

## EXECUTIVE NOTE

### THE FOOD HYGIENE (SCOTLAND) REGULATIONS 2006 SSI/2006/3

Made by Scottish Ministers in exercise of the powers conferred by section 2(2) of the European Communities Act 1972<sup>1</sup> and of all other powers enabling them in that behalf. This instrument is subject to negative resolution procedure.

#### Issue

1. This instrument provides enforcement powers in respect of the EU Food Hygiene Regulations and associated pieces of implementing and transitional legislation. In particular, it designates competent authorities and enforcement authorities and makes provision for offences and penalties. It also addresses aspects where the EU Regulations either require or allow Member States to adopt certain provisions in their national law.

#### Legislative background

2. New EU Regulations outlined in **Appendix 1** will be directly applicable in each Member State of the EU on 1<sup>st</sup> January 2006<sup>2</sup>. National legislation is neither required nor allowed, to give effect to the EU Regulations, beyond providing for their enforcement in Scotland. However, there are a number of areas where the EU Regulations either require or allow member states to adopt certain provisions in their national law and these Regulations address those aspects too.
3. This SI is made under the powers given by section 2 (2) of the European Communities Act 1972. As the subject matter of the SI is food hygiene it has been developed to mirror the provisions of the Food Safety Act 1990. It creates penalties and offences, powers of entry and other administrative measures based in the main on existing requirements. Where the EU Regulations do not apply and no more specific national provisions have been made, the general legal requirements relating to placing unsafe food on the market contained in Article 14 of Regulation (EC) 178/2002 as implemented by the General Food Regulations 2004 will apply to ensure the supply of food in such circumstances is fit for human consumption.
4. It revokes and replaces the Food Hygiene (Scotland) Regulations 2005 (SI 2005/505).

#### Policy background

5. The new EU legislation has as its primary objective the optimisation of public health protection by improving and modernising the previous sector specific EU legislation. The new EU legislation establishes the conditions under which food is produced to prevent, eliminate or acceptably control pathogen contamination of food. More risk based and flexible procedures are introduced that are better matched to the needs of individual businesses and to enforcement. The legislation introduces a "farm to fork" approach to

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<sup>1</sup> 1972 c. 68. Section 2(2) was amended by the Scotland Act 1998 (c. 46) ("the 1998 Act"), Schedule 8 paragraph 15(3). The function was conferred on the Minister of the Crown under section 2(2) of the 1972 Act, so far as within devolved competence, was transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. The competence of Scottish Ministers was extended to include all "food" as defined in EC Regulation 178/2002 by virtue of Section 63 of the 1998 Act.

<sup>2</sup> Items A-D in Appendix 1 will apply 20 days after their publication in the Official Journal of the European Community.

food safety, by including primary production in food hygiene legislation for the first time in the majority of cases.

6. The Regulations designate the Food Standards Agency as the competent authority and designate food authorities and the Food Standards Agency as enforcement authorities. The division of responsibility is set out in regulation 5.
7. There are a number of areas where the EU Regulations either require or allow Member States to adopt certain provisions in their national law. These areas cover the bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar, temperature control requirements for foodstuffs, the direct supply of small quantities of meat from poultry and lagomorphs (rabbits and hares) slaughtered on-farm, and restrictions on the sale of raw milk intended for human consumption.
8. SI 2005/505 introduced new enforcement powers in relation to the requirements of the EU Regulations that apply on 1 January 2006. It applied the required penalties and offences, powers of entry and other administrative measures. This new SI consolidates with amendments SI 2005/505. The new SI provides for the application of the European Commission transitional and implementation measures which will be directly applicable in Member States from 20 days after their publication in the Official Journal of the European Community. It also makes changes to certain enforcement provisions. These include enforcement responsibilities at the level of primary production and providing for food authorities to take enforcement action in non-approved meat plants.
9. A full consultation and RIA were completed for the EU Regulations and the Food Hygiene (Scotland) Regulations 2005. A full consultation and RIA, which was prepared on a UK basis, have been completed for the EU implementing and transitional legislation and the draft Food Hygiene (Scotland) Regulations 2006.

