

EXECUTIVE NOTE

The Food Hygiene (Scotland) (Amendment) Regulations 2007 SSI/2007/11

The above instrument is made by Scottish Ministers in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(a) and of all other powers enabling them in that behalf. This instrument is subject to negative resolution procedure.

1 Policy Objectives

- 1.1 This instrument amends The Food Hygiene (Scotland) Regulations 2006 (SSI 2006/3) by updating the definitions of certain Community instruments that are referred to in those regulations.

2 Legislative Background

- 2.1 The purpose of this instrument is to update in Scotland the existing principle Regulations in relation to Food Hygiene concerning the fish/shellfish, red meat and dairy food industry sectors. There are also implications for imports and official controls.
- 2.2 The EU Food Hygiene Regulations apply directly in each Member State of the EU from January 2006. National legislation is neither required nor allowed, to give full effect to the EU Regulations, beyond providing for their enforcement in Scotland.
- 2.3 This SSI gives effect to five Commission Regulations which amend the EU Hygiene Regulations and establish more detailed implementing or transitional provisions.

3 Policy Background

- 3.1 A package of EU food hygiene regulations was adopted in Spring 2004 and applied from 1 January 2006 (The Food Hygiene (Scotland) Regulations 2006 (SSI 2006/3)), its foremost objective being the optimisation of public health protection through consolidation and updating of the previous EU legislation. The new Regulations introduced 'horizontal' legislation across the food chain from 'farm to fork'. A previous suite of implementing measures and transitional arrangements amending the food hygiene legislation was issued by the Commission and applied from 11 January 2006.

4 Consultation

- 4.1 The Agency has been in ongoing contact with the Scottish Executive Environment and Rural Affairs Department (SERAD) and liaised with a

number of other organisations including The Meat Hygiene Service and Fisheries Research Service and Dairy Hygiene Inspectorate. These bodies are content with the line taken by the UK.

- 4.2 The Food Standards Agency carried out a public consultation in Scotland starting on the 21st September 2006 and ending on the 11th December 2006, to seek views on the draft regulations from a wide range of stakeholders including consumer organisations, non-governmental organisations, the feed industry, and enforcement authorities. There were three Scottish responses to the Regulation, two with no comment and one supporting the Regulation.

5 Manpower and Financial Implications for Central and Local Government

- 5.1 The Agency does not expect that any significant costs will arise from the legislation. No indications of extra costs were given by stakeholders during constitution.

6 Effect of the Regulations and Impact on Business and Trade

- 6.1 The Regulatory Impact Assessment (RIA) which accompanies the consultation gave an overview on the impact of the Commission Regulations rather than those in the Scottish Statutory Instruments (SSI). It was considered that there would be no additional impact on the SSI from the amended Regulations.
- 6.2 A circulation list of the interested parties consulted during the preparation of the instrument is attached at the end of this Executive Note.
- 6.3 The Agency anticipates that there may be costs to the fish oil processing industry as establishments manufacturing fish oil for human consumption will now have to be approved by the competent authority and this might result in the need for structural and/or work behavioural changes. Scotland has consulted its Local Authorities on this matter and it has been confirmed that there are no fish oil manufacturers in Scotland.

List of Interested Parties

Interested Parties List - September 2006
Aberdeen Buttery Co. Ltd
Aberdeen City Council
Aberdeen Scotch Meat Ltd
Aberdeenshire Council
AG BARR
Allied Distillers
Angus Council
Aquascot
Arbroath Fishermen's Association
Arla Foods Milk Partnership
Argyll & Bute Council
Argyll & Clyde
Association of Public Analysts
Association of Scottish Shellfish Growers
Barbour Index plc
Baxters of Speyside
Biodon International
British Cattle Veterinary Association
British Dietetic Association
British Egg Industry Council
British Egg Products Association
British Goat Society
British Hospitality Association
British Marine Finfish Association
British Nutrition Foundation
British Poultry Council
British Soft Drinks Association
British Trout Association
British Veterinary Association
Caledonian Cheese Co
Charcuterie Continental
Charis Innovative Food Services Limited
Chilled Food Association
City of Edinburgh Council
Clackmannanshire Council
Clyde Fishermen's Association
Cold Storage and Distribution Federation
Comhairie Nan Eilean Siar
Convention of Scottish Local Authorities(COSLA)
Co-operative Group (CWS) Ltd
Country Markets Ltd
Crofters Commission
Dairy UK - Scotland
Daniel's Sweet Herring Ltd
Dawnfresh Seafoods
Deans of Huntly
DEER Commission Scotland
DEVRO (Scotland) Limited
Diageo
Dumfries & Galloway Council
Dumfries & Galloway Health Board
Dundee City Council
Dundee College
Dundee Primary Care Division
Dychem Ltd.
East Ayrshire Council
East Dunbartonshire Council
East Lothian Council
East Renfrewshire Council
East of Scotland Food Liaison Group
Ecos Limited
Eden Springs UK Ltd
Environmental Services Department
Express Dairies Direct Service
Falkirk Council
Fife Council

