include national measures which will exempt (former) low throughput slaughterhouses from the need for: cleansing and disinfection facilities, and detention facilities for meat.

Consultation

A 12 week consultation took place throughout Scotland and closed on the 14 March 2008. The Food Standards Agency consulted 323 stakeholders which included Scottish businesses and Local Authorities. Two responses were received to the consultation. The responses can be viewed on the Agency's website.

Regulatory Impact Assessments (RIA)

Seven RIAs have been prepared to accompany these Regulations, two relate to the national measures and five to the transitional and implementing measures for the EU Hygiene Regulations. By adopting these measures it is considered that there will be no substantial impact on business or competent authorities.

Food Standards Agency Scotland

February 2010

FINAL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

1.1 The Food Hygiene (Scotland) Amendment Regulations 2010.

1.2 The above instrument implements a range of EC and national measures. This RIA only relates to those EC measures concerning Official Veterinarian (OV) attendance during post-mortem inspection and visual only post-mortem inspection of young animals.

2. The Objective

2.1 The above Regulations will provide for the enforcement in Scotland of Commission Regulation (EC) 1244/2007. The objective is to amend existing food hygiene legislation to ensure official controls are proportionate, and allow alternative ways of carrying out controls where there are benefits without any lowering of the protection of public health. The meat hygiene aspects of Regulation (EC) 1244/2007 covered by this RIA specifically:

(i) set the criteria for competent authorities to apply when determining official veterinarian (OV) attendance during post-mortem inspection in establishments carrying out 'discontinuous slaughter';

(ii) set criteria for the 'visual only' (i.e. without incisions) post-mortem inspection of young animals - with the public health benefit of removing the necessity, in some cases, of cutting into the meat, which might spread infection;

(iii) set criteria for the visual only inspection of fattening pigs. Revised inspection procedures have been trialled in GB and the outcome is still under discussion. This is not, therefore, an issue for the industry in Scotland. A decision will be taken on whether to exercise the discretion provided for in the new EU provisions when the discussions are completed; and,

(iv) place an additional requirement for the post-mortem examination of solipeds (horses and mules) from countries not free of glanders. This issue is not covered in this RIA as glanders is not endemic in the UK.

3. Rationale for Government Intervention

3.1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

3.2 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.

3.3 There is a need to ensure that official controls are proportionate and reflect the risk-based nature of the requirements for food businesses. It is also necessary to allow competent authorities alternative ways of carrying out their duties as long as public health protection is maintained or improved.

3.4 There is also a need to ensure that the rules for official controls are changed in order to make the widest possible use of developments in science and technology where there is no negative impact on public health.

4. Background

Relevant legislation:

4.1 A package of consolidated EC food hygiene regulations applied from 1 January 2006. Regulation (EC) 852/2004 lays down the general rules for all food business operators (FBOs). Specific rules for FBOs manufacturing or handling foods of animal origin are laid down in Regulation (EC) 853/2004. However, Regulation (EC) 854/2004 sets out the role /obligations of 'official controls' (i.e. the requirements on Member States' competent authorities as regards enforcement). Detailed information on the hygiene legislation can be found on the Food Standards Agency's web site at: http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/

4.2 Regulation (EC) 2074/2005 provides implementing measures for certain products of animal origin under Regulation 853/2004, and for official controls under Regulations 854/2004 and 882/2004. It also makes changes to official controls by amending EC Regulation 854/2004.

4.3 Commission Regulation 1244/2007 amends Regulation (EC) 2074/2005. It is the amendments related to meat that are the subject of this RIA.

Issues – background and detail:

4.4 Annex I, Section 3, Chapter II, 1(a) – 'Frequency of Controls' of 854/2004 sets out that at least one Official Veterinarian (OV) is required during post-mortem inspection in slaughterhouses.

4.5 However, Article 5, point 5 (b) of Regulation (EC) 854/2004 allows competent authorities (this is the Meat Hygiene Service (MHS) for meat hygiene in Scotland) to adapt, on a risk basis, the number of official staff on a slaughter line at any given slaughterhouse, as long as the Regulation's requirements are met.

4.6 Regulation 1244/2007 amends the criteria to be taken into account in the risk assessment. Drawing upon reports of EU scientific committees, the Regulation established that some integrated production systems were of such a nature that the inspection criteria could be revised without a negative impact on public health. However, the amendment allows the competent authority (i.e. the MHS) to reduce OV attendance at post-mortem only to those slaughterhouses that practise 'discontinuous slaughter', effectively restricting any benefits of reduction of OV attendance solely to smaller establishments, as larger slaughterhouses will not be practising 'discontinuous slaughter'.

4.7 Regulation 1244/2007 applied directly in the UK from November 2007 (i.e. 20 days after being published in the EU Official Journal on 25 October 2007).

Prior to October 2009, nearly all slaughterhouses in the UK were charged for OV attendance on the basis of their throughput (i.e. number of animals) rather than time costs (i.e. the time taken by the OV or Official Auxiliary), with the difference being subsidised by the Government. This implies that the majority of any cost savings resulting from reduced OV hours would have accrued to the Government between November 2007 and October 2009 through a reduction in the level of subsidy. It is unlikely that cost savings will have accrued to those businesses that paid for OV attendance on a time cost basis as these tend to be larger establishments that do not normally engage in discontinuous slaughter.

4.8 On 28 September 2009 charging for official controls on a time cost basis was introduced for all slaughterhouses in the UK. A level of subsidy has remained for all slaughterhouses, and the long term goal is for support to small and geographically remote plants to have ongoing support, but now that all charges are conducted on a time cost basis, even with ongoing subsidy, any additional time on controls will have a cost implication for the plant as well as the taxpayer.

UK negotiating position:

4.9 The UK strongly supports flexible legislation that reduces the burden on small businesses as long as public health is protected. However, the UK also argued against limiting this flexibility only to food business operators practising 'discontinuous slaughter' because of concerns that it would only help small slaughterhouses, and the proposal was not risk-based. However, the UK was outvoted by other Member States on this point. Summaries of meetings where this issue was discussed can be found on the Agency's website at: http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu/

4.10 Regulation 854/2004 did not allow for simplification of the inspection of calves, lambs and goat kids. The amendment introduced by 1244/2007 allows visual-only inspection as long as the requirements set down are met. Potential benefits should arise to public health from removing the necessity, in some cases, of cutting into certain parts of those animals.

Other issues:

4.11 The Commission Regulation also provides for an alternative screening method for Amnesic Shellfish Poisoning. This issue is now the subject of a separate Regulatory Impact Assessment (RIA) (during consultation all three measures were part of one RIA).

5. Devolution

5.1 Separate domestic legislation will be made to provide for the enforcement of Regulation (EC) 1244/2007 in England, Wales and Northern Ireland.

6. Consultation

6.1 The Agency carried out a full public consultation, including stakeholders and other Government Departments in Scotland between 18 December 2007 and 14 March 2008.

6.2 No comments were received on these measures.

7. Options

i. Option 1 - do nothing;

ii. Option 2 - amend the Food Hygiene (Scotland) Regulations as described to provide for enforcement of Regulation 1244/2007 in Scottish law.

7.1 Analysis of options

i. Option 1 (doing nothing) – If effect to Regulation (EC) 1244/2007 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.

ii. Option 2 – The measure is intended to reduce Official Veterinarian (OV) attendance during post-mortem inspection in some circumstances and describes the criteria that determine this. It also sets criteria for 'visual only' inspection of young animals. This is the preferred option as it will allow alternative ways of carrying out controls where there are benefits without any lowering of the protection of public health.

7.2 Option 2 is proposed.

8. Costs and Benefits

8.1 Sector and groups affected

8.2 Regulation 1244/2007 affects all slaughterhouses approved to slaughter red meat and game species. There are currently 38 red meat slaughterhouses in Scotland, and 20 premises approved to slaughter wild game.

8.3 Regulation (EC) 854/2004 allows competent authorities to adapt, on a risk basis, the need for Official Veterinarian (OV) attendance during post-mortem inspection at these premises. The proposed measure sets the criteria to be taken into account in the risk assessment. By prescribing these factors and limiting the opportunity for the enforcement authority (the MHS) to reduce OV attendance to those slaughterhouses that practise 'discontinuous slaughter', the Commission measure restricts the flexibility of the original Regulation and the ability to give larger establishments earned autonomy.

8.4 Coupled with the fact that nearly all establishments were charged on the basis of their throughput rather than time costs prior to October 2009, very few

establishments will have benefitted financially from reductions in OV attendance since the measures took effect. However, now that all establishments are charged for official controls on a time cost basis, reductions in OV hours for smaller businesses engaged in discontinuous slaughter are likely to yield cost savings.

8.5 The following cost analysis examines the forgone cost savings to larger businesses, which no longer benefit from the original flexibility in Regulation 854/2004 to reduce OV attendance at post-mortem inspection.

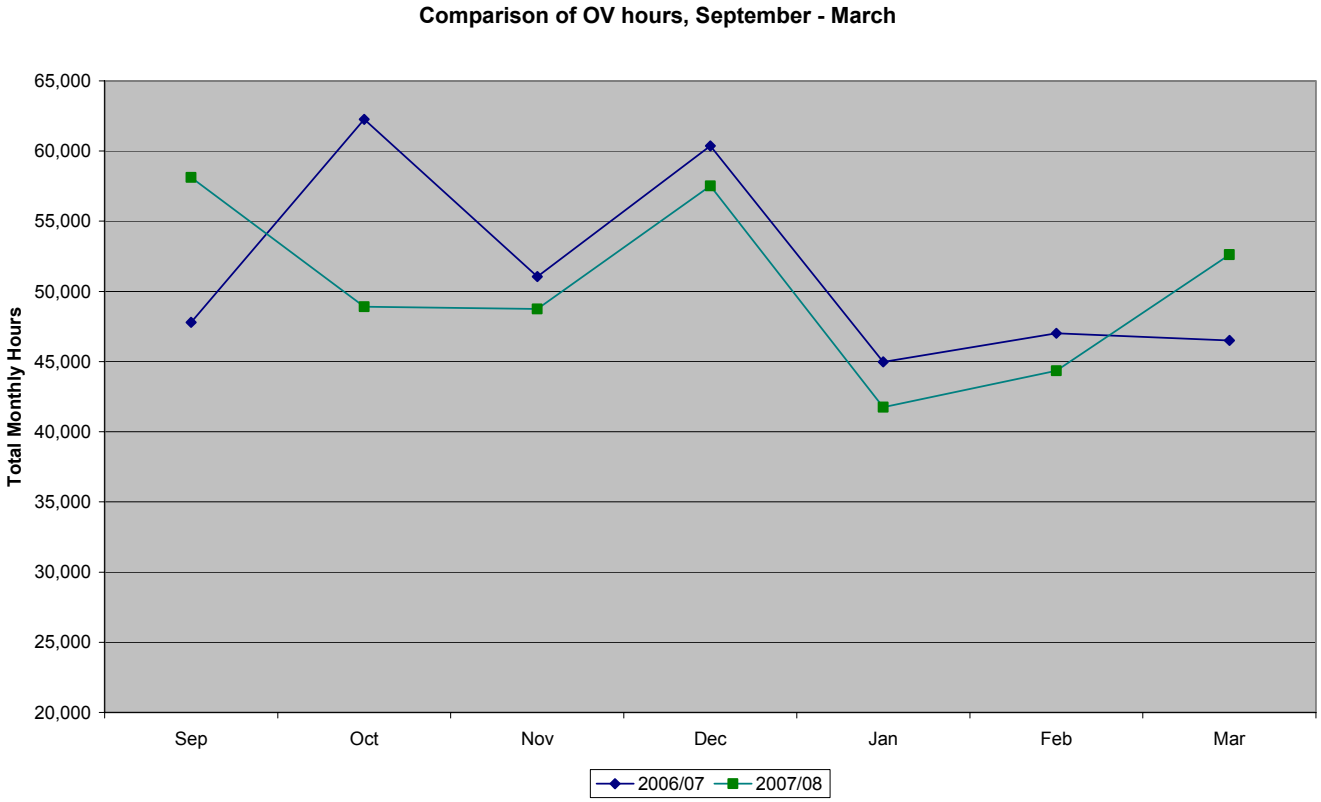
8.6 Costs

8.7 As far as the foregone benefits are concerned, there are potential savings which have *not* been made by the FSA/MHS owing to the 'discontinuous slaughter ' restriction.[1] That is, plants practising continuous slaughter were previously eligible to make use of flexibilities in OV time and are no longer able to do so to the same extent.

