

## EXECUTIVE NOTE

## THE FOOD HYGIENE (SCOTLAND) REGULATIONS 2005 SSI/2005/505

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. New secondary legislation meeting our Community obligation to give full effect to new EC food hygiene legislation from 1 January 2006. The new EC legislation includes:
  - EC Regulation 852/2004 *On the hygiene of food stuffs*;
  - EC Regulation 853/2004 *Laying down specific hygiene rules for products of animal origin*;
  - EC Regulation 854/2004 *Laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption*;
  - EC Directive 2004/41 *repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC*.
2. The Statutory Instrument will provide enforcement powers, designate competent authorities and enforcement authorities and make provision for offences and penalties. These Regulations also contain provisions where the EC Regulations require national hygiene measures to be adopted or allow them to be maintained to secure the objective of public health protection.

**Background**

3. The new EU legislation has as its primary objective the optimisation of public health protection by improving and modernising 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 food safety, by including primary production in food hygiene legislation for the first time in the majority of cases.

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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.

4. The SI is made under the powers given by section 2 (2) of the European Communities Act (ECA) 1972. As the subject matter of the SI is food hygiene it has been developed to generally 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.
5. The EU Food Hygiene Regulations will be directly applicable in each Member State of the EU. 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 some of those aspects too, in so far they apply to Scotland. Where no provision has been made in this SI to cover areas of national flexibility as permitted in the EC Regulations, then it is intended that the Food Safety Act 1990 will continue to apply. The 1990 Act allows, among other things, enforcement officers to seize and destroy unsafe food.
6. The Regulations designate the Food Standards Agency as the competent authority in Regulation 4, unless competence has been delegated by the Agency to another body. The Regulations also designate food authorities and the Food Standards Agency as enforcement authorities. This 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. Those areas where the Agency has sought to apply national rules include: 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 an extension to the ban on the sale of raw milk or raw cream intended for human consumption.
8. Whilst the majority of national measures adopted are broadly similar in each of the UK countries, this SI proposes to extend the ban on the sale of raw cows milk or raw cream to milk from all milk producing animals in Scotland. Only raw cows milk is subject to such a ban at present. This proposal goes further than similar provisions elsewhere in the UK, and fully reflects the views of stakeholders received in Scotland following extensive consultation.
9. Further measures containing more detailed rules in relation to transitional measures and microbiological criteria in food stuffs have been proposed by the EU. A further amending statutory instrument has been made to incorporate these additional European measures and went out to consultation on Friday 23 September.
10. The principle reason for progressing with these domestic regulations now is to ensure that stakeholders are given as much time as possible to adjust to a new legal base for the administration of revised food hygiene rules in Scotland. Given that the additional EU measures may not be agreed until December, there is a

danger that in waiting to implement all the measures at once, the basic enforcement framework covered by this SI would not be in place.

11. A full revocations schedule have not been included in this Instrument as would normally be the case. That will also follow in the second set of Regulations which will amend these Regulations by way of rolling consolidation prior to their entry into force on 1 January 2006.

### **Consultation**

12. An initial consultation with stakeholders on the policy content of these measures was undertaken and concluded on 9 June 2004. A further consultation was carried out on this statutory instrument and associated guidance giving effect to the EU legislation which concluded on 31 January 2005. A number of sector-specific discussion groups and meetings have also been held over the course of negotiations and during implementation.
13. The responses of stakeholders to the initial policy consultation were generally in favour of the FSA preferred options (which are outlined in the Regulatory Impact Assessment). 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 developing the SI 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 approaches being taken in each of the UK countries.
14. A summary of consultation comments and the Agency's response to them will be made available at the address below. A full list of consultees is available on request.

### **Other Government Departments**

15. The Agency in Scotland also consulted with SEERAD, Justice Department, Improving Regulation Unit in Scotland, 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. A summary of the EU regulations and the Agency's approach to their negotiation is at **Annex 1**.

### **Other Administrations**

16. Similar Regulations were recently laid in English and Northern Ireland. Wales also intend to make similar provisions shortly.

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

17. The instrument itself is not considered to incur significant additional costs to either industry or enforcement authorities. A Regulatory Impact Assessment for both the EU and the Food Hygiene (Scotland) Regulations has been prepared and is available at the address below.

**Parliamentary Procedure**

18. The regulations are subject to negative resolution procedure, and the 21-day rule applies.

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**Regulation 852/2004**

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.

#### **Regulation 853/2004**

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.

#### **Regulation 854/2004**

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.

### ***Directive 2004/41***

13. This repeals the existing EU legislation and amends other related legislation.

### **The approach taken to the negotiation of the legislation**

14. The FSA's overall aim is that food hygiene legislation should protect public health. It must also be of such a nature that food business operators can understand and take their proper responsibility for producing food safely. The controls should be proportionate to the risks and must not impose unnecessary burdens on either food business operators or on enforcement bodies. They must also safeguard the wider interests of consumers in relation to food, by ensuring they have access to foods from a wide variety of sources. This means the hygiene legislation should not be framed in such a way that it impacts disproportionately on any given sector or size or type of business. The FSA considers that adoption of a risk-based approach to food hygiene provides a flexible and proportionate system of control, which is adaptive to innovation in food production.