Fife Council Environmental Services
Fife Health Board
Fife Primary Care N.H.S. Trust
First Milk Ltd
Food Certification (Scotland) Ltd
Food Microbiology and Fish Handling and Processing
Food Training & Consultants Company
Forth Valley Primary Care NHS Trust
FRS Marine Laboratory
Fusion Linking
Glasgow Caledonian University
Glasgow City Council
Glasgow College of Food Technology
Glasgow Metropolitan College
Glasgow Scientific Services
Glenrothes College
Grampian Country Food Group Ltd
Grampian Health Board
Grampian University Hospitals NHS Trust
Greenwood Academy
Greggs Scotland
Handmade Cheese of Scotland
Hannah Research Institute
Health and Safety Executive
Health Protection Scotland
Herriot-Watt University
Highland & Island Enterprise
Highland Council
Highland Health Board
Highland Spring Ltd
Hilton Group Plc.
HUSH
Hutchison Associates Ltd
Ian Hain Associates
International Federation of Environmental Health
Inverclyde Council
IRIS
Isabella's Preserves
James Finlay Ltd.
John Hogarth Ltd.
Kettle Produce Ltd.
Kingdom Bakers Ltd.
Lacors
Lees Of Scotland
Lightbody Celebration Cakes
Lothian & Borders Food Liaison Group
Lothian Health Board
M&D Catering
M.D. Longhorn & Co
Mackays Ltd.
MacPhie of Glenbervie Ltd.
MacRae Foods Ltd.
Macsween of Edinburgh
Mallaig & North-West Fishermen's Association
McAusland Crawford Ltd.
McIntosh Donald Ltd.
Meat and Livestock Commission
Meat Hygiene Service
Microgram
Midlothian Council
Moray Coast Produce
Moray Seafood Ltd
Moredun Research Institute
Munchies Sandwich Bar
Napier University
National Dairy Farm Assured Scheme Ltd
NBA Scotland
Neogen Europe Ltd.
Neville Craddock Association

New Community Schools
NFU Scotland
NHS Health Scotland
NHS Lanarkshire Board
North Atlantic Fisheries College
North Ayrshire Council
North Lanarkshire Council
North of Scotland Food Liaison Group
NOSCO & University of Aberdeen
Orkney Fisheries Association
Orkney Herring Co Ltd
Orkney Islands Council
Pataks Frozen Food
Paterson Arran Limited
Perth & Kinross Council
Purely Scottish Mineral Water Distribution Ltd
Pure Malt Products Ltd.
Quality Meat Scotland
Queen Margaret University College
R&M Limited
R.M.P.R. Ltd
Renfrewshire Council
Renshaw Scott Ltd.
Robert Gordon University
Robert Wisemans Dairies
Roslin Institute
Rowett Research Institute
Royal Environmental Health Institute for Scotland
Royal Highland Agricultural Society of Scotland
Sanquhar Academy
Scot Trout Ltd.
Scotch Whisky Research Institute
Scotia Produce
Scottish Agricultural College
Scottish Association of Master Bakers
Scottish Association of Meat Wholesalers
Scottish Beekeepers Association
Scottish Borders council
Scottish Chambers of Commerce
Scottish Civic Forum
Scottish Committee Public Health Medicine
Scottish Consumer Council
Scottish Crofting Foundation
Scottish Egg Producer Retailers Association
Scottish Enterprise
Scottish Enterprise/Food & Drink
Scottish Environment Protection Agency
Scottish Federation of Meat Traders
Scottish Fishermen's Federation
Scottish Flour Millers Association
Scottish Food & Drink Federation
Scottish Food Advisory Committee
Scottish Food Enforcement Liaison Committee
Scottish Food Quality Certification Ltd
Scottish Food Safety Officers Association
Scottish Foodservice Project
Scottish Game/Dealers Processors Ass.
Scottish Gamekeepers Association
Scottish Grocers Federation
Scottish Health Food Retailers Association
Scottish Licensed Trade Association
Scottish Midland Co-op Society
Scottish Organic Producers Association Ltd
Scottish Parliament
Scottish Pelagic Fishermen's Association Ltd.
Scottish Qualifications Authority
Scottish Retail Consortium
Scottish Salmon Producers Organisation
Scottish Salmon Smokers Association
Scottish Sea Farms Ltd.