8.8 At the time of consultation there was limited information on both the flexibility that plants would lose and the number of plants that this would apply to. No assumption was made on the number of plants that would be affected, although it was assumed that each affected plant would forego savings of 25% of daily OV hours (2 hours per day), 5 days per week, 50 weeks per year.

8.9 Updated information from the MHS on the total OV hours over the relevant period indicates that plants previously eligible for the flexibility appear to have made relatively small reductions in OV time, and those that did appear to have been few in number.

[1] Slaughterhouses are required to have full time OV presence unless they slaughter intermittently, in which case they are classed as practising 'discontinuous slaughter'.



Source: Meat Hygiene Service

8.10 The above graph shows the pattern of OV hours for the period September – March in both the 2006/07 and the 2007/08 financial years. There appears to be a broadly similar pattern in the number of hours used for inspection between the two years. The requirement to have full-time OV presence in slaughterhouses was reintroduced in November 2007, and there does not appear to have been any substantial increase in OV hours after this point other than would be expected in line with seasonal variation, as indicated by the similarities between 2006/07 and 2007/08 in the above graph.

8.11 Uncertainty remains regarding the precise number of plants affected and the actual number of hours saved which are foregone, therefore we use a range for the key assumptions. We estimate that the actual costs relate to between 5% and 15% of the 37 slaughterhouses and 21 wild game handling establishments that were in operation in Scotland in 2007/08, with hours savings foregone in the range of 5% to 15% (revised from 25%). Using an hourly OV full cost rate of £43.80, these ranges yield cost estimates of between £13,140 and £118,260 per annum (see table below). A best estimate of the annual costs is made by taking the mid-point of the range, yielding approximately £52,560 (2007 prices).

Estimated Range of Costs			
Scenario	**5% of plants affected, 5% OV hours foregone**	**10% of plants affected, 10% OV hours foregone**	**15% of plants affected, 15% OV hours foregone**
Total number of plants affected	3	6	9
Foregone reduction in hours per plant	100	200	300
Total Cost	£13,140	£52,560	£118,260

8.12 There is a possibility that potential forgone cost savings may increase in future years, particularly in light of the move to a time cost basis for Official Control charges in slaughterhouses from 28th September 2009. Time cost charging is expected to improve the efficiency in use of Official Control time and potentially reduce OV hours. As the majority of slaughterhouses have to date had less incentive to reduce OV time when full presence was not always required, the full potential OV hour savings foregone since November 2007 have not been realised. Potential foregone savings may therefore increase under time cost charging, as a number of slaughterhouses are likely to seek ways of reducing Official Control time but may be restricted by the requirement of full time OV presence.

8.13 No comments on this issue were received during the public consultation.

8.14 Benefits

8.15 There are potential savings to small slaughterhouses engaged in discontinuous slaughter resulting from the flexibility to reduce the presence of the OV at post-mortem inspection. The potential savings will depend on the extent to which the Competent Authority (the MHS) seeks to make use of the flexibility and allow an Official Auxiliary (a Meat Hygiene Inspector) to carry out these duties. The current hourly rate for an OV is £37.10 and for a Meat Hygiene Inspector it is £30.70. Now that charges are based on time costs rather than throughput it is likely that the MHS will come under pressure from eligible businesses to make use of this flexibility where resources allow.

8.16 Extension of the possibility for post-mortem inspection without incision ('visual-only inspection') to calves, lambs and goat kids has a potential public health benefit, although negligible financial impact. Only small numbers of calves and kids are slaughtered for human consumption in Scotland. Visual only inspection of lambs in specified circumstances has benefits for public health protection in the potential reduction of cross-contamination and will result in a small reduction of effort by inspectors, but is unlikely to generate any operational cost savings.

8.17 Thirty slaughterhouses were approved in Scotland for slaughter of sheep in 2007/08, although all may not have been actually be doing so. They were paying on throughput rather than time cost, and so any reduced MHS inspection time per lamb would not reduce their own costs, but would result in a reduction in the level of subsidy. However, there are unlikely to be benefits from reduced incisions at post-mortem inspection, as the time saved is likely to be invested in increased visual inspection.

8.18 On balance Option 2 was preferred as, despite there being significant forgone cost savings, it enables the benefits to improvements in the proportionality of enforcement activity in certain animal product sectors with no danger to public health – there may even be a benefit to public health in one case. Providing for the enforcement of Commission Regulation 1244/2007 in Scottish law also avoids any risk of the UK failing in its Treaty obligations, with the consequence of monetary sanctions by the European Commission.

9. Impact on Small Firms

9.1 As outlined in paragraph 8.15 there are potential savings to small slaughterhouses engaged in discontinuous slaughter from the flexibility to reduce the presence of the OV at post-mortem inspection. It is likely that these businesses will seek to put pressure on the MHS to make use of this flexibility now that charges are based on time costs rather than throughput.

10. Test Run of Business Forms

10.1 There are no administrative costs associated with this option. No new or additional forms will be introduced.

11. Competition Assessment

11.1 The measures are unlikely to have affected competition prior to October 2009 because most businesses would have been paying for meat inspection charges according to throughput. As outlined in the graph in paragraph 8.9 the total number of OV hours continues to follow seasonal variations and does not seem to have been affected by the new measures. Therefore it is unlikely that competition will be affected now that charges are based on time costs rather than throughput.

12. Enforcement, Sanctions & Monitoring

12.1 The Meat Hygiene Service, an Executive Agency of the Food Standards Agency, will remain responsible for enforcement, sanctions and monitoring for the meat hygiene provisions set out in the Regulations.

13. Sustainable Development

13.1 The Agency considers that Option 2 is the most sustainable as it is intended to provide for an alternative inspection method and provides flexibility with no impact on sustainability.

14. Implementation & Delivery Plan

14.1 Regulation 1244/2007 applied directly in the UK from November 2007 (i.e. 20 days after being published in the EU Official Journal on 25 October 2007).

14.2 The above Regulations providing for the enforcement of Regulation (EC) 1244/2007 in Scotland is expected to come into force on 13 April 2010.

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15. Post-Implementation Review

15.1 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in November 2012 (i.e. 5 years from the direct application of Regulation 1244/2007 in the UK)

16. Summary & Recommendation

16.1 The above Regulations will provide for the enforcement in Scotland of Commission Regulation (EC) 1244/2007, which amends existing food hygiene legislation to ensure official controls are proportionate, and allows alternative ways of carrying out controls where there are benefits without any lowering of the protection of public health.

16.2 The UK argued strongly against limiting the flexibility for reducing OV attendance at post-mortem inspection only to food business operators practising 'discontinuous slaughter' because of concerns that it would only help small slaughterhouses, and the proposal was not risk-based. However, the UK was outvoted by other Member States on this point, and there have been potential forgone cost savings as a result.

16.3 Nonetheless, there will be potential savings for small slaughterhouses engaged in discontinuous slaughter should the MHS seek to make use of the remaining flexibilities, especially now that meat inspection charges are based on time costs rather than throughput.

16.4 Therefore the Minister for Public Health and Sport is recommended to agree to Option 2.

17. Declaration

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

Signed:

Date:

Minister for Public Health and Sport

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FINAL REGULATORY IMPACT ASSESSMENT

3. Title of Proposal

1.1 The Food Hygiene (Scotland) Amendment Regulations 2010.

1.2 The above instrument implements a range of EC and national measures. This RIA only relates to those EC measures concerning the use of liquid pepsin for the detection of *Trichinella* in meat.

2 The Objective

2.1 The above Regulations will provide for the enforcement in Scotland of Commission Regulation (EC) 1245/2007. The objective is to amend existing food hygiene legislation, which lays down specific rules on the official controls for *Trichinella* in meat, to ensure that alternative ways in which official controls can be undertaken are available where they will bring benefits without any consequent weakening of public health safeguards. Commission Regulation (EC) 1245/2007 provides for the use of liquid pepsin for the detection of *Trichinella* in meat by competent authorities. This provides a choice of form of the reagent pepsin for laboratory staff undertaking official controls to use, with the potential of benefitting their health, and with no consequent lowering of the protection to public health.

3. Rationale for Government Intervention

3.1 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

3.5 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.

3.6 *Trichinella* is a zoonotic disease, transmissible to humans through consumption of raw and uncooked meat from infected animals. Testing for *Trichinella* is carried out to protect public health using methods set out in EU legislation. However, there is some evidence that the pepsin powder, previously the only form of pepsin authorised for use in these tests undertaken in laboratories, can cause allergic reactions in some persons. Therefore, there was a need to amend the EU legislation to provide for the use of an alternative form of the reagent which does not lower public health safeguards.

4. Background

4.1 The UK supported the introduction of this Regulation, which provides for use of liquid pepsin in the *Trichinella* detection method by laboratories undertaking duties for the purposes of official controls.

4.2 Methods of detection of the parasite *Trichinella* in meat destined to be human food are set out in EU legislation, and are applied consistently across Member States to protect public health. *Trichinella* as a zoonotic disease is transmissible to humans through consumption of raw or uncooked meat from animals infected with the larvae *Trichinella spiralis*, and in severe cases can cause death.

4.3 Normally, samples are taken by plant staff from pigs at the slaughterhouse and sent from there to approved laboratories as a public health measure.

4.4 Testing is also undertaken as part of a general surveillance programme – horses are also tested, as are some wild animals (carnivores and omnivores), even when they would not be expected to enter the human food chain.

4.5 Pepsin powder is a prescribed reagent for use in laboratories for detecting *Trichinella*. However, there is some evidence that pepsin powder can cause allergic reactions in some persons and, therefore, there is a need to amend the EU legislation to provide for the use of an alternative form of the reagent as long as safeguards for public health are maintained.

4.6 If used, there may be a negligible cost for competent authorities. There is no impact on business. This RIA therefore contains no monetised costs or benefits.

5. Devolution

5.1 Separate domestic legislation will be made to provide for the enforcement of Regulation (EC) 1245/2007 in England, Wales and Northern Ireland.

