

POLICY NOTE

THE FOOD SAFETY, FOOD HYGIENE AND OFFICIAL CONTROLS (SPROUTING SEEDS) (SCOTLAND) REGULATIONS 2013

SSI 2013/333

1. Description

- 1.1 The above instrument 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. The instrument is subject to negative resolution procedure.

2. Policy Objectives

- 2.1 This instrument amends The General Food Regulations 2004 (regulation 2) the Food Hygiene (Scotland) Regulation 2006 (regulation 3) and the Official Feed and Food Controls (Scotland) Regulations 2009 (regulation 4) and provides for the enforcement in Scotland of the provisions of:

- Commission Implementing Regulation (EU) No 208/2013 on traceability requirements for sprouts and seeds intended for the production of sprouts;
- Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts pursuant to Regulation EC No 852/2004 of the European Parliament and of the Council; and
- Commission Regulation (EU) No 211/2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts.

2.2 The Regulations improve public health protection through the introduction of specific hygiene controls in the sprouts and seeds for sprouting sector and the corresponding enforcement ensures that:

- primary producers of sprouts have in place the necessary safety controls by the introduction of approval of such establishments;

- it can be demonstrated that seeds imported into the EU have been produced in compliance with hygiene rules by the introduction of import certification; and

- seeds and sprouts can be traced to the producer in the event of a problem through enhanced traceability requirements.

2.3 The above EU Regulations should be read with Commission Regulation (EU) No 209/2013 amending Regulation EC No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcasses and fresh poultry meat, which ensures that the risk of unsafe products entering the food chain is reduced by introducing specific microbiological criteria.

3. Matters of special interest to the Delegated Powers and Law Reform Committee

3.1 The four aforementioned EU Regulations were published in the Official Journal on 12 March 2013 and entered into force on 1 July 2013, with exception of EU Regulation 211/2013 which came into force on 1 April 2013 with a transitional period until 1 July 2013.

3.2 The EU Regulations are binding and directly applicable from the dates they come into force, however, in order to protect public health and reduce the potential health risk to consumers it is necessary to provide for the enforcement of Regulations 208/2013, 210/2013 and 211/2013 by making amendments to the following domestic Regulations:

- inserting into Schedule 1 (definitions of EU legislation) to the Food Hygiene (Scotland) Regulations 2006, a reference to the Commission Regulation (EU) 210/2013 on the approval of establishments producing sprouts;

- inserting into the definition of Regulation (EC) No 178/2002 in the General Food Regulations 2004 an ‘as read with’ reference to Commission Implementing Regulation (EU) No 931/2011 on the traceability requirements set by Regulation (EC) No 178/2002, and to Commission Implementing Regulation (EU)208/2013 on traceability requirements for sprouts and seeds intended for the production of sprouts;
 - amending the definition of import provision within the Official Feed and Food Controls (Scotland) Regulations 2009 and inserting a reference within the regulation dealing with offences and penalties to those who import into Scotland or place on the market any sprouts or seeds intended for sprouting which do not comply with the certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts, to make this an offence.
- 3.3 The FSA consulted on the draft EU proposals throughout 2012 but when the four EU Regulations were published in March 2013, with little notice, this led to a delay as the domestic Regulations were drafted and impacts assessed.
- 3.4 The FSA plans a common coming into force date of 31 December 2013 for these Regulations, subject to differences in scrutiny procedure and parliamentary timetables, which is to ensure consistency of enforcement provisions across the internal UK market.

4. Legislative Context

- 4.1 The four EU Regulations on sprouting seeds introduced more effective hygiene controls in the sprouts and seeds for sprouting sector to ensure the protection of public health in the European Union as follows:
- **Commission Implementing Regulation (EU) No 208/2013 on the traceability requirements for sprouts and seeds intended for the production of sprouts.** This requires food business operators (“FBOs”) to keep records of the names and addresses of the businesses they receive sprouts or seeds from, and the businesses to which they supply these products.

- **Commission Regulation (EU) No 209/2013 amending Regulation (EC) 2073/2005 as regards microbiological criteria for sprouts.** This Regulation introduces requirements for Shiga toxin-producing E.coli (“STEC”) testing. There are already requirements for Salmonella testing, which are retained, and as the sprouts are considered to be ‘ready-to-eat’ foods, the Listeria criteria will also apply. The legislation introduces a requirement for preliminary testing of seeds and sets out the frequency for testing sprouts. Preliminary testing will be associated with costs for the testing of seeds; costs of any facilities required for the testing to be undertaken be considered with the costs of the analytical tests. In relation to STEC, the legislation sets out the requirement to show compliance with the criteria for absence of six specific serotypes. Due to the effect of SSI 2012/75, references to Regulation (EC) 2073/2005 in the Food Hygiene (Scotland) Regulations 2006 are ambulatory as regards any amendments to the EU Regulation’s Annexes and therefore there is no need for additional enforcement provisions in domestic legislation in respect of this Regulation,
- **Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) 852/2004.** This amends Regulation (EC) 852/2004 so that food business establishments producing sprouts need to be approved. As well as meeting the requirements of Annex I of 852/2004 (which they would already need to do as primary producers) such establishments will also need to meet the requirements, not wholly different, in the Annex to Regulation (EC) 210/2013.
- **Commission Regulation (EU) No 211/2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts.** This requires that imports of sprouts intended for human consumption, or seeds for the production of sprouted seeds, are accompanied by a declaration that the sprouts or seeds were produced in accordance with adequate hygiene and manufacturing practices. The import declaration will be signed by an official inspector in the exporting country and follow the sprouts or seeds through the food chain.