Scottish Seafood Processors Federation
Scottish Shellfish Marketing Group Ltd.
Scottish Socialist Party
Scottish Trading Standards Institute
Scottish White Fish Producers Association
Scottish Wholesale Association
Scottish Women's Rural Institutes (SWRI)
Sea Fish Industry Authority
Seafood Scotland
SEERAD, Animal Health & Welfare Branch
Shetland Aquaculture
Shetland Fishermen's Association
Shetland Islands Council
SIMBOIS
Simply Organic
Society of COs Environmental Health In Scotland
South Ayrshire Council
South Lanarkshire Council
Speyside Glenlivet Water co Ltd.
Spicemanns Ltd.
Stirling Council
Stirling Council (Catering & Cleaning)
Stirling Environmental Group
Strathaird Salmon Ltd
Strathmore Mineral Water Co Ltd
Tain Royal Academy
TESCO Stores Ltd
The Association of Meat Inspectors
The Cheese Company
The Edinburgh Smoked Salmon
The Haggis Specialists
The Halal Food Authority
The Law Society of Scotland
The Moray Council
The Robert Gordon University
The Scotch Whisky Association
The Scottish Gourmet (Scotland Direct)
U.S.D.A.W.
UKASS of Frozen Food Producers
UNIQ Prepared Foods
Unison Scotland
United Central Bakeries Ltd
United Fish Products
University of Aberdeen
University of Edinburgh
University of Glasgow
University Of Paisley
University of St Andrews
University of Stirling
University of Strathclyde
Verner Wheelock Associates
Walkers Shortbread Ltd
Wellington Church
West Coast Sea Products Ltd
West Dunbartonshire Council
West Lothian Council
West Lothian Domestic Services
West of Scotland Fish Producers Organisation Ltd
West of Scotland Food Liaison Group
Western Isles Fishermans association
Which
Whitbread PLC.
Wm Pearce & Sons (St Ronan's) Ltd
Woodrows Of Dunfermline Ltd.

FULL REGULATORY IMPACT ASSESSMENT

1. Title of proposal

1.1 This Full Regulatory Impact Assessment (RIA) concerns European Commission Regulations that amend the EU Hygiene Regulations or previous implementing measures.

1.2 The Commission Regulations, which entered into force seven days after their publication in the EU Official Journal on 18 November 2006, are:

- Commission Regulation (EC) No 1662/2006 of 6 November 2006 amending Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin;
- Commission Regulation (EC) No 1663/2006 of 6 November 2006 amending Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;
- Commission Regulation (EC) No 1664/2006 of 6 November 2006 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and repealing certain implementing measures;
- Commission Regulation (EC) No 1665/2006 of 6 November 2006 amending Regulation (EC) No 2075/2005 laying down specific rules on official controls for *Trichinella* in meat; and,
- Commission Regulation (EC) No 1666/2006 of 6 November 2006 amending Regulation (EC) No 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council.

These Commission Regulations have been made available on the Food Standards Agency's web site¹.

1.3 It should be noted that the Draft Partial RIA, which preceded this Full RIA, was put out to consultation on the basis of draft versions of the Commission Regulations, which are listed at Annex A.

¹ <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>

2. Purpose and intended effect

(i) The objective

- 2.1 The Commission Regulations (listed in paragraph 1.2) make amendments to existing EU measures. As Regulations, they are directly applicable legislation.
- 2.2 This RIA covers the UK. However, amendments will be required to the national legislation that gives effect to that EU food hygiene legislation in each country of the UK. The RIA describes the impact of the Commission Regulations, but not the national legislation giving effect to the Regulations, which in itself has no impact.

(ii) Background

EU food hygiene legislation

- 2.3 A package of EU food hygiene regulations² was adopted in Spring 2004 and applied from 1 January 2006, its foremost objective being the optimisation of public health protection through consolidation and updating of the previous EU legislation. The new Regulations introduced 'horizontal' legislation across the food chain from 'farm to fork'³. A previous suite of implementing measures and transitional arrangements⁴ amending the food hygiene legislation was issued by the Commission and applied from 11 January 2006.
- 2.4 A Final RIA⁵ for the EU legislation, titled 'Consolidation of EU Food Hygiene Legislation' (the 'Final RIA') has already been produced on the legislation and was signed off by the then Minister for Public Health in July 2005. The 'Final RIA' provides a detailed examination of the legislation's impact on all food industry sectors and enforcement bodies.
- 2.5 The most recent Commission implementing Regulations, which are the concern of this RIA, were first presented (in draft form) to Member States at a meeting of Standing Committee for the Food Chain and

² Regulation (EC) 852/2004 on the hygiene of foodstuffs; Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin and Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Also part of the package were:

Directive 2004/41 repealing the previous EU legislation or, in some cases, amending still existing legislation and

Directive 2002/99 that lays down the animal health rules on products of animal origin for human consumption and came into force from 1 January 2005. (Defra policy responsibility.)