6. Consultation

6.1 The Agency carried out a full public consultation, including stakeholders and other Government Departments in Scotland between 18 December 2007 and 14 March 2008.

6.2 No comments were received on these measures.

7. Options

i. Option 1 - do nothing;

ii. Option 2 - Support application of the legislation and to amend the Food Hygiene (Scotland) Regulations 2006 (as amended) to provide for the Regulation's enforcement.

7.1 Analysis of Options

iii. Option 1 (do nothing) – This Option would mean that the only prescribed form of detection of *Trichinella* in meat in EU law would be the pepsin powder reagent. This might lead to allergic reactions in those handling the pepsin powder where it could have been avoided by use of the liquid form. There are no incremental costs and benefits from this option.

iv. Option 2 – The UK supported the introduction of Regulation (EC) 1245/2007, which provides for the use of liquid pepsin in the Trichinella detection method by competent authorities.

7.2 Option 2 is proposed.

8. Costs and Benefits

8.1 Sector and groups affected

8.2 This Regulation is not considered to have any substantial impact on the Competent Authorities and has no impact on business.

8.3 Costs

8.4 The Regulation is not considered to have any substantial impact on competent authorities or business and therefore contains no monetised costs.

8.5 Should laboratories choose to use it, liquid pepsin may be more expensive than powdered pepsin. However, the additional cost is likely to be insignificant.

8.6 The Agency considers that Option 2 imposes no additional costs on business or the private sector. None of the responses to the three month public consultation exercise carried out in Scotland commented on this proposal.

8.7 Benefits

8.8 There are no monetised benefits associated with this Regulation.

8.9 The policy has two non-monetised benefits:

i. Enhanced flexibility for the Competent Authority.

ii. Reduced possibility of allergic reactions amongst laboratory staff who handle pepsin for the purposes of official controls.

9. Impact on Small Firms

9.1 This Regulation will not have any impact on small meat producing companies because it relates to the choice of testing procedures available to laboratories performing Trichinella testing.

10. Test Run of Business Forms

10.1 There are no administrative costs associated with this option. No new or additional forms will be introduced.

11. Competition Assessment

11.1 No firms are affected by this Regulation.

12. Enforcement, Sanctions & Monitoring

12.1 The Meat Hygiene Service, an Executive Agency of the Food Standards Agency, will remain responsible for enforcement, sanctions and monitoring for the meat hygiene provisions set out in the Regulations.

13. Sustainable Development

13.1 The Agency considers that Option 2 is more sustainable as there is a possible benefit to the health of competent authority staff.

13.2 No environmental impact has been identified.

14. Implementation and Delivery Plan

14.1 Regulation 1245/2007 applied directly in the UK from November 2007 (i.e. 20 days after being published in the EU Official Journal on 25 October 2007).

14.2 The above Regulations providing for the enforcement of Regulation (EC) 1245/2007 in Scotland is expected to come into force on 13 April 2010.

15. Post-Implementation Review

15.1 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in November 2012 (i.e. 5 years from the direct application of Regulation 1245/2007 in the UK)

16. Summary and Recommendation

16.1 The above Regulations will provide for the enforcement in Scotland of Commission Regulation (EC) 1245/2007, which amends existing food hygiene legislation to which lays down specific rules on the official controls for *Trichinella* in meat, to ensure that alternative ways in which official controls can be undertaken are available where they will bring benefits without any consequent weakening of public health safeguards.

17. Declaration

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

Signed:

Date:

Minister for Public Health and Sport

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FULL REGULATORY IMPACT ASSESSMENT

1 Title of Proposal

1.1 The Food Hygiene (Scotland) Amendment Regulations 2010.

2 Purpose and Intended Effect

Objective

2.1 To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1244/2007 ('the Regulation'), which amends Regulation (EC) 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption, and laying down specific rules on official controls for the inspection of meat.

2.2 The Regulation amends Regulation (EC) 2074/2005 to permit Member State competent authorities the use of an alternative screening method for the detection of the Amnesic Shellfish Poisoning (ASP) biotoxin, which may bring high capacity at low cost without lowering the standards of public health protection.

2.3 The intended effect is to allow alternative ways of carrying out controls, which make use of developments in science and technology; in this case, to permit the use of an alternative screening method for the detection of ASP toxins, which may have the benefit of being cheaper.

2.4 The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulation (EC) 2074/2005. 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) 1244/2007.

2.5 *This RIA concerns only those amendments to Regulation (EC) 2074/2005 relating to the proposed alternative methods of detecting ASP. Separate RIAs are being prepared for the other amendments to Regulation (EC) 2074/2005 resulting from Regulation (EC) 1244/2007.*

Background

2.6 Regulation (EC) 854/2004 requires Member State competent authorities to fix the location and boundaries of live bivalve mollusc (LBM) production and relaying areas. It also requires the competent authority to classify authorised LBM production areas as being Class A, B or C, with A being the cleanest. The Food Standards Agency, as the UK competent authority, is directly responsible for ensuring these rules are complied with.

2.7 One of the requirements set down in Annex II, B of Regulation (EC) 854/2004 is for competent authorities to monitor LBM for the presence of biotoxins. The role of the Agency, as competent authority, as regards the designation and classification of shellfish harvesting areas is set out in the National Control Plan (NCP)[2] which the Agency is required to produce in line with EU Regulation (EC) 882/2004[3].

2.8 This measure concerns the way in which competent authorities carry out official controls, and will not have any impact on industry as testing costs are borne solely by the Agency.

Detecting ASP

2.9 The specified method for detecting the ASP biotoxin laid down in Chapter II of Regulation (EC) 2074/2005 is the high-performance liquid chromatography (HPLC) method. However, the Regulation now permits, for the purpose of screening the edible parts of molluscs, use of the 2006.02 ASP ELISA Method (as published in the AOAC Journal of June 2006). The measure proposes a possible alternative that the Agency could consider for testing official control samples and which may be more cost effective. The Agency will assess this alternative test and ensure it is at least as safe as the current testing regime before it is further considered for use.

2.10 Regulation (EC) 1244/2007 amends Regulation (EC) 2074/2005 to provide for this alternative screening method.

Devolution

2.11 The Food Hygiene (Scotland) Amendment Regulations 2010 will apply in Scotland only. Separate but parallel domestic legislation will be made to

[2] The UK National Control Plan 2007– 2011. Reference to shellfish harvesting can be found in Appendix C, paragraph 16 of the FSA web site at: http://www.food.gov.uk/multimedia/pdfs/uknationalcontrolplan.pdf

[3] Regulation (EC) 882/2004 sets down the principles and approach to be taken by competent authorities in EU Member States that have responsibility for monitoring and enforcing compliance with feed, food animal health and animal welfare rules.

provide for the enforcement of Regulation (EC) 1244/2007 in England, Wales and Northern Ireland.

Rationale for government intervention

2.12 Failure to provide enforcement provisions for Regulation (EC) 1244/2007 may leave the UK open to monetary sanctions from the European Commission.

2.13 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

2.14 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 ensure the hygiene standards of food business operators.

2.15 In this specific situation, government intervention takes the form of monitoring LBM from classified shellfish beds for the presence of biotoxins. The Food Standards Agency is responsible for this monitoring. To be efficient, the monitoring methods need to be cost effective and in line with the latest scientific understanding. Therefore, there is a need to update the legislation in line with the latest scientific evidence concerning a potential alternative screening mechanism.

3 Consultation

3.1 The draft RIA was subject to a full three-month public consultation with stakeholders, including stakeholders and other Government Departments in Scotland, between December 2007 and March 2008. There were no responses from Scottish stakeholders in relation to this amendment, and no further evidence was received with regard to costs or benefits resulting from the measure, or the effect on sustainability, or other identified areas of impact.

3.2 The Agency is obliged to place a summary of stakeholders' responses to each of its public consultations on its website within 3 months of the closure of the consultation. The summary for this consultation can be found at: http://www.food.gov.uk/multimedia/pdfs/consultationresponse/responsesfoodhygieneregs08.pdf

3.3 The draft Scottish Statutory Instrument (SSI) was issued with the public consultation in December 2007. Following revision, the UK was obliged to re-notify it to the European Commission under the provisions of Directive

98/43/EC, (this was the same for the corresponding Statutory Instruments in England, Wales and Northern Ireland), which it did 30 October 2008.

3.4 The requisite three month notification period provided the Commission and Member States with the opportunity to scrutinise national legislation to ensure that it did not provide barriers to trade. In the case of this SSI, the notification period ended on 2 February 2009.

4 Options

i. Option 1: Do nothing

ii. Option 2: Support the Regulation's application and provide for its enforcement by amending the existing Food Hygiene (Scotland) Regulations 2006 (as amended).

Option 1:

4.1 Doing nothing would mean that enforcement of the Regulation in Scotland would not be provided for and the UK would be in breach of its EU Treaty obligations. This could leave us open to monetary sanctions by the European Commission.

Option 2:

4.2 This option fully meets the UK Government's commitment to fulfil 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 is the preferred option because it allows the use of an alternative screening method, providing a choice and the potential for lower cost monitoring, while maintaining public health protection.

5 Costs and Benefits

Sectors and Groups affected

5.1 Member State competent authorities (in this case the Agency) will be affected by costs in relation to administration, inspections, surveillance, managing research and development, education, publicity and publications.

Benefits

Option 1 – Do nothing

5.2 Doing nothing maintains the current position and has no incremental benefits.

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)

5.3 Providing for the enforcement, in Scotland, of Commission Regulation (EC) 1244/2007 avoids any risk of the UK failing in its EU Treaty obligations, with the consequence of monetary sanctions by the European Commission.

5.4 The availability of an approved alternative to HPLC would mean that if HPLC became unavailable for any reason the competent authority would still be able to carry out the requirements for testing classified shellfish beds for ASP biotoxins. If no alternative to HPLC were available, the compentent authority would be unable to carry out these tests, perhaps leading to monetary sanctions by the European Commission.

5.5 The measure proposes an alternative method that the Agency could consider for testing official control samples, which is potentially both cheaper and faster, and which could lead to savings for competent authorities when screening for ASP. The Agency will assess this alternative test and any potential savings, and ensure it is at least as safe as the current testing regime, before it is further considered for use.

5.6 Option 2 is preferred as it enables competent authorities to benefit from potential improvements in the efficiency and choice of sampling methods for ASP biotoxins in LBMs, with no lowering of public health protection.

Costs

Option 1 – Do nothing

5.7 There could be costs to the UK government in relation to monetary sanctions by the Commission as a result of failing to meet our EU Treaty obligations by not providing for the enforcement of EC legislation.

5.8 There is a possiblity of higher costs to competent authorities when screening for ASP, as those competent authorites would only be able to use the existing HPLC method, and would not be able to take advantage of the potentially cheaper and faster method proposed in the Regulation.

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)

Costs to the Agency as the competent authority

5.9 As the competent authority, the Agency bears all testing costs. The Agency will assess this alternative test and ensure it is at least as safe as the current testing regime before it is further considered for use and any potential savings made.

6 Small Firms Impact Test

6.1 The Agency does not expect the Regulation to have a significant impact on small firms in Scotland. This measure concerns the way in which competent authorities carry out official controls, and will not have any impact on industry as testing costs are borne solely by the Agency.