### **Consultation**

10. An initial consultation with stakeholders on the policy content of these measures was undertaken and concluded on 9 June 2004. A full consultation was carried out on the Food Hygiene (Scotland) Regulations 2005 and associated guidance giving effect to the EU legislation which concluded on 31 January 2005. The responses of stakeholders to the initial policy consultation were generally in favour of the FSA preferred options. Stakeholders overwhelmingly called for practical and flexible application of the EU legislation in the UK and for national measures that respected existing practice and did not add to the burden on business. This approach has been respected in SI 2005/505 and associated guidance to give effect to the legislation. The FSA Board reviewed the results of the consultation at its open meeting in March 2005 and endorsed the approach being taken.
11. All of the consultation documents were sent to a wide range of stakeholders. A full list is available at the address below.
12. A further consultation on the draft Food Hygiene (Scotland) Regulations 2006 began on 23 September and ended on 13 December 2005. The most significant issue for respondents was the FSA's proposal to extend to all food businesses the use of Remedial Action Notices (RANs) as an enforcement mechanism to secure compliance with the legislation. Under the terms of SI 2005/505, RANs, (which have been available for

enforcement action in fresh meat plants for a number of years) have been extended to all approved products of animal origin premises. Responses from enforcement stakeholders endorsed the proposed extension to the use of RANs. Whilst specific business interests in Scotland did ask that these new powers be used appropriately, stakeholder views across the UK as a whole were polarised, with business sectors elsewhere strongly against their extension in this way.

13. The FSA acknowledges the need to evaluate fully the range of opinions expressed from across the UK and the need for further stakeholder engagement. This cannot be adequately undertaken in the time available, dictated by the EU timetable. The FSA will therefore pursue this course separately with stakeholders and will inform them accordingly.

#### **Other Government Departments**

14. The Agency in Scotland also consulted with Scottish Executive as well as London based departments during the development of these regulations. Scottish Ministers endorsed the Agency's negotiating stance throughout the development of the EU proposals.

#### **Other Administrations**

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

#### **Financial affects/ Regulatory Impact Assessment**

16. The instrument itself is not considered to incur significant additional costs to either industry or enforcement authorities. Regulatory Impact Assessments for the EU measures themselves have been prepared on a UK basis and are available at the address below.

#### **Parliamentary Procedure**

17. The instrument will breach the 21 day rule. This has been caused by late publication by the Commission of the implementing and transitional legislation to which this SI gives effect and as such has been unavoidable.

Food Standards Agency Scotland December 2005

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## Appendix 1

### EC Regulation 852/2004 *On the hygiene of foodstuffs: Applies from 1<sup>st</sup> January 2006*

1. This applies to the production of all foodstuffs and establishes the following key principles:
  - the paramount concern to protect human health,
  - the use of procedures based on Hazard Analysis and Critical Control Point (HACCP) principles (but not necessarily HACCP *per se*) to identify, control and monitor critical food safety points in food businesses,
  - the possibility of adopting microbiological criteria and temperature control measures in accordance with scientifically accepted principles,
  - the development of good practice guides to aid compliance,
  - the monitoring of food hygiene by the competent authorities of the Member States,
  - the obligation on food business operators to ensure that only foodstuffs not harmful to human health are placed on the market.
2. This is the cornerstone of the legislation. It applies to all stages of production, processing and distribution of food (including primary production) other than:
  - primary production for private domestic use
  - domestic preparation, handling or storage of food for private domestic consumption and
  - the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments supplying the final consumer. (This is to be controlled nationally).
3. The Regulation contains “horizontal” rules which are those which will apply across all food sectors. It describes the duties of food business operators (as opposed to describing how control is to be exercised by enforcement authorities). It introduces for all food sectors, other than for primary production, a requirement for food safety management procedures based on HACCP principles. It establishes the voluntary use of either national or Community good practice guides. These are to be developed by the food business sectors concerned and are intended to assist food business operators to comply with the general high-level requirements and objectives of the regulation. The guides will be able to include more detailed requirements, specific to the sectors concerned, than would be necessary or appropriate in the simplified legislation.
4. The Regulation establishes the idea that food businesses need to be registered with the competent authority so that enforcers know where food businesses are and may factor them into official control programmes. This Regulation also lays down basic hygiene requirements for premises, staff, packaging, storage, transport, and handling of foodstuffs.
5. With regard to primary production, the Regulation does not require the application of HACCP-based procedures at this level. It does however require that primary producers control the hazards associated with their operations. As with other food sectors, good practice guides may need to be produced.