³ Background to the legislation, including links to pdf copies of the Regulations can be found on the Agency's web site at: <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>

⁴ An explanation of the role of the implementing and transitional measures as well as copies of the measures in pdf format can be found at

<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg>

⁵ The most recent version of the Final RIA can be viewed on the Agency's web site at: <http://www.food.gov.uk/multimedia/pdfs/EURegulationsRIA.pdf>

Animal Health (SCOFCAH) on 19/20 June 2006⁶. They were adopted at SCOFCAH on 18 July 2006⁷ and were published in the EU Official Journal on 18 November 2006.

Consultation on the most recent implementing Regulations

- 2.6 The formal consultation on the most recent Commission implementing Regulations was issued on 21 September 2006 and closed on the 11 December 2006⁸. Prior to this, the swiftness of the development of the legislation meant that there was little opportunity for the Agency to consult informally the relevant stakeholders (e.g. industry, enforcers), although what consultation that did take place is detailed in Part 3 of this RIA. Therefore, during the formal consultation stakeholders were particularly asked for comments regarding benefits and/or costs associated with the legislation, which would be of use in updating the RIA.
- 2.7 The Commission Regulations, which are covered by this RIA, mainly concern the fish/shellfish, red meat and dairy food industry sectors. There are also implications for imports and official controls.

Fish and shellfish industry

- 2.8 There are implications for shellfish harvesting. Until 31 December 2005, legislation required that 90% of samples of live bivalve molluscs (LBMs) harvested from a 'Class B area'⁹ used for the classification of that shellfish bed should meet the specified E.coli level; this 90% requirement was removed by the EU Commission and has not been in operation since 1 January 2006. The Commission had sought to replace this tolerance level with scientific and risk based criteria. This was not forthcoming in the required time and the UK and other EU Member States were concerned about the absence of this and the possible implications of 100% of samples needing to meet the Class B classification criteria. However, the draft requirement effectively re-establishes the 90% figure. There is therefore no change to current practice resulting from this.

⁶ A report on this meeting was made available to stakeholders on the Agency's web site at: <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu/scofcah060619>

⁷ A report on this meeting was made available to stakeholders on the Agency's web site at: <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu/scofcah06071819>

⁸ The consultation documents can currently be found on the Agency's web site at: <http://www.food.gov.uk/consultations/consulteng/2006/hygieneeng07>

⁹ 'Class B area' – molluscs from these areas can be marketed for human consumption only after purification in an approved plant, or after relaying in an approved Class A relaying area, or after being subjected to an EC approved process. Additionally, the end product standards, including microbiological (*E. coli*) criteria, laid down in Section VII, Chapter V of Annex III to Regulation (EC) 853/2004, must be met.

- 2.9 The 'Lawrence Method' is permitted as an alternative method of detecting paralytic shellfish poisoning (PSP) in live bivalve molluscs in particular cases. However, this will have no impact at the moment, as the UK does not intend to consider the use of this method until all the technical issues identified with this method have been resolved by the Commission and the Community Reference Laboratory.
- 2.10 The Commission Regulations now identify that fish oil for human consumption is subject to the food hygiene legislation under the fishery products criteria. This has implications for the UK fish oil processing industry, as establishments will now have to be approved to manufacture fish oil, or products from fish oil.
- 2.11 Establishments processing fish oil will need to be approved by the local food authority in the same way as other establishments that require approval for handling fishery products under Regulation (EC) 853/2004. An establishment handling fishery products can only be given approval if it meets all of the relevant requirements of Annex II and Section VIII, Annex III of Regulation (EC) 853/2004 (and other requirements of Regulation (EC) 852/2004 and relevant requirements of food law.)
- 2.12 Approvals are at the cost of the local authority. However, operators may incur costs as a result of approval inspections if they are required to make improvements to comply with the hygiene requirements. The Agency has not been able to obtain via consultation any information relating to the costs of individual approval inspections, nor on how much it would cost fish oil processors to meet the relevant standards.
- 2.13 The Commission Regulations provide model health certificates for the import of LBMs and fishery products, thus removing the need for a large number of Commission Decisions concerning import conditions for particular countries. Prior to November 2006, import requirements and model health certificates for fishery products and LBMs from various authorised third countries were contained in individual Commission Decisions. These Decisions have now been revoked and replaced by one model health certificate. In practice this means that industry need only refer to that one model in the appropriate Regulation which will apply to all authorised third countries rather than go to individual Decisions for each country. The new model health certificate in Regulation (EC) 1664/2006 also includes a new animal health attestation, which previously was a separate document required in addition to the attestation in the public health certificate.