5. Territorial Extent and Application

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

6. European Convention on Human Rights

6.1 This instrument does not raise any issues regarding the European Convention.

7. Consultation

7.1 The Food Standards Agency consulted with stakeholders including industry, trade bodies, enforcement bodies and other Government departments throughout the development and negotiation of these measures in 2012. Three hundred and thirty three stakeholders were consulted by FSA Scotland. We received comments from the James Hutton Research Institute, VTEC Action Group, and Scottish Government colleagues in Food and Drink and Rural Communities Division and from the Agricultural, Food and Rural Communities Directorate.

7.2 The responses across the UK were similar and were in relation to the proposed positive release system under the microbiological criteria proposal which would have allowed sprouts to be placed on the market only after testing results were available. They also supported the introduction of risk based controls ensuring safe agricultural and hygiene practices amongst producers of sprouts and taking the view that it is the most effective way of preventing contamination. Responses have been taken into consideration when developing the EU proposals at an early stage and also the drafting of this SSI and Business and Regulatory Impact Assessment.

7.3 In February, July 2012 and in January 2013 there were further UK stakeholder meetings, and workshops for industry, local authorities and trade associations to assist in the development of guidance for sprouted seeds. In March 2013, a UK technical experts meeting took place on testing and sampling methods for sprouted seeds. At this, there was representation from

all four Public Analysts from across Scotland and from the Scottish E.coli reference laboratory.

7.4 In September 2013, FSA in Scotland carried out a short consultation on the draft Scottish Statutory Instrument and on the Business and Regulatory Impact Assessment, and which formed part of a wider UK consultation. Comments were sought on the impact to primary producers of sprouts and official control laboratories.

7.5 FSA in Scotland received two responses one from a Scottish Local Authority and the other from a Scottish Public Analyst. The Local Authority who commented was responsible for the approval of the Scottish establishment producing sprouted seeds. Their comments included estimates of costs for approval of the premises and the estimated costs of familiarisation to the legislation. The LA also included estimates of costs to the business. The Public Analysts comments were on the costs of becoming an accredited laboratory and for carrying out the validation method and work.

7.6 One Scottish business was identified which grows sprouted seeds. FSA in Scotland and the Scottish LA have worked closely with the business affected, in order to establish the costs and impact of meeting the requirements for approval, testing and import certification. These comments are discussed in the Business Regulatory Impact Assessment and will be considered in the consultation summary response table published on the FSA website.

8. Financial Effects

8.1 A Business and Regulatory Impact Assessment has been completed and the impact to the one Scottish business producing sprouts is associated with the approval process, sampling and testing from the six STEC, familiarisation with the legislation and import controls. There will be associated costs to the local authority involved with the approval process. In addition there will also be costs of the accreditation process to the four official control laboratories in Scotland. The Business and Regulatory Impact Assessment is attached.

9. Regulating small business

9.1 This instrument will apply to all food businesses producing sprouts and importing seeds intended for the production of sprouts (Commission Regulation (EU) N0 210/2013, amending Regulation (EC) 852/2004). It is expected that there are over 23 businesses (primary producers) micro, medium and large requiring approval across the UK, including one micro producer in Scotland. These establishments should already comply with the requirements set out for primary producers in Annex 1 to Regulation (EC) 852/2004 and the new Annex to Regulation (EU) No 210/2013 requirements are not wholly different to those in Regulation (EC) 852/2004. The costs and impact to the Scottish micro business is discussed within section 7 of this policy note, on consultation.

9.2 The Commission Regulation (EU) No 209/2013 (amending Regulation (EC) 2073/2005) on microbiological criteria for sprouts lays out new requirements for the food business to carry out tests both on the seeds intended for sprouting and again once the seeds have been sprouted. This Regulation introduces requirements for STEC testing setting out the requirements to show compliance with the criteria for absence of six specific serotypes. There are already requirements for Salmonella testing, which are retained, and as the sprouts are considered to be 'ready-to-eat' foods, the Listeria criteria will also apply. The legislation introduces a requirement for preliminary testing of seeds for sprouting and sets out the frequency for testing sprouts. The required preliminary testing will mean that there will be added costs to businesses for the testing of seeds. Further details are included within the final BRIA.

10. Monitoring and Review

10.1 The FSA is expected to carry out a review of the policy in five years, in December 2018. The effectiveness of these Regulations will also be monitored via general feedback from industry and enforcement authorities.

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