7 Test Run of Business Forms

7.1 The Food Hygiene (Scotland) Amendment Regulations 2010 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

8 Competition Assessment

8.1 The measure is not considered to have any effect on competition as it impacts solely on control bodies and not upon businesses.

9 Enforcement Sanctions and Monitoring

9.1 Enforcement of the Regulation will be the responsibility of Local Authority Environmental Health Departments.

9.2 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

10 Sustainability Assessment

10.1 The measure is considered to be more sustainable in that it provides for an alternative and potentially cheaper screening method with more flexibility, but with no impact on sustainability and no lowering of public health protection.

11 Implementation and Delivery Plan

11.1 Regulation (EC) 1244/2007 applied directly in the UK from October 2007 (i.e. 20 days after it was published in the EU Official Journal on 24 October 2007).

11.2 The Food Hygiene (Scotland) Amendment Regulation 2010, providing for the enforcement, in Scotland, of Regulation (EC) 1244/2007, is expected to come into force on 13 April 2010. Its publication will be communicated to stakeholders through the Agency's website, FSA News, etc.

12 Post- implementation Review

12.1 A review to establish the actual costs and benefits, and the achievement of the desired effects, will take place in October 2012 (i.e. 5 years from the direct application, in the UK, of Regulation (EC) 1244/2007.

12.2 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 Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulation (EC) 2074/2005. The Agency therefore recommends the proposed Food Hygiene (Scotland) Amendment

Regulations 2010 in order to provide for the enforcement, in Scotland, of Regulation (EC) 1244/2007, as outlined in Option 2 above.

13.2 Therefore the Minister for Public Health and Sport is recommended to agree Option 2.

14 Declaration

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

Signed……

Date

Minister for Public Health and Sport

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FULL REGULATORY IMPACT ASSESSMENT

15 Title of Proposal

15.1 The Food Hygiene (Scotland) Amendment Regulations 2010.

16 Purpose and Intended Effect

Objective

16.1 To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1243/2007 ('the Regulation'), which amends Annex III of Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin.

16.2 The Regulation:

(i) provides a derogation for small coastal fishing vessels from some record keeping requirements, thus reducing administrative budens for food business operators in that sector; and

(ii) provides for the addition of two further methods of production of gelatine, changed requirements for wrapping and packaging, and other minor changes to Regulation (EC) 853/2004 that provide clarity of interpretation in order that gelatine manufacturers can make use of all available technologies where it is established that there is no negative impact on public health.

The intended effects are (i) to ensure that record keeping requirements in the fishing industry are proportionate to risk, and (ii) to update the legislation for gelatine manufacture in line with current evidence on the food safety impacts of available technologies.

16.3 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) 1243/2007.

Background

16.4 Regulation (EC) 1243/2007 amends Regulation 853/2004:

i. to include a derogation from the record keeping requirements set out in Regulation (EC) 852/2004, currently applying to small-scale coastal fishing vessels carrying out their activities for periods under twenty-four hours; and,

ii. to allow two further methods of producing gelatine for human consumption, an change the requirement for wrapping and packaging to indicate the date of preparation of the gelatine in favour of an indication of the date of minimum durability.

The legislation for record-keeping for fishing vessels and manufacture of gelatine needed to be amended because (i) it created an administrative burden beyond that necessary to safeguard public health, and (ii) it needed to take account of developments in science and technology so that food businesses could make full use of such developments, as long as public health protection remained safeguarded.

Devolution

16.5 The Food Hygiene (Scotland) Amendment Regulations 2010 will apply in Scotland only. Separate but parallel domestic legislation will be made to provide for the enforcement of Regulation (EC) 1243/2007 in England, Wales and Northern Ireland.

Rationale for government intervention

16.6 Failure to provide enforcement provisions for Regulation (EC) 1243/2007 may leave the UK open to monetary sanctions from the European Commission.

16.7 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

16.8 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 ensure the hygiene standards of food business operators.

16.9 To be efficient, hygiene standards need to be proportionate to the risk, with the costs of compliance fully justified by the benefits. To this end, the requirement in the EU food hygiene legislation on food businesses to keep records can be applied flexibly, in proportion to the nature of the business and its food safety risks, as long as public health is safeguarded. Where the legislation creates unnecessary burdens it should be reviewed and amended, to ensure that this proportionality is available to all food business operators.

16.10 The EU food hygiene legislation also needed to be amended to take account of developments in science and technology, to ensure food businesses could make full use of such developments, as long as public health protection remained safeguarded.

17 Consultation

17.1 The RIA was subject to a full three-month public consultation with stakeholders, including stakeholders and other Government Departments in Scotland, between December 2007 and March 2008. There were no responses from Scottish stakeholders in relation to this amendment, and no further evidence was received with regard to costs or benefits resulting from the measure or the effect on sustainability or other identified areas of impact.

17.2 The Agency is obliged to place a summary of stakeholders' responses to each of its public consultations on its website within 3 months of the closure of the consultation. The summary for this consultation – the draft Food Hygiene (Scotland) Amendment Regulations 2008 - can be found at: http://www.food.gov.uk/multimedia/pdfs/consultationresponse/responsesfoodhygieneregs08.pdf

17.3 The draft Scottish Statutory Instrument (SSI) was issued with the public consultation in December 2007. Following revision, the UK was obliged to re-notify it to the European Commission under the provisions of Directive 98/43/EC, (this was the same for the corresponding Statutory Instruments in England, Wales and Northern Ireland), which it did 30 October 2008.

17.4 The requisite three month notification period provided the Commission and Member States with the opportunity to scrutinise national legislation to ensure that it did not provide barriers to trade. In the case of this SSI, the notification period ended on 2 February 2009.

18 Options

i. Option 1: Do nothing

ii. 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).

Option 1:

18.1 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 Treaty obligations. This could leave the us open to monetary sanctions by the European Commission.

18.2 It would also mean that certain fishing vessels might continue to have to keep records where it was not justifiable on public health grounds, with possible long-term unnecessary costs.

18.3 Furthermore, it would mean that manufacturers of gelatine could not take advantage of alternative methods of production and other flexibilities provided.

Option 2:

18.4 This option fully meets the UK Government's commitment to fulfil its EU Treaty obligations. Under these obligations we are required to give effect, in Scotland, to the enforcement provisions of the Regulation.

18.5 The UK was involved with the Commission and other Member States throughout the negotiations that developed the Regulation and we supported its adoption.

18.6 Option 2 is the preferred option because there is a strong likelihood that the measures will (i) lower the administrative burden on a small business sector and (ii) provide flexibilities in the manufacture of gelatine.

19 Costs and Benefits

Benefits

Option 1 – Do nothing

19.1 Doing nothing maintains the current position and has no incremental benefits.

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)

19.2 Providing for the enforcement, in Scotland, of Regulation (EC) 1243/2007 avoids any risk of the UK failing its Treaty obligations, with the consequence of monetary sanctions by the European Commission.

(i) Fishing Vessels

19.3 The derogation from record-keeping requirements for small coastal fishing vessels (within the meaning of Article 26(1) of Regulation (EC) 1198/2006) from the requirement to 'keep and retain records relating to measures put in place to control hazards' (Regulation (EC) 852/2004, Annex I, Part A, 7), will reduce administrative burdens for the operators of these vessels and will result in some small cost savings, equivalent to the cost of recording previously required information over and above that that would have been undertaken commercially.

19.4 We estimate the salient wage rate to be £8.44 per hour for time used filling these forms (which coincides with the salient rate from the Annual Survey of Hours and Earnings (ASHE) in 2007 figures). This includes a 30% uplift to cover overheads. We further estimate 5-6 minutes for daily form completion, and that 45% of the currently required record keeping per salient fishing trip will anyway continue commercially, regardless of government obligations.

19.5 In Scotland, it is estimated that around 26,500 day trips (of less than 24 hours) occurred for vessels less than 12 metres in length between June 2006 and May 2007. Given this information and the assumptions stated there would be an estimated annual administrative burden reduction of approximately £11,500.

19.6 However, comments received out with Scotland during public consultation, suggest this may be an overestimate because the legislation already allows vessels proportionate record-keeping, and vessels supplying small quantities to local markets are anyway exempt. For example, guidance for the industry produced by the organisation SEAFISH suggests record-keeping is only required in limited circumstances such as fish-room temperature and cleaning. These comments suggest that the real impact of the derogation is unlikely to be significant.

(ii) Local Authorities

19.7 There may also be some benefit to Local Authority enforcement officers who no longer have to check the appropriate records. Secondary inspections of vessels will be reduced by the amount of time required for checking records.

(iii) Gelatine manufacturers

19.8 Regarding the introduction of changes to the manufacture of gelatine, the FSA is not aware of any existing businesses in Scotland which may be affected by the Regulation. The UK industry on which the measure has an impact is based in Wales. Nonetheless, the provision may benefit (and increase the likelihood of) future gelatine manufacturing operations in Scotland.

Costs

Option 1 – Do nothing

19.9 There could be costs to the UK government in relation to monetary sanctions by the Commission as a result failing to meet our EU Treaty obligations and not providing for the enforcement of EC legislation.

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)

(i) Fishing Vessels

19.10 The derogation assumes that the absence of the record keeping activity will not affect the hygiene standards employed on these vessels. It is also assumed that, because the fishing and storing of fish do not extend beyond 24 hours, the risk to public health is insignificant.

19.11 Concern was raised prior to the consultation that there might be a cost to the 'on shore' industry arising from the Regulation. Under the previous legislation, recipients of the catches from these vessels could request records relating to the health measures put in place. In the possible absence of these records, on shore food business operators may consider carrying out more detailed checks of the fish or shellfish landed. However, comments out-with Scotland from the consultation suggest that checks would only be undertaken in the case of high-risk activities anyway, and since much fishing is not high-risk, impact would be negligible.

(ii) Local Authorities

19.12 Secondary inspections carried out by Local Authority enforcement officers will not require the checking of the vessels records. As noted above, this will reduce the burden of inspection, but might remove confidence that the fishing vessel has been operating to the highest safety standards. Without this assurance, enforcement officers may feel that the inspection rating and frequency for some vessel operators should be adjusted. No comments were forthcoming on this issue from the public consultation.

Gelatine manufacturers

19.13 As noted above, the Agency is unaware of any gelatine manufacturers in Scotland. Nonetheless, the addition of additional permitted methods for the production of gelatine would not result in any costs to industry, as any affected firms could continue with their current practices if they so choose. Firms that choose to move to a new production method would do so in pursuit of a commercial benefit. Regarding the minor change to labelling requirements, this will not impose a cost as there are no manufacturers of gelatine in Scotland, and would nonetheless be taken care of during the normal labelling cycle. No further information about gelatine manufacture was forthcoming from the public consultation.

20 Small Firms Impact Test

20.1 The derogation introduced by the Regulation provides for the status quo or a positive benefit to small fishing businesses. Theoretically, where small on-shore businesses are the recipient of the catches and further work is incurred through more detailed checks, this benefit may be cancelled out, although other comments received during the public consultation suggest this will be negligible.

21 Test Run of business Forms

21.1 The Food Hygiene (Scotland) Amendment Regulations 2010 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

22 Competition Assessment

22.1 Due to the minor nature of the benefits to small fishing vessels of reduced record keeping, we do not anticipate a significant effect on competition. Other comments received during the public consultation did not suggest even a negligible impact on competition.