Red meat industry

- 2.14 In the red meat sector, the draft legislation introduces one new feature that allows the muzzle and lips of adult cattle to enter the food chain, provided they are handled hygienically. Other amendments, such as the requirement for the operator, instead of an official, to remove

tonsils from pig carcasses or changes to health certificates simply correct or clarify the existing statutory requirements.

Dairy industry

2.15 In the dairy sector, specific provisions for colostrum and colostrum-based products are introduced in the food hygiene Regulations for the first time. Also, a new reference method has been introduced for the determination of alkaline phosphatase activity in heat-treated milk (a measure of whether pasteurisation has been undertaken successfully) and the maximum permitted amount of alkaline phosphatase has been reduced.

(iii) Rationale for Government Intervention

2.16 If the Government did not intervene, there would be a failure to:

- satisfy the UK's Treaty obligations to properly apply EU legislation;
- fully contribute to public health protection by helping to ensure that the framework of Regulations governing food hygiene is optimised; and,
- put in place the necessary enforcement arrangements, which could lead to inconsistency across the food business sectors.

3. Consultation

(i) Within Government

3.1 With regard to changes or amendments brought about by the most recent Commission implementing legislation:

- fish and shellfish - the Agency has been in on-going contact with Defra and with the Scottish Executive Environment and Rural Affairs Department (SEERAD) (Animal Health issues) and the Centre for Environment, Fisheries & Aquaculture Science (CEFAS) and Fisheries Research Services (FRS). These bodies are content with the line taken by the UK and CEFAS have advised on some issues in their role as the UK National Reference Laboratory for microbiological contamination of shellfish. The Scottish Fish Hygiene Working Group which is attended by Local Authority Officers has also been updated and briefed on an on going basis. Both SEERAD and FRS are supportive of the use of the HPLC Lawrence method for PSP detection;
- red meat – the Agency has kept the Meat Hygiene Service (MHS) informed of these developments. The MHS has not made any comments either informally, or formally through the consultation, but is amending its Manual for Official Controls to reflect the changes; and,

- dairy - the Agency has been in regular contact with the Dairy Hygiene Inspectorate (DHI) on the issue of colostrum. The DHI is content with the legislation. Informal contact with sector stakeholders suggests that colostrum production in the UK is insignificantly small, perhaps only one or two establishments on a seasonal basis; no further information arose from the formal consultation. The impact therefore on the DHI will be minimal.

(ii) Non-Governmental stakeholders

3.2 The formal consultation on the most recent Commission implementing Regulations was sent to over 170 stakeholders. From this, the Agency received four responses to the consultation only¹⁰. Three of these stated formally that they had no comments. The other response made comments referring to the labelling of cheese made from raw milk. The Commission Regulations do not introduce any labelling requirements, which would be the subject of entirely separate legislation and therefore this issue is not relevant to this RIA. Where the Agency is aware of relevant information from sources other than the consultation, it has been added to the comments on the industry sectors below:

- fish and shellfish - the Agency has been in on-going contact with industry on all of the issues and notably through the Seafish Legislative Expert Meetings and meetings with the Association of Scottish Shellfish Gatherers which are made up of a number of the main fish and shellfish organisations in the UK. On the 90% tolerance level for classification of B class shellfish harvesting areas, the UK industry and CEFAS have supported the retention of this until such time as scientific risk based criteria is developed to replace it. The Industry in Scotland has indicated its full support for replacement of the mouse bioassay with the HPLC Lawrence Method for the detection of PSP once full technical ability is available. On fish oil for human consumption, the Agency has informed and discussed the provisions with the known UK industry. The Agency held a meeting with fish oil industry stakeholders in November 2006, prior to the formal publication of the amendments.
- red meat –The public consultation, including the Draft Partial version of this RIA, was issued to a wide range of meat industry stakeholders, but no comments were received. Slaughterhouse operators were advised by letter of the relevant changes, which have also been reflected in the Meat Industry Guide¹¹ issued by the Agency in December 2006; and,

¹⁰ The Agency aims to provide a summary of the consultation responses on its web site within three months from the closing date of the consultation.

