EXECUTIVE NOTE

THE FOOD HYGIENE (SCOTLAND) AMENDMENT REGULATIONS 2012

SSI 2012/75

1. Description

1.1 The above instrument ("the Regulations") was made by the Scottish Ministers in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972(a) and all other powers enabling them to do so.

1.2 The Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Scottish Ministers that it is expedient for any reference to an EU instrument defined in Schedule 1 to be construed, in accordance with regulation 2(3), as a reference to that instrument as any Annex to it is amended from time to time.

2. Policy Objective

2.1 The Regulations amend the Food Hygiene (Scotland) Regulations 2006 (SSI 2006/3) ("the 2006 Regulations") by providing for the execution and enforcement in Scotland of a suite of amending, implementing measures and transitional arrangements for EU Food Hygiene legislation listed below in Section 2.2. The Regulations provide for a new mechanism (an ambulatory reference) to ensure that, in future, the execution and enforcement of new technical amendments to the Annexes of the EU instruments listed in Schedule 1 to the Regulations will apply automatically thereby significantly reducing the number of occasions the 2006 Regulations will require amendment. They also provide for the application of a new national measure laying down the format of a special health and identification mark to be used on the carcasses of animals subject to emergency slaughter outside a slaughterhouse and on the meat and meat products derived from such carcasses. Finally, the Regulations extend to all food businesses the availability of Remedial Action Notices (RANs) for enforcers as a more proportionate enforcement tool.

List of EU food hygiene amending, implementing measures and transitional arrangements

2.2 The following list of instruments provides, for transparency, a list of EU food hygiene instruments which have been introduced since the 2006 Regulations were last amended in April 2010 and which contain provisions that require execution and enforcement. This includes certain amendments to the EU Instruments which have themselves been further amended since that time. The convention adopted when the 2006 Regulations were first introduced was to describe the Community (now "EU") law as 'last amended by', therefore some of the listed instruments below, where they themselves have been superseded by subsequent amendments, are not referenced in regulation 2(2) and Schedule 1 of the Regulations. The Regulations and the following list also contain some EU instruments which were published prior to April 2010 when the 2006 Regulations were last amended, but which were not included in that amendment since they had not been consulted on in compliance with Article 9 of Regulation (EC) No. 178/2002. The

following list contains instruments which have been the subject of consultation since April 2010:

- COMMISSION REGULATION (EC) No 1019/2008 of 17 October 2008 amending Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs.
- COMMISSION REGULATION (EC) No 1020/2008 of 17 October 2008 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products.
- COMMISSION REGULATION (EC) No 1021/2008 of 17 October 2008 amending Annexes I, II and III to 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 and Regulation (EC) No 2076/2005 as regards live bivalve molluscs, certain fishery products and staff assisting with official controls in slaughterhouses.
- COMMISSION REGULATION (EC) No 1022/2008 of 17 October 2008 amending Regulation (EC) No 2074/2005 as regards the total volatile basic nitrogen (TVB-N) limits.
- COMMISSION REGULATION (EC) No 1023/2008 of 17 October 2008 amending Regulation (EC) No 2076/2005 as regards the extension of the transitional period granted to food business operators importing fish oil intended for human consumption.
- COMMISSION REGULATION (EC) No 1029/2008 of 20 October 2008 amending Regulation (EC) No 882/2004 of the European Parliament and of the Council to update a reference to certain European standards.
- COMMISSION REGULATION (EC) No 1162/2009 of 30 November 2009 laying down transitional measures 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.
- COMMISSION REGULATION (EU) No 505/2010 of 14 June 2010 amending Annex II to Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of officials controls on products of animal origin intended for human consumption.
- COMMISSION REGULATION (EU) No 558/2010 of 24 June 2010 amending Annex III to 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 (EU) No 15/2011 of 10 January 2011 amending Regulation (EC) No 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs.
- COMMISSION REGULATION (EU) No 150/2011 of 18 February 2011 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards farmed and wild game and farmed and wild game meat.
- COMMISSION REGULATION (EU) No 151/2011 of 18 February 2011 amending Annex I to Regulation (EC) No 854/2004 of the European Parliament and of the Council as regards farmed game.
- COMMISSION IMPLEMENTING REGULATION (EU) No 739/2011 of 27 July 2011 amending Annex I to Regulation (EC) No 854/2004 of the European Parliament

and of the Council laying down specific rules for the organisation of officials controls on products of animal origin intended for human consumption.

- COMMISSION REGULATION (EU) No 1086/2011 of 27 October 2011 amending Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Annex I to Commission Regulation (EC) No 2073/2005 as regards *Salmonella* in fresh poultry meat.
- COMMISSION IMPLEMENTING REGULATION (EU) No 1109/2011 of 3 November 2011 amending Annex I to Regulation (EC) No 2075/2005 as regards the equivalent methods for *Trichinella* testing.
- COMMISSION REGULATION (EU) No 1276/2011 of 8 December 2011 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the treatment to kill viable parasites in fishery products for human consumption.
- COMMISSION REGULATION (EU) No 16/2012 of 11 January 2012 amending Annex II to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the requirements concerning frozen food of animal origin intended for human consumption.