23 Enforcement Sanctions and Monitoring

23.1 Enforcement of the Regulation will be the responsibility of Local Authority Environmental Health Departments.

23.2 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.

24 Sustainability Assessment

24.1 We do not envisage that the measure will be unsustainable as the economic effects are unlikely to endanger the business survival, or increase the burden on fish stocks. No comments were received during the consultation on sustainability.

25 Implementation and Delivery Plan

25.1 Regulation 1243/2007 applied directly in the UK from November 2007 (i.e. 20 days after being published in the EU Official Journal 24 October 2007).

25.2 The Food Hygiene (Scotland) Amendment Regulations 2010, providing for the enforcement in Scotland of Regulation (EC) 1243/2007, is expected to come into force on 13 April 2010. Its publication will be communicated to stakeholders through the Agency's website, FSA News, etc.

26 Post- implementation Review

12.1 A review to establish the actual costs and benefits, and the achievement of the desired effects, will take place in November 2012 (i.e. 5 years from the direct application in the UK of Regulation 1243/2007)

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

27 Summary and Recommendation

27.1 The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulation (EC) 853/2004. The Agency therefore recommends the proposed Food Hygiene (Scotland) Amendment Regulations 2010 in order to provide for the enforcement, in Scotland, of Regulation (EC) 1243/2007, as outlined in Option 2 above.

27.2 Therefore the Minister for Public Health and Sport is recommended to agree Option 2.

28 Declaration

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

Signed……

Date……

Minister for Public Health and Sport

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FULL REGULATORY IMPACT ASSESSMENT

29 Title of Proposal

29.1 The Food Hygiene (Scotland) Amendment Regulations 2010.

2. Purpose and Intended Effect

Objective

2.1. To provide for the enforcement, in Scotland, of Commission Regulation (EC) 1441/2007 ('the Regulation'), which replaces Annex 1 of Regulation (EC) 2073/2005 laying down microbiological criteria for food businesses.

2.2. It is necessary that the Regulation reflects up-to-date scientific understanding in order to protect public health. Therefore, following opinions by EU scientific bodies, the Regulation:

- revises the microbiological criteria for infant formula;
- imposes new criteria for infant and follow-on formula;
- harmonises testing requirements for carcasses; and
- updates the standard test method for staphylococcal enterotoxins

2.3. The Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulation (EC) 2073/2005. 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) 1441/2007.

Background

The Microbiological Criteria Regulation (Regulation (EC) 2073/2005)

Food business operators (FBOs) have an obligation to withdraw unsafe food from the market. Article 4 of Regulation (EC) 852/2004 requires FBOs to comply with microbiological criteria. In order to contribute to the protection of public health and to prevent differing interpretations, Regulation (EC) 2073/2005, which applied from 1 January 2006, established pursuant to Article 4 of Regulation (EC) 852/2004, harmonised safety criteria regarding the presence of certain pathogenic micro-organisms.

Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. Where appropriate, the use of microbiological criteria should form an integral part of an FBO's implementation of HACCP-based procedures and other hygiene control measures.

Detail of Regulation (EC) 1441/2007, which amends Regulation (EC) 2073/2005

Commission Regulation (EC) 1441/2007 provides a replacement, in its entirety, of Annex 1 of Regulation (EC) 2073/2005, in which the criteria are laid down, and introduces a number of revisions to Regulation (EC) 2073/2005 as follows:

- Parallel criteria for Enterobacteriaceae (process hygiene criteria) and *Salmonella* and *Enterobacter sakazakii* (food safety criteria) in dried infant formulae, unless a correlation had been demonstrated between Enterobacteriaceae and *Enterobacter sakazakii* at individual plants. Regulation (EC) 2073/2005 provides a two-tier approach where presence of Enterobacteriaceae triggers testing for *Salmonella* and *Enterobacter sakazakii;*
- New process hygiene criteria for *Bacillus cereus* in infant formula;
- New criteria for Enterobacteriacea (process hygiene criteria) and *Salmonella* (food safety criteria) in follow-on formulae;
- A new analytical reference method for Staphylococcal enterotoxins; and
- Harmonised carcase sampling rules

2.4. The revised criteria have been introduced as the previous criteria did not reflect current scientific understanding, with the result that there were some deficiencies in the statutory controls. This could have resulted in a lack of clarity over requirements for businesses and enforcement authorities leading to a greater risk of illness occurring from certain pathogenic micro-organisms in food.

2.5. Furthermore, where microbiological criteria do not properly reflect up-to-date science, this could weaken public health protection and lead to erosion of consumer confidence in food (as well as in regulators), and raises the possibility of legal action by consumers against FBOs.

Devolution

2.6. The Food Hygiene (Scotland) Amendment Regulations 2010 will apply in Scotland only. Separate but parallel domestic legislation will be made to provide for the enforcement of Regulation (EC) 1441/2007 in England, Wales and Northern Ireland.

Rationale for government intervention

2.7. Failure to provide enforcement provisions for Regulation (EC) 1441/2007 may leave the UK open to monetary sanctions from the European Commission.

2.8. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

2.9. 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 ensure the hygiene standards of food business operators.

2.10. Food business operators are required to ensure that the foodstuffs they handle or produce meet established microbiological criteria. There is a need to ensure these criteria are revised, or introduced where necessary, in order to take account of developments in scientific understanding.

2.11. Revision of the microbiological criteria to reflect updated scientific understanding will reduce the risks of illness caused by certain pathogenic micro-organisms in food and improve public health protection.

3. Consultation

3.1. The draft RIA was subject to a full three-month public consultation with stakeholders, including stakeholders and other Government Departments in Scotland, between December 2007 and March 2008. There were no responses in from Scottish stakeholders in relation to this amendment, and no further evidence was received with regard to costs or benefits resulting from the measure or the effect on sustainability or other identified areas of impact.

3.2. The Agency is obliged to place a summary of stakeholders' responses to each of its public consultations on its website within 3 months of the closure of the consultation. The summary for this consultation 9 the draft Food Hygiene (Scotland) Amendment Regulations 2008 - can be found at: http://www.food.gov.uk/multimedia/pdfs/consultationresponse/responsesfoodhygieneregs08.pdf

3.3. The draft Scottish Statutory Instrument (SSI) was issued with the public consultation in December 2007. Following revision, the UK was obliged to re-notify it to the European Commission under the provisions of Directive 98/43/EC, (this was the same for the corresponding Statutory Instruments in England, Wales and Northern Ireland), which it did 30 October 2008.

3.4. The requisite three month notification period provided the Commission and Member States with the opportunity to scrutinise national legislation to ensure that it did not provide barriers to trade. In the case of this SSI, the notification period ended on 2 February 2009.

3.5. Agency officials were involved in constant informal consultation with industry during the negotiations on the Regulation. Consumer bodies were among those originally consulted but they did not provide comments.

3.6. The amendments to Regulation (EC) 2073/2005, introduced by Regulation (EC) 1441/2007, reflect issues raised either by the Commission, or by other Member States.

3.7. The UK was able to influence the outcome through active participation in the Expert Working Group on *Bacillus*, and the Working Group on Microbiological criteria. To assess the impact of the proposed changes, industry stakeholders were engaged throughout the process, including those most likely to be affected. The UK negotiating position was based on assessment of the available scientific evidence, with the aim of securing a proportionate outcome which protects public health without placing unnecessary burdens on the industry.

4. Options

i. Option 1: Do nothing

ii. 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).

Option 1:

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 Treaty obligations. This could leave us open to monetary sanctions by the European Commission.

Option 2:

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.

4.3. Option 2 is the preferred option.

5. Costs and Benefits

Sectors and Groups affected

Infant Formula Industry

5.1. The majority of the amendments affect the infant formula sector. This sector mainly comprises large businesses with established control plans. The Agency's understanding is that there is a small amount of infant formula production in the UK, but most of the product on the UK retail market is produced in other Member States (where, of course, the Regulation also applies). The infant and follow-on formulae sectors are currently characterised by significant concentration with three firms, Nutricia, H.J. Heinz and SMA Wyeth, accounting for 97% of sales in the UK.

5.2. We are not aware of any infant formula or follow-on formula manufacturers in Scotland.

5.3. The Agency does not expect the revisions introduced by Regulation (EC) 1441/2007 (as outlined above) to have significant impact on the UK industry. These revisions mainly formalise existing procedures followed by industry, although the new criterion for *Bacillus cereus* may result in an increase in testing by businesses to demonstrate compliance. The Agency is not aware that compliance with the revised criteria is causing industry difficulties.

5.4. Quantifying the benefits of the revised criteria is difficult, particularly as feedback suggests the industry is already likely to be observing the new standards for infant and follow-on formulae. However, the measures provide necessary revisions to the protection of public health as provided by Regulation 20073/2005 and the other food hygiene legislation. They also provide greater clarity for businesses and enforcement officials on the requirements for these products.

Parallel criteria for Enterobacteriaceae and *Salmonella* and *Enterobacter sakazakii* in dried infant formulae

5.5. 'Parallel criteria'are criteria intended to apply independently along side or 'in parallel' with other criteria specified. Compliance is always demonstrated separately. In contrast, linked criteria are intended to apply sequentially, whereby failure to comply with one such criterion would trigger the requirement to demonstrate compliance with a further criterion. The application of linked criteria in this way is also referred to as a two-tier approach.

5.6. Regulation 2073/2005 provides a two-tier approach in respect of the process hygiene criterion for Enterobacteriaceae – absence in 10g of infant formula – linked to food safety criteria for *Salmonella* and *E.sakazakii* also requiring

absence. In this case, if Enterobacteriaceae are detected, this would trigger additional testing specifically for *Salmonella* and *E.sakazakii*. If either of these two organisms is detected, the product should be removed from the market. The amendment introduced by Regulation (EC) 1441/2007 changed the arrangement set out in Regulation (EC) 2073/2005 rather than introducing new criteria. The effect of this change is to remove the link between these criteria, so that the two food safety criteria generally apply independently or 'in parallel' with the process hygiene criterion. This is further explained below.

5.7. A similar two-tier approach was suggested for follow-on formula where presence of Enterbacteriaceae would trigger testing for *Salmonella* (an *E.sakazakii* criterion was not considered appropriate for follow-on formula at this time). During informal consultations on the proposals, stakeholders questioned whether there was a correlation between *Salmonella* and Enterobacteriaceae detection. The potential for *Salmonella* to be present when Enterobacteriaceae are not detected by the standard method was of particular concern to the Agency, as the two-tier approach might not therefore adequately protect public health.

5.8. The relationship between the presence of Enterobacteriaceae and *E.sakazakii* was also being questioned by other groups such as the Codex Working Group on infant formula. The UK therefore raised this issue during the negotiations on Regulation (EC) 1441/2007, and although there was some support from other Member States, the Commission was reluctant to make changes to existing criteria in the Regulation so soon after its adoption, without firm evidence. The Commission therefore requested an EFSA opinion[4] on the relationship between Enterobacteriaceae and *Salmonella* and *E.sakazakii* in infant and follow-on formula. The Agency also requested data from stakeholders in preparation for EU Working Group discussions.