¹¹ The Meat Industry Guide is available on the Agency's web site at: <http://www.food.gov.uk/multimedia/pdfs/mguide6dec06.pdf>

- dairy - the Agency has on-going informal contact with dairy industry representatives and the National Farmers' Union. Informal contact with industry stakeholders suggests colostrum production in the UK is insignificantly small, perhaps only one or two establishments on a seasonal basis; no further information arose from the formal consultation. As regards the changes to determination of alkaline phosphatase activity, contact has suggested that the majority of dairy firms are already working to the revised level and the new reference method is in common usage for routine testing by all but the smallest companies.

4. Options

4.1 The Agency has identified two options in regard to giving full effect to the Commission Regulations. Those options are identified below:

- Option A - Do nothing. EU Regulations are directly applicable law. Failure to amend the national legislation that gives effect to EU Regulations (and therefore not providing properly for the draft Regulations in national law) could be seen as a failure to undertake the UK's Treaty obligations to properly apply EU law. This could lead to action being taken against the UK by the European Commission. It would also mean a failure to give effect to the Commission Regulations where they might have benefits (e.g. by simplifying procedures) and hamper developments that would lead to greater long-term public health protection.
- Option B – Give full effect to the Commission Regulations in national law by amending national legislation. Although EU Regulations are directly applicable law, giving full effect to the Regulations in UK national law should ensure that the UK fulfils its Treaty obligations obviating the need for action against the UK being taken by the Commission. It would also mean that benefits provided by the amendments to legislation are given effect by national legislation and appropriately enforced.

5. Costs and Benefits

i) Sectors and Groups affected

5.1 The groups affected are the fish and shellfish industry, the red meat industry, the dairy industry and the enforcement sector.

ii) Costs and Benefits for the Options (A – B) identified at paragraph 4.1

5.2 The significant cost and benefit impacts of the food hygiene legislation on all food business sectors, including the fish / shellfish, red meat and dairy sectors are described in the 'Final RIA'. Costs and benefits highlighted for the purposes of this RIA refer only to the legislation detailed in paragraph 1.2. The Agency expects that the monetary benefits of this legislation, mainly arising through a decreased administration burden, will outweigh any incurred costs. As already mentioned, no indication of extra costs was given by stakeholders or consumers during the formal consultation.

Option A - Do nothing

Costs

- 5.3 Failure to give effect to the Commission Regulations in UK national laws could lead to the European Commission instigating infraction procedures against the UK including fines (see paragraph 4.1, Option A.)
- 5.4 Failure to properly implement the legislation in regards to import certificates might impact on intra-Community trade as other Member States might refuse to accept goods originally imported into the UK from third countries if there did not seem to be adequate enforcement arrangements in place in the UK.

Benefits

- 5.5 None identified.

Option B - Give full effect to the Commission Regulations in national law by amending national legislation.

Costs

Red meat industry

- 5.6 The amendment requiring removal of tonsils from pig carcasses by operators instead of by an official carries forward previous requirements and corrects an error in the hygiene legislation. The Agency's understanding is that operators are continuing previous practice and that this will not introduce new procedures or costs.

Fish oil industry

- 5.7 The Agency anticipates that there may be costs to the fish oil processing industry as establishments manufacturing fish oil for human consumption will now have to be approved by the competent authority and this might result in the need for structural and/or work behavioral changes. However, the Agency does not know if there are any UK manufacturers in this sector that will be affected in this way; much of the processing is believed to go on outside of the UK. Most of the fish oil imported from third countries is from large co-operatives and UK industry was unable to provide information on individual suppliers. However, the Agency has been unable to attain further information on any burdens either through informal or formal consultation. Scotland has consulted its Local Authorities on this matter and it has been confirmed that there are no fish oil manufacturers in Scotland.

Enforcement of legislation applying to fish oil manufactured for human consumption

- 5.8 The Agency considers that the clarification of the position of fish oil under food hygiene legislation as a fishery product may incur costs to competent authorities in terms of an increase in inspections. In relation to paragraphs 5.6 and 5.7, the Agency is unable to come to any solid conclusions in view of the lack of information.

Dairy

- 5.9 It is not anticipated that there will be any significant costs associated with the measures regarding colostrum. Contact with sector stakeholders suggests that colostrum or colostrum products are only produced in the UK in one or two establishments.