Provision of an Ambulatory Reference

2.3. The Regulations provide in regulation 2(3) for an ambulatory reference to ensure that, in future, under the 2006 Regulations, the execution and enforcement of new technical amendments to the Annexes of the EU instruments listed in Schedule 1 will apply automatically, thereby significantly reducing the number of occasions where, in future, the 2006 Regulations will require amendment. This will also ensure alignment of the application date for the enforcement and execution sanctions with the application date specified in the EU provisions thereby obviating delays such as those experienced for the application of the EU instruments listed in section 2.2 above. By removing the burden of the formal legislative drafting process, for these technical amendments, time will be liberated to ensure the more significant changes to the EU hygiene rules will be introduced timeously in future. Future technical amendments will still be the subject of the required consultation, but the consultation process itself will be concentrated at the earlier EU drafting stage.

Remedial Action Notices (RANs)

2.4 Regulation 2(4) of the Regulations extend the use of RANs to all food businesses, not just those manufacturing products of animal origin which are currently required to be approved under EU Regulation 853/2004. This will ensure consistency throughout the food chain and will provide competent authorities with an enforcement tool that, in certain circumstances, is more appropriate, proportionate and effective than those currently available. This will help to ensure improved compliance with food law by all food business operators, thereby improving public health. It will therefore also help in improving consumer confidence and as a consequence, protect compliant businesses from reputational damage. Provision is made in regulation 2(5) for compensation to be payable where a food business suffers loss by complying with a RAN which, on appeal to the Sheriff or Court, is subsequently cancelled.

National Mark provision

2.5 Regulation 2(6) of the Regulations makes provision for a national measure that lays down the format of a special health mark required to be applied to carcases of animals that have undergone emergency slaughter outside the slaughterhouse, and the identification mark on packages of fresh meat, minced meat, meat preparations, mechanically separated meat and meat products produced from such carcases. This will enable the identification of carcases subject to emergency slaughter outside a slaughterhouse so the meat and products derived from such carcases can be distinguished from other meat and ensure that they are restricted to the national (UK) market as provided for in EU Regulation 853/2004.

3. Consultation

3.1 To comply with the requirements of Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety, the Food Standards Agency in Scotland (FSAS) has carried out extensive consultation with stakeholders on the impact of the Regulations and the EU provisions to which they give effect.

3.2 The majority of the instruments listed in section 2.2, either make permanent the derogations which were provided for by Regulation (EC) No. 2076/2005, continuing the arrangements that were in place under the previous hygiene legislation prior to 1 January 2006, or make minor amendments to the Annexes of the EU Regulations.

3.3 Public consultation was carried out in Scotland on a previous version of the Regulations, and relevant Business and Regulatory Impact Assessments (BRIAs) concerning a range of Commission proposals, from 1 April to 24 June 2010. No objections were raised by stakeholders.

3.4 A further consultation was launched on 13 December 2011 with an amended version of the Regulations to make it clear that the ambulatory reference provisions apply only to technical amendments. Further BRIAs on new Commission Regulations were also issued and comments were sought from stakeholders on the impact of those amendments to the EU food hygiene legislation, to ascertain whether the FSAS's assumptions were a fair reflection of costs, benefits and wider impacts for stakeholders. Three responses were received from stakeholders; two from Scottish trade associations on the ambulatory reference and on the national identification mark for emergency slaughtered animals, the other from a Local Authority on the classification of gastropods and changes to the live bivalve mollusc requirements. These comments are summarised within the relevant BRIAs relating to these areas.

3.5 Since the second tranche of consultation in December 2011, two new EU Regulations have come into force, which have been the subject of separate consultation. They are Regulations (EU) No. 1276/2011 and (EU) No. 16/2012 - the former EU Regulation is not listed in Schedule 1 as it has been superseded by the latter, and only the most recent amendment to the EU Regulations is required to be listed. With respect to Regulation (EU) No 1276/2011, which has specific resonance with a key Scottish stakeholder sector, the FSAS carried out extensive detailed consultation. Regulation (EU) No. 1276/2011

provides a freezing derogation for certain farmed fish and is of particular importance to the Scottish salmon producing sector. The consultation exercise included a number of face to face visits with Scottish stakeholders, which was useful in helping to shape a proportionate regulation protecting public health but minimising burdens on businesses. Regulation (EU) No. 16/2012 has also been the subject of consultation, of which one response was received from a Scottish industry association. Full details of the impact of these EU Instruments are contained within the attached BRIAs.

3.6 In February 2011, FSAS also carried out a separate consultation on the proposal to extend the use of Remedial Action Notices and received 24 responses in total. The comments received from 21 Local Authorities and 2 Food Liaison Groups and 1 industry stakeholder were in agreement that the RANs should be extended to establishments not subject to approval under EU Regulation 853/2004, recognising the need for proportionality and consistency of approach. As part of this process detailed face to face visits were also undertaken with affected food businesses. Once more the overwhelming majority of businesses contacted were supportive of the proposals, although some raised the issue of the need for adequate compensation provisions. These have been accommodated in the instrument.

4. Impact Assessments (Financial Effects)

4.1 Full and detailed Business Regulatory Impact Assessments (BRIAs) which show the effect of the Regulations and the associated EU Instruments have been completed and are attached. In accordance with Scottish Government guidance, full or part BRIAs were not provided for all of the instruments, such as those which contained only minor technical changes. During the consultation exercise, stakeholders were invited to comment if they considered that BRIAs should have been made and, if this was the case, were asked to provide information on the costs and benefits which may result from the instruments. No adverse comments were received indicating that stakeholders were in agreement with the FSAS's assessment.

5. Other Administrations

5.1 This instrument applies in relation to Scotland only. Separate legislation is being made for England, Wales and Northern Ireland.

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