5.9. Stakeholders were able to provide some information but, as *Salmonella* is rarely detected, it was not possible to determine whether a correlation existed. This was in line with the EFSA opinion which concluded:

- There is a relationship between the presence of *E. sakazakii* and Enterobacteriaceae, but no universal correlation can be established. There are indications a relationship can be established at an individual plant level;

- It is not possible to establish a correlation between *Salmonella* and Enterobacteriaceae in infant or follow-on formula as *Salmonella* is so rarely present, suitable data are not available; and

- Concentrations and/or presence of Enterobacteriaceae in the production environment and in the products are useful indicators of the application of GHP/GMP

[4] EFSA opinion on the relationship between Ents, Sal and Esak

5.10. The Agency considers the available evidence supports the amendment to the Regulation to provide for parallel criteria for *Salmonella, E. sakazakii* and Enterobacteriaceae . This includes flexibility for a two-tier approach for *E. sakazakii* and Enterobacteriaceae when FBOs can satisfy the competent authority that a correlation exists within a particular premise. We would not expect this change to have a major impact on the industry as previous feedback indicated stakeholders did not carry out two-tier testing, particularly for Enterobacteriaceae and *Salmonella*.

Process hygiene criteria for *Bacillus cereus* in infant formula

5.11. Following adoption of Regulation 2073/2005, the Commission considered harmonisation of national criteria implemented by Member States. Several Member States had national criteria for *Bacillus* spp in food and the EFSA opinion on *Bacillus cereus* and other *Bacillus* spp in foodstuffs[5] had reviewed the available evidence on these organisms so the Commission established an Expert Working Group to considered harmonised criteria for *Bacillus* spp. The UK participated in the Expert Group.

5.12. The basis for the discussions was the EFSA opinion, a risk assessment by Food Standards Agency Australia/New Zealand[6] , and information on infectious diseases from the Netherlands. The UK assessed the evidence, seeking views from relevant stakeholders in the process. It concluded that there was very little evidence to support microbiological criteria for *Bacillus* in foods and also took into account information from the UK study[7] on infectious intestinal disease (IID). It was recognised that *B. cereus* could cause food poisoning. However, food poisoning figures and the study did not indicate a particular problem with this organism.

5.13. However, the Commission and some Member States were very keen to see microbiological criteria for *Bacillus* in food and there was strong support for a food safety criterion. If a food fails to meet food safety criteria, food businesses must remove the affected produce from the market. This could include a full scale recall with the associated costs which, in the case of Bacillus, the UK does not believe would be a proportionate response with little demonstrable evidence of public health protection.

5.14. As the UK considered there was limited evidence available to support the need for a criterion for *Bacillus spp* or suggest *B. cereus* was a particular concern, it could not support a food safety criterion, and expressed that view during negotiations (a food safety criterion has not been introduced). The Expert Group concluded a Process Hygiene Criteria should be introduced for *B.cereus* in infant formula. This was supported by the EFSA opinion which recommended 10^5 spores per gram at consumption should be used as a target for

[5] EFSA opinion on *Bacillus cereus* and other *Bacillus* spp in foodstuffs
[6] FSA Aus/NZ RA
[7] IID study

food business operators to verify their HACCP system and could be considered as microbiological criteria to test the acceptability of a process.

5.15. The aim of a process hygiene criterion is to help demonstrate whether a process is functioning correctly, and provide an indicative level above which corrective action is required to ensure good process hygiene. If a process hygiene criterion is not met, food businesses must review the food safety management procedures and take action to ensure the criterion is met in future. The affected product can still remain on the market.

5.16. *B.cereus* is a potential hazard associated with infant formula and should already, therefore, be considered by producers as part of their food safety management procedures. While the UK had reservations (shared by stakeholders) about the public health benefits of the introduction of any criteria, it considered the impact of a process hygiene criterion to be more proportionate and supported the conclusions of the Expert Group as a compromise. Stakeholders were asked to provide information on the impact of the proposal during the negotiations, and there was no indication that the introduction of a process hygiene criterion would have a major impact on the industry.

5.17. The initial proposals from the Commission provided a process hygiene criterion with a limit of 100 CFU per gram. There was some support for this from some Member States. The European Trade's Federation for Infant Formula (IDACE) suggested these limits were too stringent and offered some alternatives. Various suggestions were made and the Commission requested views from Member States. The UK indicated it had some sympathy with the industry's position. The Commission initiated discussions with IDACE which eventually resulted in a proposal which reflected limits suggested by the industry – a 3 class sampling plan where n=5, c=1, m=50 and M=500. The UK supported these limits as they were relevant to public health protection and would not have a disproportionate effect on the industry. The proposal was adopted with unanimous agreement in the working group and standing Committee.

5.18. With regard to the process for *Bacillus*, Regulation (EC)1441/2007 reflects the limits considered appropriate by the industry. There may be some impact on the industry as they demonstrate compliance with the criterion. However, feedback from the industry indicates some routine testing is already carried out.

<u>New criteria for Enterobacteriacea (process hygiene criteria) and *Salmonella* (food safety criteria) in follow-on formulae</u>

5.19. The EFSA opinion[8] on microbiological risks in infant and follow-on formula recommended a performance objective for powdered follow-on formula aiming at very low levels of *Salmonella* e.g. absence in 1, 10 or 100kg, and verification of compliance with the performance objective is confirmed by testing for Enterobacteriaceae in the environment and in the product. As noted earlier, another EFSA opinion reviewed the relationship between *Salmonella* and

[8] www.efsa.eu.int/science/biohaz/biohaz_opinions/691_en.html.

Enterobacteriaceae in infant and follow-on formula, and concluded it was not possible to establish a correlation. The Commission therefore proposed criteria for Enterobacteriace (process hygiene) and *Salmonella* (food safety). As with the infant formula criteria these are parallel criteria.

5.20. Feedback from the UK industry has indicated the *Salmonella* criterion (absence in 30 x 25g) would have little impact as the industry have been working to the standard for a number of years. More concerns were raised about the initial proposals for Enterobacteriaceae criterion, and IDACE wrote to the Commission outlining its position. The amendment to the Regulation provides a more stringent criterion than that supported by IDACE. However discussions with the UK industry indicated that the impact of this standard will not be a great concern.

Dairy Industry

5.21. There are approximately 1350 registered milk production holdings in Scotland and 90 approved dairy processing establishments. Many larger processing establishments have their own laboratories that will be affected by the new analytical reference method for Staphylococcal enterotoxins. The National Milk Laboratory is used by larger milk purchasers/collectors for the testing of both farm samples and tanker/silo samples. Their laboratory in Paisley, Scottish Milk Laboratories, will also be affected.

<u>A new analytical reference method for Staphylococcal enterotoxins</u>

5.22. The Community Reference Laboratory for *Staphylococcus* had updated their reference method for detecting staphylococcal enterotoxins in milk and milk products referenced in Annex 1 of the Regulation (EC) 2073/2005. An update of the reference method listed in Regulation (EC) 2073/2005, introduced by Regulation (EC) 1441/2007, was agreed unanimously by Member States without comment.

5.23. The amendment impacts mainly on the dairy sector and laboratories that carry out testing. The Agency continues to seek information on the impact of this change but no concerns have come to light. Improved testing methods are likely to offer increased protection to public health through improved detection of the staphylococcal enterotoxin. Also, the method may be easier for laboratories to use.

5.24. Regulation (EC) 2073/2005 (Article 5.5) allows for methods other than the reference method to be used, as long as they are appropriately validated against the reference methods and, in some cases, certified by a third party. It is possible that the introduction of a new reference method may impact on the validation of these alternative methods. There may also be limited increased costs as laboratory staff are trained to use the new method. Stakeholders have been asked to provide information on the impact of the new method's

introduction but none has so far been received, which indicates that this impact is not significant.

Meat Industry

5.25. There are 36 red meat slaughterhouses within Scotland which would be affected by this Regulation.

Harmonised carcase sampling rules

5.26. Several Member States supported a suggestion for further harmonisation of carcass testing, in particular the specification of the number of sites that must be sampled when testing for *Salmonella* on red meat carcasses (June 06 - Member States, including the UK, argued for less prescription as this is process hygiene criteria and the sample site should be selected taking the slaughter technology into consideration). Currently, only the minimum area per site selected was specified. The UK suggested that amending the "minimum area of 100 sq cm per site selected" to "a total minimum area of 400 square cm" could be an acceptable proposal. This accommodated the Member States wishing to use the same 4 sites as specified for APC and Enterobacteriaceae, as well as those that wish to use the USDA method for export or the UK side sponge method as currently included in the Meat Industry Guide .This was accepted by the Working Group.

5.27. There is expected to be no impact on the UK industry as the method currently used (side sponge wipe) covers at least the minimum 400 square cm. Industry is content with this following the explanation that, in effect, there is no change. The Meat Industry Guide and ukmeat.org website have been updated accordingly.

Local Authorities

5.28. Local Authorities are responsible for enforcing the legislation with respect to food safety and will therefore be affected.

Benefits

Option 1 – Do nothing

5.29. Doing nothing maintains the current position and has no incremental benefits.

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)

5.30. Providing for the enforcement, in Scotland, of Regulation (EC) 1441/2007 avoids any risk of the UK failing its EU Treaty obligations, with the consequence of monetary sanctions by the European Commission.

5.31. The revisions to the microbiological criteria for food businesses will have an impact on three different sectors, mainly the Infant Formula, Dairy and Meat industries.

5.32. The benefits will be limited and it is therefore not possible to quantify the benefits of the individual amendments, particularly as feedback suggests the industry is already likely to be observing the standards for infant and follow-on formula. The Regulation will, however, contribute to the protection of public health and provide greater clarity for businesses and enforcement officials on the requirements for these products.

Costs

Option 1 – Do nothing

Doing nothing maintains the current position and has no incremental costs.

5.33. There will be some adjustment costs for some FBOs, but the Agency does not expect the Regulation to have a major costs impact on the UK. These amendments will mainly formalise existing procedures followed by the industry, although the new criterion for *Bacillus cereus* may result in an increase in testing by businesses to demonstrate compliance with the Regulation.

6. Small Firms Impact Test

6.1. The Agency does not expect the measures to have a significant impact on small firms in Scotland. It is understood that there are no small firms manufacturing infant formula or follow-on milk in Scotland so the vast majority of the burden from the change to the Regulations will fall mainly on the larger businesses in the Dairy and Meat sectors**.**

7. Test Run of Business Forms

7.1. The Food Hygiene (Scotland) Amendment Regulations 2010 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

8. Competition Assessment

8.1. The Food Hygiene (Scotland) Amendment Regulations 2010 are unlikely to either directly or indirectly limit the number or range of suppliers to these sectors nor will they reduce the incentives for competitive action. As such the Agency does not consider that the amendments have the scope to significantly effect competition adversely in these sectors.

9. Enforcement Sanctions and Monitoring

9.1. Enforcement of the Regulation will be the responsibility of Local Authority Environmental Health Departments.

9.2. 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 for a, stakeholder meetings, surveys, and general enquiries from the public.

10. Sustainability Assessment

10.1. We do not envisage that the measure will be unsustainable as the economic effects are unlikely to endanger the business survival, or increase burdens. No comments were received during the consultation on sustainability.

11. Implementation and Delivery Plan

11.1. Regulation (EC) 1441/2007 applied directly in the UK from December 2007 (i.e. 20 days after being published in the EU Official Journal on 5 December 2007).