6. The Regulation requires that food imported into the Community complies with same or equivalent standards. It also contains the capacity for Member States to adapt certain of the provisions (without compromising the objectives of the Regulation) in certain circumstances, subject to Commission "approval" under comitology.

**EC Regulation 853/2004** *Laying down specific hygiene rules for products of animal origin: Applies from 1<sup>st</sup> January 2006*

7. This Regulation reflects the fact that products of animal origin tend to represent the highest risk, so additional controls are needed. It lays down specific controls which apply additional to those in 852/2004. They do not (in general) apply at the level of retail sale, nor do they apply to food containing both products of plant origin and processed products of animal origin.
8. In bringing all the existing controls together, it has been possible for the Commission to remove some repetition and inconsistency which existed in the current legislation.
9. The Regulation will require the approval by enforcement authorities of premises handling products of animal origin (POAO). POAO will have to bear an identification mark displaying information about where the product was produced or handled. Fresh red meat and game meat will have to bear a health mark, applied under the supervision of the Official Veterinarian (OV). As with 852/2004, the same, or equivalent, standards are to be applied to imported products.

**EC Regulation 854/2004** *Laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption: Applies from 1<sup>st</sup> January 2006*

10. The majority of this Regulation concerns detailed rules for the conduct of meat hygiene controls, although rules are also laid down for controls on live bivalve molluscs and the areas from which they may be gathered, fishery products and raw milk and dairy products.
11. The changes to controls on meat hygiene are intended to take account of the introduction of HACCP-based procedures in slaughterhouses. It is also intended to take account of the fact that the traditional meat organoleptic based inspection regime is not equipped to cope with the presence of pathogenic micro-organisms which now account for most meat-related foodborne disease incidents.
12. The proposed system of meat inspection does not affect current Transmissible Spongiform Encephalopathy (TSE) or animal welfare controls but introduces a number of other changes:
  - Although ante-mortem inspection will still be carried out by the Official Veterinarian (OV) and post-mortem inspection will remain his or her responsibility, operators are given clear responsibility for the hygienic production of meat, with the role of officials changing from supervision to audit.

- All animals will have to be accompanied to slaughter by “chain information” supplied by the farmer. This will contain information relevant to food safety. If this information is not available the animals will be slaughtered, but their meat will not be allowed into the food chain.
- Unnecessary post-mortem inspections for some conditions may not have to be carried out, where area or herd guarantees of disease freedom can be provided.
- Post-mortem handling of the carcasses and offal will be progressively minimised, following advice from the European Food Safety Authority (EFSA) on procedures for individual types of animal.
- Ante and post-mortem inspection findings of significance for public health or animal health and welfare will be required to be included on relevant databases and communicated to public and animal health officials as appropriate, as well as to the farmer of origin and his/her veterinary surgeon.
- The strict requirement for the full time presence of an OV is removed allowing OAs to take on more of the OV duties.

13. The following additional measures are intended to supplement the main provisions outlined above. The main purpose of the 2006 regulations is to provide the enforcement and sanction provisions associated with these measures in addition to the measures outlined above. These additional measures were published in the Official Journal of the European Community on 22 December 2005 and will apply from 11 January 2006. Regulatory Impact Assessments have been prepared on a UK basis for items B-D and are available at the contact address.

- A. Commission Regulation (EC) No 1688/2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs
- B. Commission Regulation 2073/2005 on microbiological criteria for foodstuffs.
- C. Commission Regulation 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004, for the organisation of official controls under Regulations (EC) Nos 854/2004 and 882/2004, derogating from Regulation (EC) No 852/2004 and amending Regulations (EC) Nos 853/2004 and 854/2004.
- D. Commission Regulation 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) Nos 854/2004 and 882/2004 of the European Parliament and of the Council and amending Regulations (EC) Nos 853/2004 and 854/2004.

- E. Commission Regulation 2075/2005 laying down specific rules on official controls for *Trichinella* in meat.