Benefits

Red meat industry

- 5.10 The Agency sees a benefit arising from food businesses being permitted to supply muzzle and lips of adult cattle ('pomos') for human consumption. The Agency believes that there might be a niche market for these products, which will extend consumer choice; the Agency is aware of some trade related to 'pomos' from calves, although no further information on this market was forthcoming from the recent formal consultation.

Enforcement of red meat industry

- 5.11 The revised model health certificates remove the need for reference to numerous Commission Decisions and by improving layout and references, they should be simpler to enforce.

Imports of fish / shellfish

- 5.12 The introduction of a generic model health certificate will remove the need for reference to numerous Commission Decisions and should be simpler to enforce. The Agency considers that benefits might arise from the simplification of these certificates.

Fish oil industry

- 5.13 The clarification of the position of fish oil under hygiene legislation as a fishery product should help to ensure that protection of public health is extended and that the manufacture of fish oil for human consumption is consistent with the manufacture of other products of animal origin for food. The Agency considers that this development will bring a public health benefit.

6. Small firms impact test

- 6.1 The short period of time since the draft Regulations were first issued means that the Agency has not had the opportunity to undertake a small firms impact test on the Regulations. The Agency is not aware that the draft measures will impact disproportionately on small firms. No comments were received during the consultation from small firms or their representative organisations as regards the impact on small firms.

7. Charities and Voluntary Organisations

- 7.1 No added burdens to charities and voluntary organisations are anticipated by the Agency. These measures do not appear to impact at all on food business sectors in which charities or voluntary organisations might usually be involved (i.e. distribution of food to final consumers). No comments were received from charities or their representative organisations during the consultation.

8. Competition Assessment

- 8.1 The Cabinet Office Competition Filter Test suggests that a Simple Competition Assessment is most suitable.
- 8.2 The markets that may be affected are the fish, red meat and dairy food sectors. Importers of animal origin products will also be affected.
- 8.3 The Agency has little information on the fish oil industry at present, as this industry has not previously been subject to food hygiene legislation and no substantive information came from the formal consultation. The Agency estimates that there may be 10 – 30 firms processing fish oil throughout the UK, at least some of which are known to be larger firms. Unfortunately, the Agency was unable to ascertain any substantive information as to the of the fish oil processing industry when it met stakeholders at a meeting it held in November 2006. No information was gained either during the formal consultation.
- 8.4 In the UK, the slaughter of cattle is an important industry carried out by businesses of all sizes. The Agency expects that the change to allow the legal supply of muzzle and lips of adult cattle will have a limited impact on the market as a whole, but will provide an outlet for these specialist products. Statistics indicate, that in the cattle slaughtering sector, the largest of more than 300 plants in the UK accounts for less than 5% of total cattle throughput, which indicates a low degree of concentration within the industry. Currently, there is no legitimate international trade in these products.
- 8.5 The Agency does not expect that any part of the pig slaughter industry will be unduly affected by the new measure, which merely corrects an omission in the legislation. Businesses involved in this industry will carry on unaffected.

8.6 The dairy manufacturing industry is a large industry UK-wide, with a range of size of businesses. Regarding the introduction of the new reference method phosphatase testing to this sector, it has been noted by an industry representative organisation that there may be a competition issue arising from smaller firms feeling compelled commercially to use the phosphatase test, although it will not be a legal obligation only a reference method. The Agency is aware from informal contact with the industry that larger dairy firms are working to go beyond the method's minimum requirement.

8.7 Because little detail is known about the markets affected, the Agency hoped that responses to the public consultation would have resulted in more relevant information so that an analysis of the effects of the measures on the markets and on competition can be undertaken. In the absence of further information however, the Competition Assessment remains unchanged.

9. Sustainability

9.1 Section 5 of the RIA looks at the economic and social pillars of sustainability. No substantive impacts on the environment were identified.

9.2 There would be less waste and therefore an environmental benefit if industry were able to make use of the muzzle and lips of adult cattle as food for human consumption rather than disposing of them as animal by-products.

9.3 There might be an increase in trips in road vehicles as a result of extra enforcement of fish oil manufacturers, but there are perhaps only thirty firms in this sector and so the Agency considers that the environmental impact from extra vehicle journeys would be insignificant.

9.4 In terms of the relative sustainability of each option, for

- Option A. By not complying with its obligations under EU legislation, significant costs to the UK could result following infraction procedures being taken against the UK by the European Commission. This is not set off against any benefits and therefore not sustainable.
- Option B. The benefits, although not hugely significant, do exist and therefore a better balance of costs and benefits with Option B and so this is the most sustainable.