11.2. The Food Hygiene (Scotland) Amendment Regulations 2010, providing for the enforcement, in Scotland, of Regulation (EC) 1441/2007, are expected to come into force on 13 April 2010. Its publication will be communicated to stakeholders through the Agency's website, FSA News, etc.

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12. Post- implementation Review

12.1. A review to establish the actual costs and benefits, and the achievement of the desired effects, will take place in December 2012 (i.e. 5 years from the direct application in the UK of Regulation (EC) 1441/2007.

12.2. 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 Food Hygiene (Scotland) Regulations 2006 (as amended) provide for the enforcement, in Scotland, of Regulation (EC) 2073/2005. The Agency therefore recommends the proposed Food Hygiene (Scotland) Amendment Regulations 2010 in order to provide for the enforcement, in Scotland, of Regulation (EC) 1441/2007, as outlined in Option 2 above.

13.2. Therefore the Minister for Public Health and Sport is recommended to agree Option 2.

14. Declaration

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

Signed……

Date

Minister for Public Health and Sport

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FINAL REGULATORY IMPACT ASSESSMENT

7. Title of Proposal

1.1 The Food Hygiene (Scotland) Amendment Regulations 2010

1.2 The above instrument implements a range of EC and national measures. This RIA only relates to those national measures concerning cleansing and disinfection facilities at small slaughterhouses.

2 The Objective

2.1 The objective of the proposed statutory instrument is to implement, in Scotland, a national measure under Article 10 of Regulation (EC) No. 853/2004. The national measure makes provision for certain small, and often rural, slaughterhouses across the UK to be approved as meeting the legal requirements relating to equipment and structures without the need for cleansing and disinfection facilities for livestock vehicles. This proportionate measure will help maintain jobs and the services such businesses provide to the local economy, while maintaining consumer health protection.

3. Rationale for Government Intervention

3.1 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

3.2 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. To be efficient these hygiene standards need to be proportionate to the risk with the costs of compliance fully justified by the benefits.

3.3 For certain small slaughterhouses, the requirement in the EU Food Hygiene regulations (which came into effect in January 2006) for cleansing and disinfection facilities for livestock vehicles is disproportionately costly. The national measure is needed to allow such small slaughterhouses, which were not previously required to have cleaning and disinfection facilities, to be given approval to operate without these facilities where there is no increased risk to public health.

3.4 In the short term the measures will primarily benefit small, rural slaughterhouses in England who have been unable to meet the EC requirements for cleaning and disinfection facilities, although similar rural slaughterhouses in Scotland will also benefit from the flexibilities introduced by the national measure in the future.

4. Background

4.1 Three EU Food Hygiene Regulations applied in all Member States on 1 January 2006, replacing and revoking 17 Directives leading to the revocation of a series of meat regulations including the Fresh Meat (Hygiene and Inspection) Regulations (as amended) 1995.

4.2 The Regulations are: Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004 and Regulation (EC) No. 854/2004. These lay down, respectively, hygiene requirements for all food businesses, additional hygiene requirements for food businesses dealing in products of animal origin, and specific rules for the organisation of official controls on products of animal origin for human consumption.

4.3 Article 4 of Regulation (EC) No. 853/2004 requires that food business operators placing products of animal origin manufactured in the Community on the market must meet the requirements of Regulation (EC) No. 852/2004 as well as the requirements of Annexes II and III of Regulation (EC) No. 853/2004 and other relevant requirements of food law. These establishments must have been approved by the competent authority as meeting the necessary requirements.

4.4 Point 3 of Article 10 of Regulation (EC) No. 853/2004 permits Member States to adopt national measures adapting the requirements laid down in Annex III, provided they do not compromise the achievement of the objectives of the Regulation, and point 4(b) states that the national measures shall apply to the construction, layout and equipment of establishments.

4.5 Annex III, Section I, Chapter II, paragraph 6 of Regulation (EC) No. 853/2004 requires all slaughterhouses in which domestic ungulates are slaughtered to have *"a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock. However, slaughterhouses need not have these place and facilities if the competent authority so permits and if official authorised places and facilities exist nearby."* There is a similar requirement in Section II, Chapter II, paragraph 6 (b) which requires all slaughterhouses in which poultry and lagomorphs are slaughtered to have *"a separate place with appropriate facilities for the cleaning, washing and disinfection of… means of transport. These places and facilities are not compulsory if officially authorised places and facilities exist nearby."*

4.6 Some slaughterhouses that were licensed as low throughput[9] under the now revoked Fresh Meat (Hygiene and Inspection) Regulations (as amended) 1995 were exempted from having facilities for cleansing and disinfecting of livestock vehicles on site. They are now required to have those facilities on site, unless these facilities exist nearby, before they can be approved by the competent authority.

4.7 Discussions with the meat industry have revealed that some slaughterhouses, especially those in England, are unable to meet the new requirement because of their location and lack of physical space. Additionally, where officially authorised facilities exist, they are not necessarily nearby or open at appropriate times.

4.8 The national measure is needed to allow such small slaughterhouses, which were not previously required to have cleansing and disinfection facilities, to be given approval to continue to operate without such facilities where there is no increased risk to public health.

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[9] The Fresh Meat (Hygiene and Inspection) Regulations 1995 (as amended) defined a low throughput slaughterhouse as: *"a throughput of animals whose meat is intended for sale for human consumption of not more than 1,000 livestock units each year at a rate not exceeding 20 each week".*

4.9 Adoption of the national measure will effectively maintain the exemption that was available to these businesses under the Fresh Meat (Hygiene and Inspection) Regulations 1995 (as amended).

5. Devolution

5.1 The proposed regulations will apply in Scotland only. Separate domestic legislation will be made to provide for this national measure in England, Wales and Northern Ireland.

6. Consultation

6.1 The Agency carried out a full public consultation, including stakeholders and other Government Departments in Scotland between 18 December 2007 and 14 March 2008.

6.2 No comments were received on these measures.

6.3 Following revision of the statutory instrument the UK was obliged to re-notify it to the European Commission under the provisions of the Technical Standards and Regulations Directive 98/34/EC (this was the same for the corresponding instruments in England, Wales and Northern Ireland), which it did so on 30 October 2008. This three month period provides the Commission and Member States with the opportunity to scrutinise national legislation to ensure that it does not provide barriers to trade. In the case of this statutory instrument, the period ended on 2 February 2009.

7. Options

7.1 The options considered in this case to implement the hygiene requirements of Regulation (EC) No. 853/2004 in Scotland were:

i. Option 1 - Do nothing;

ii. Option 2 - Adopt a national measure to adapt the requirements of the EC Regulation in respect of facilities for the cleansing and disinfection of livestock vehicles to exempt certain slaughterhouses with a low throughput from the need to have these facilities.

7.2 A third option of submitting the proposal as part of EU hygiene review was considered. This was put to consultation but did not gain any stakeholder support. In view of the lengthy timescale for a wholesale review of the hygiene regulations and the possibility of infraction proceedings in the meantime, unless cleaning and disinfection facilities were installed at a total cost of between £120,000 and £200,000 to the UK meat industry, this option was discounted.

<u>Analysis of options</u>

7.3 Below are the analyses of the Options that were considered as part of the consultation.

7.4 Option 1 is the do nothing option and so has no incremental costs and benefits. It provides the baseline to which all other options are compared.

7.5 Option 2 is the preferred Option. Low throughput slaughterhouses without cleansing and disinfection for livestock vehicles facilities do not pose an increased risk to public health. A national measure is needed to exempt the affected slaughterhouses from the requirement to have these facilities, which would be disproportionately costly, and allow them to continue to operate.

7.6 In Scotland, all former low throughput slaughterhouses met the new legal requirements concerning cleansing and disinfection facilities and were fully approved by December 2008. However, the national measure will allow them to make use of this national flexibility in the future and continue to operate as an approved establishment.

7.7 The conditions for approval without facilities for cleaning and disinfection of livestock vehicles would be that:

- the food business was approved as a low capacity slaughterhouse at 31 December 2005;
- the slaughterhouse otherwise meets the requirements of Regulations (EC) No. 852/2004 and 853/2004;
- vehicle drivers will need to confirm in writing with the operator that they will clean their vehicles between consignments of animals; and
- the operator accepts that they may be required, subject to the epidemiological situation and animal health legislation, to stop operating in times of an animal disease outbreak (such closures were required during the last foot and mouth disease outbreak).

8. Costs and Benefits

Sector and groups affected

8.1 The national measure will affect slaughterhouses that were licensed as a low throughput slaughterhouse under the Fresh Meat (Hygiene and Inspection) Regulations 1995 (as amended). There are currently 10 of these slaughterhouses in Scotland.

Costs

8.2 There are considered to be no incremental costs associated with Option 2 in Scotland.

Benefits

8.3 Although all former low throughput slaughterhouses in Scotland have been fully approved under the new European regulations, the national measure will provide them with a degree of flexibility in terms of meeting the cleansing and disinfection requirements in the future.

9. Impact on Small Firms

9.1 The Meat Hygiene Policy Forum was consulted and discussions took place with representatives' bodies of the meat industry. They welcomed the proposal for a national measure as without it the affected small businesses in England could not gain approval and would be forced to close, and similar businesses in the rest of the UK would not benefit from the additional flexibility.

10. Test Run of Business Forms

10.1 There are no administrative costs associated with this option. No new or additional forms will be introduced.

11. Competition Assessment

11.1 The preferred option is not expected to have an impact on the way that business is conducted at these premises. It is therefore not considered likely to directly or indirectly limit the range of suppliers and neither is it considered likely that it will limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously.

11.2 The exemption from the requirements to install cleansing and disinfection facilities may be perceived as unfair to new businesses wishing to enter the meat industry, which would have to install them as a condition of approval. However, any impact on competition is limited because the exemption is restricted only to slaughterhouses that were licensed as low throughput on 31 December 2005 under the previous legislation, and, for the reasons set out in paragraph 4.7, would find provision of the facilities in existing premises unnecessarily burdensome or impractical. This would not be the case with brand new premises which would be built with compliance with the law being taken into account during design and construction.

12. Enforcement, Sanctions and Monitoring

12.1 The Meat Hygiene Service will remain responsible in Scotland and elsewhere in GB for enforcement, sanctions and monitoring for meat hygiene requirements set out in the Regulations.

13. Sustainable Development

13.1 Impacts under all three pillars of Sustainable Development - economic, social and environmental - have been considered in preparing this RIA. Option 2 is considered relatively more sustainable as it will mean the avoidance of unnecessary costs for smaller establishments (SMEs), often based in rural areas, which could have potential adverse economic consequences for local employment. The impact of the national measure will contribute towards the future viability of such small, rural slaughterhouses, and help to minimise food miles through the transport of animals to other slaughterhouses.

14. Rural Proofing

14.1 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.

14.2 To survive, some small slaughterhouses offer additional services to local farmers, for example cutting and packaging meat for farmers to sell at farmers' markets. The closure of small slaughterhouses would impact on farmers. This proposal will ensure a number of small slaughterhouses in England are able to continue to operate, and will provide similar slaughterhouses in Scotland with additional flexibility concerning their current cleansing and disinfection facilities.

15. Implementation and Delivery Plan

15.1 The above Regulations implementing this national measure in Scotland is expected to come into force on 13 April 2010.