10. Enforcement, sanctions and monitoring

10.1 Enforcement responsibilities are essentially the same as in the Final RIA. There appears to be little or no substantial extra burdens except perhaps for the enforcing of fish oil hygiene. Any enforcement of colostrum production would be of insignificant extra burden at present. There may be benefits resulting from the consolidation of the health certificates.

11. Post-implementation review

11.1 The Commission Regulations that are the subject of this RIA cannot be seen in isolation, but as amendments or additions to the food hygiene legislation as a whole that was introduced from 1 January 2006. There would, therefore, be little or no benefit in looking solely at these measures at some point in the future.

11.2 The European Commission is at the beginning of a review of the food hygiene legislation with the current intention of making any proposals for change at the end of 2008. Indications at this stage are that the scope of the review is unlikely to be wide-ranging; however, this might impact on the nature of any review of the legislation in a UK context. The UK is of the opinion that the legislation does not need a major overhaul, but will anyway need to consider the issue of legislative review generally. Clearly, consultation with stakeholders, such as those representing industry and enforcement, would need to be part of such a review. The Agency will regularly update stakeholders with reports of the progress of the Commission review on its web site¹². The Agency will also formally consult on legislative proposals which the Commission may bring forward following its review.

11.3 The Food Standards Agency, as 'owner' of the policy remit for the whole of the food hygiene legislation will anyway keep the legislation under review as part of its on-going work. This includes regular informal contact with stakeholder groups, and formal consultations when new legislation or any substantial changes (e.g. to national legislation) are proposed. Stakeholders are always likely to bring to the Agency's attention any areas of the legislation which are problematic for them and the Agency will work with stakeholders to seek improvements to, or resolution of, those problems.

12. Declaration and publication

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

¹² Reports on the meetings where progress of the hygiene legislation review will be reported will be accessible from this web address:
<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu/>

Signed.....

Date.....

Lewis Macdonald, MSP
Deputy Minister for Health and Community Care
Scottish Executive

Contact point

Jill Gay
Strategy & Co-ordination Branch
Food Standards Agency Scotland
6th Floor St. Magnus House
25 Guild Street
Aberdeen AB11 6NJ

Tel: 01224 288376

Fax: 01224 285168

e-mail: Jillian.Gay@foodstandards.gsi.gov.uk

ANNEX A

Draft Commission Regulations

The draft Commission Regulations put out to consultation were:

- SANCO/2372/2006 Draft Commission Regulation amending Regulation (EC) No 853/2004
- SANCO/2375/2006 Draft Commission Regulation amending Regulation (EC) No 854/2004
- SANCO/2376/2006 Rev 2 Draft Commission Regulation amending Commission Regulation (EC) No 2074/2005
- SANCO/2378/2006 Draft Commission Regulation amending Commission Regulation (EC) No 2075/2005
- SANCO/2379/2006 Rev 1 Draft Commission Regulation amending Commission Regulation (EC) No 2076/2005

ANNEX B

Implementation and delivery plan

Dairy sector

The Agency intends to write to sector stakeholders before the end of January 2007, highlighting the new legislation and any significant changes. The Agency also intends to make full use of the provision¹³ in Commission Regulation (EC) 1664/2006 to allow 6 months before entry into force of Annex III (test methods for raw and heat treated milk).

Very regular contact with industry and enforcement authorities will continue with regard to all the recent changes in the legislation, including involvement in the development of an industry guide for the dairy sector.

Fish sector

Where appropriate, the Agency will issue guidance to assist in the implementation and enforcement of the new provisions and amendments. In considering the implementation of the new provisions, the Agency will look to minimise the administrative requirements where at all possible while ensuring that necessary records and procedures are maintained to meet EU audit requirements.

In implementing the new provisions and amendments the Agency will continue to liaise with all stakeholders (including industry and enforcers) generally and in the product specific areas to which the Regulations apply. This will be important as there are a number of staged implementation dates within the legislation.

¹³ Article 3 of Commission Regulation (EC) 1664/2006 states 'Annex III to this Regulation shall apply at the latest six months after the entry into force of this Regulation.' This would be 25 May 2007.

Red meat sector

The changes brought about by the most recent set of Commission implementing measures largely correct omissions or errors in the legislation or widen the choice of industry in what products it can use. The legislation does not introduce burdens and the Agency is satisfied that having issued revised guidance (both the industry and enforcement guidance have been amended and issued) and continued contact with the industry would be enough to address any concerns the industry might have.