16. Post-Implementation Review

16.1 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in April 2015.

17. Summary and Recommendation

17.1 The national measure is needed to ensure that certain small, and often rural, slaughterhouses in the UK without cleansing and disinfection facilities for livestock vehicles can be approved as meeting the legal requirements relating to equipment and structures, and can therefore continue to operate. All such former low throughput premises have already been approved in Scotland, and the national measure will provide them with additional flexibility with respect to their cleansing and disinfection facilities, helping to ensure their future viability as rural businesses.

18. Declaration

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

Signed:

Date:

Minister for Public Health and Sport

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FINAL REGULATORY IMPACT ASSESSMENT

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2. The Objective

2.1 The objective of the proposed statutory instrument is to implement, in Scotland, a national measure under Article 10 of Regulation (EC) No. 853/2004. The national measure makes provision for certain small, and often rural, slaughterhouses across the UK to be approved as meeting the legal requirements relating to equipment and structures without the need for refrigerated detained meat facilities. This proportionate measure will help maintain jobs and the services such businesses provide to the local economy, while maintaining consumer health protection.

3. Rationale for Government Intervention

3.1 Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

3.2 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. To be efficient, the intervention needs to be proportionate to the risk.

3.3 For certain small slaughterhouses, the requirement in the European Food Hygiene Regulations (which came into effect on 1 January 2006) for detained facilities for meat is disproportionately costly. The national measure is needed to allow such small slaughterhouses, that were not previously required to have facilities for detaining meat, to be given approval to operate without these facilities where there is no increased risk to public health.

3.4 In the short term the measures will primarily benefit small, rural slaughterhouses in England who have been unable to meet the EC requirements for refrigerated detained meat facilities, although similar rural slaughterhouses in Scotland will also benefit from the flexibilities introduced by the national measure in the future.

4. Background

4.1 Three EU Food Hygiene Regulations came into force in all Member States on 1 January 2006, replacing and revoking the previous seventeen EU Directives, including the Fresh Meat (Hygiene and Inspection) Regulations (as amended) 1995.

4.2 The EU Food Hygiene Regulations are: Regulation (EC) No. 852/2004, which lays down the basic hygiene requirements for all food business operators; Regulation (EC) No. 853/2004, which lays down additional hygiene requirements for food businesses dealing in products of animal origin and Regulation (EC) No. 854/2004, which lays down rules for the organisation of official controls on products of animal origin for human consumption.

4.3 Article 4 of Regulation (EC) No. 853/2004 requires that food business operators placing products of animal origin manufactured in the Community on the market must meet the requirements of Regulation (EC) No 852/2004, of Annexes II and III of Regulation (EC) No. 853/2004 and other relevant requirements of food law and have been approved by the competent authority as meeting the necessary requirements.

4.4 Point 3 of Article 10 of Regulation (EC) No. 853/2004 permits Member States to adopt national measures adapting the requirements laid down in Annex III, provided they do not compromise the achievement of the objectives of the Regulation, and point 4(b) states that the national measures shall apply to the construction, layout and equipment of establishments.

4.5 Annex III, Section I, Chapter II, point 5 of Regulation (EC) 853/2004 requires slaughterhouses slaughtering domestic ungulates to have *"lockable facilities for the refrigerated storage of detained meat, and separate lockable facilities for the storage of meat declared unfit for human consumption."* Similarly, Annex III, Section II, Chapter II, point 5 requires slaughterhouses slaughtering poultry and lagomorphs to have *"lockable facilities for the refrigerated storage of detained meat, and separate lockable facilities for the storage of meat declared unfit for human consumption."*

4.6 Some slaughterhouses that were licensed as low throughput[10] under The Fresh Meat (Hygiene and Inspection) Regulations (as amended) 1995, were exempted from having refrigerated detention facilities. They are now required to have those facilities before they can be approved by the competent authority.

4.7 Initial discussion with the meat industry has revealed that some slaughterhouses, especially those in England, are unable to meet the new requirement because of their location, lack of physical space or because they occupy a building of historical significance.

4.8 The national measure is needed to allow such small slaughterhouses, which were not previously required to have detained meat facilities, to be given approval to continue to operate without such facilities where there is no increased risk to public health.

4.9 Adoption of the national measure will effectively maintain the exemption that was available to these businesses under the Fresh Meat (Hygiene and Inspection) Regulations 1995 (as amended).

5. Devolution

5.1 The proposed regulations will apply in Scotland only. Separate domestic legislation will be made to provide for this national measure in England, Wales and Northern Ireland.

6. Consultation

6.1 The Agency carried out a full public consultation, including stakeholders and other Government Departments in Scotland between 18 December 2007 and 14 March 2008.

6.2 No comments were received on these measures.

6.3 Following revision of the statutory instrument the UK was obliged to re-notify it to the European Commission under the provisions of the Technical Standards and Regulations Directive 98/34/EC (this was the same for the corresponding instruments in England, Wales and Northern Ireland), which it did so on 30 October 2008. This three month period provides the Commission and Member States with the opportunity to scrutinise national legislation to

[10] The Fresh Meat (hygiene and inspection) Regulations 1995 (as amended) defined a low throughput slaughterhouse as: '*a throughput of animals whose meat is intended for sale for human consumption of not more than 1,000 livestock units each year at a rate not exceeding 20 each week*'

ensure that it does not provide barriers to trade. In the case of this statutory instrument, the period ended on 2 February 2009.

7. OPTIONS

7.1 The options considered in this case to implement the hygiene requirements of Regulation (EC) No. 853/2004 in Scotland were:

i. Option 1 - Do nothing;

ii. Option 2 - Adopt a national measure to adapt the requirements of the EC Regulation in respect of refrigerated detention facilities to exempt certain slaughterhouses with a low throughput from the need to have these facilities.

7.2 A third option of submitting the proposal as part of EU hygiene review was considered. This was put to consultation but did not gain any stakeholder support. In view of the lengthy timescale for a wholesale review of the hygiene regulations and the possibility of infraction proceedings in the meantime, unless detention facilities were installed at a total cost of between £120,000 and £200,000 to the UK meat industry, this option was discounted.

Analysis of options

7.3 Below are the analyses of the Options that were considered as part of the consultation.

7.4 Option 1 is the do nothing option and so has no incremental costs and benefits. It provides the baseline to which all other options are compared.

7.5 Option 2 is the preferred Option. Low throughput slaughterhouses without detained facilities do not pose an increased risk to public health. A national measure is needed to exempt the affected slaughterhouses from the requirement to have detained facilities, which would be disproportionately costly, and allow them to continue to operate. Additionally, it will be permissible for detained meat to be detained at an alternative location if one exists in the locality.

7.6 In Scotland, all former low throughput slaughterhouses met the new legal requirements concerning detained meat facilities and were fully approved by December 2008. However, the national measure will allow them to make use of this national flexibility in the future and continue to operate as an approved establishment.

7.7 The conditions for approval without refrigerated detention facilities would be:

- that the food business was approved as a low capacity slaughterhouse on 31 December 2005;
- that the slaughterhouse otherwise meets the requirements of Regulations (EC) No. 852/2004 and 853/2004;
- that the operator has such control over the acceptance of animals for slaughter that the establishment rarely, if ever, produces meat that requires detention for further examination by the official veterinarian (OV);

- that either an alternative detention facility is available in the locality, in which case the meat must be marked as 'Detained' and then consigned there, *or* any meat deemed by the OV to require further inspection must be destroyed; and,
- that no processing for human consumption of cattle or of pigs over 48 months requiring Trichinella testing that would require carcases to be held while awaiting test results, takes place.

8. Costs and Benefits

Sector and groups affected

8.1 The national measure will affect slaughterhouses that were licensed as a low throughput slaughterhouse under the Fresh Meat (Hygiene and Inspection) Regulations 1995 (as amended). There are currently 10 of these slaughterhouses in Scotland.

Costs

8.2 There are considered to be no incremental costs associated with Option 2 in Scotland.

Benefits

8.3 Although all former low throughput slaughterhouses in Scotland have been fully approved under the new European regulations, the national measure will provide them with a degree of flexibility in terms of their future arrangements for detained meat facilities.

9. Impact on Small Firms

9.1 The Meat Hygiene Policy Forum was consulted and discussions took place with representatives' bodies of the meat industry. They welcomed the proposal for a national measure as without it the affected small businesses in England could not gain approval and would be forced to close, and similar businesses in the rest of the UK would not benefit from the additional flexibility.

10. Test Run of Business Forms

10.1 There are no administrative costs associated with this option. No new or additional forms will be introduced.

11. Competition Assessment

11.1 The preferred option is not expected to have an impact on the way that business is conducted at these premises. It is therefore not considered likely to directly or indirectly limit the range of suppliers, and neither is it considered likely that it will limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously.

11.2 The exemption from the requirements to install refrigerated detention facilities may be perceived as unfair to new businesses wishing to enter the meat industry, which would have to install them as a condition of approval. However, any impact on competition is limited because the exemption is

restricted only to slaughterhouses that were licensed as low throughput on 31 December 2005 under the previous legislation, and, for the reasons set out in paragraph 4.7, would find provision of the facilities in existing premises unnecessarily burdensome or impractical. This would not be the case with brand new premises which would be built with compliance with the law being taken into account during design and construction.

12. Enforcement, Sanctions and Monitoring

12.1 The Meat Hygiene Service will remain responsible in Scotland and elsewhere in GB for enforcement, sanctions and monitoring for meat hygiene requirements set out in the Regulations.

13. Sustainable Development

13.1 Impacts under all three pillars of Sustainable Development - economic, social and environmental - have been considered in preparing this RIA. Option 2 is considered relatively more sustainable as it will mean the avoidance of unnecessary costs for smaller establishments (SMEs), often based in rural areas, which could have potential adverse economic consequences for local employment. The impact of the national measure will contribute towards the future viability of such small, rural slaughterhouses, and help to minimise food miles through the transport of animals to other slaughterhouses.

13.2 While the provision to allow detained meat to be moved to an alternative facility in the locality may entail additional costs, it could provide sustainability benefits in that meat that would ordinarily be discarded as waste rather than being detained for later inspection may be passed fit for human consumption following detention.

14. Rural Proofing

14.1 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. This would also help to reduce food miles and may enhance animal welfare.

14.2 To survive, some small slaughterhouses offer additional services to local farmers, for example, cutting and packaging meat for farmers to sell at farmers' markets. The closure of small slaughterhouses would impact on farmers. This proposal will enable a number of small slaughterhouses in England to continue to operate, and will provide similar slaughterhouses in Scotland with additional flexibility concerning their current detained meat facilities.

15. Implementation and Delivery Plan

15.1 The above Regulations implementing this national measure in Scotland is expected to come into force on 13 April 2010.

16. Post-Implementation Review

16.1 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in April 2015.

17. Summary and Recommendation

17.1 The national measure is needed to ensure that certain small, and often rural, slaughterhouses in the UK without refrigerated detained meat facilities can be approved as meeting the legal requirements relating to equipment and structures, and can therefore continue to operate. All such former low throughput premises have already been approved in Scotland, and the national measure will provide them with additional flexibility with respect to their detained meat facilities, helping to ensure their future viability as rural businesses.

18. Declaration

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

Signed:

Date:

Minister for Public Health and Sport

Contact point

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