

FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT (BRIA)

The Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013.

**Package of EU Regulations on sprouts and seeds intended for
sprouting: Regulations (EU) No 208/2013, No 209/2013,
No 210/2013 and No 211/2013**

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Contact for enquiries: Karen Robertson
Phone No: 01224 288362
Email: karen.robertson@foodstandards.gsi.gov.uk

1. Title of Proposal

- 1.1 The Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013. This instrument provides for the enforcement of a package of EU Regulations on sprouts and seeds intended for sprouting: Regulations (EU) No 208/2013, No 209/2013, No 210/2013 and No 211/2013.

2. Purpose and Intended Effect

Objectives

- 2.1 The objective of the package of Regulations is to ensure public health protection through the introduction of more effective hygiene controls in the sprouts and seeds for sprouting production sector. EU Member States are required to put in place provisions for the enforcement of these Regulations.

Background

- 2.2 In May 2011 a major outbreak of Shiga toxin-producing E.coli (STEC¹) occurred in Germany and France resulting in over 3,000 cases of illness and 40 or more deaths. On 15 November 2011, the European Food Safety Authority (EFSA) published a [scientific opinion](#) on the public health risk of STEC and other pathogenic bacteria² that may contaminate seeds and sprouts (this opinion was revised on 6 March 2013). EFSA noted that the particular production processes for seeds, including high humidity, were favourable for the growth of any bacterial pathogens present.
- 2.3 The Commission Working Group on hygiene legislation, which includes representation from the UK, considered various options to improve controls in regard to the risk from STEC in sprouts and seeds for sprouting. Consequently it was agreed to develop four new legislative proposals amending and strengthening existing hygiene rules. These would include new requirements for the approval of establishments producing sprouts, microbiological criteria for sprouts, traceability and import declaration for seeds intended for the production of sprouts.
- 2.4 These proposals were discussed at a number of Working Group meetings during 2012. During the negotiations, the UK repeatedly pressed for amendments that would support development of proportionate controls for all the proposals in line with the rest of the hygiene legislation, particularly on the microbiological criteria. The UK raised a number of concerns highlighted by stakeholders, particularly 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.
- 2.5 The UK supported the introduction of risk-based controls ensuring safe agricultural and hygiene practices amongst producers of sprouts, taking the view that it was the most effective way for tackling and preventing contamination. The requirement at Article 5 of Regulation (EC) No 852/2004 for food safety procedures based on Hazard, Analysis and Critical Control Point (HACCP) principles does not apply to primary production. The UK recognises that implementation of HACCP based systems at primary production is not generally feasible.

¹ The specific strain identified was O104:H4.

² <http://www.efsa.europa.eu/en/efsajournal/doc/3138.pdf>

- 2.6 The UK supported the proposed Regulation on import controls. However the UK did not agree that decontamination should be a mandatory requirement, as the introduction of a decontamination step should remain a commercial decision based on a risk analysis of the specific product, albeit one that is good practice. The UK did not think import requirements on their own would be sufficient to control risks from imported seeds intended for the production of sprouts. Therefore the UK supported the development of lists of approved establishments and third countries from which imports are allowed.
- 2.7 In agreeing Regulation (EU) No 209/2013, amending microbiological criteria, the UK was successful in securing amendments to the requirement for preliminary testing of a batch of seeds as this reflected the approach already taken by most UK producers. The UK was also successful in securing a delay in the coming into effect of the Regulations until 1 July 2013 to allow FBOs time to introduce the required changes.
- 2.8 The UK made the case that most FBOs producing sprouts already have well established food safety management systems in place which is likely to mean that they have the six months supporting historical data so it was assumed that many of them would be in a position to take advantage of the derogation contained in the Regulation that pre-testing was not required if this information was available. For the FBOs that did not have this evidence, the UK still had concerns that the sampling sizes contained in the proposal would cause difficulties³ and would result in an increased burden to those businesses with little additional public health benefit, but were unable to achieve any further amendments.

The EU Regulations

2.9 The four EU Regulations⁴ introduced are:

- ***Commission Implementing Regulation (EU) No 208/2013 on the traceability requirements for sprouts and seeds intended for the production of sprouts.*** This requires 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***⁵. The Regulation introduces requirements for 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.

³ Regulation (EU) No 209/2013 Annex, Part A (1) requires that preliminary sampling sizes to be at least 0.5% of the weight of a batch of seeds which stakeholders were of the opinion was too large for proportionate testing and could lead to practical problems

⁴ The Regulations were published in the Official Journal in March 2013 and entered into force on 1 July 2013 (with the exception of Regulation (EU) No 211/2013 which came into force on 1 April 2013 with a transitional period until 1 July 2013.)

⁵ Regulation (EC) No 2160/2003 on the control of Salmonella and other specified food-borne zoonotic agents aims at ensuring that proper and effective measures are taken to detect and control Salmonella and other zoonotic agents throughout the food chain. The issues covered by the Regulation are not part of the consideration of this IA.

Preliminary testing will be associated with costs for the testing of seeds; costs of any facilities required for the testing to be undertaken to 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.

- **Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) 852/2004.** This amends Regulation (EC) No 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) No 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 Regulation 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 accompany the sprouts or seeds throughout the food chain.

2.10 The Food Standards Agency (FSA) will be producing guidance on the implementation and practical application of these Regulations.

Rationale for Government Intervention

2.11 Investigation into the outbreaks of STEC in Germany and France in 2011 identified sprouts and seeds for sprouting as the most likely source of contamination. This demonstrated the need for better controls of hygiene risks in the sprouts and seeds for sprouting sector. As consumers are unable to assess whether pathogenic bacteria is present in sprouted seeds they buy to eat, Government intervention is necessary to reduce the public health risk by improving controls in sprouts and seeds for sprouting production.

2.12 The Advisory Committee on the Microbiological Safety of Food (ACMSF) reported that consumption of sprouts had been previously associated with significant outbreaks of foodborne infection in the UK and other EU member states. For example, in 2010 there was a large outbreak of foodborne Salmonella bareilly infection across the UK, with a total of 241 cases including one death.

2.13 Intervention to update EU legislation through the introduction of more effective hygiene controls, in the sprouts and seeds for sprouting production sector, will ensure public health protection. This is in accordance with the Scottish Government's national performance framework target to ensure that we live longer, healthier lives.

Devolution

2.14 The Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013 will apply in Scotland only. This domestic legislation will make enforcement provisions for the four EU Regulations on sprouts and seeds intended for sprouting and similar legislation will be made in England, Wales and Northern

Ireland. However, as part of the Westminster Red Tape Challenge exercise, the statutory instrument in England will also consolidate the national legislation on food safety and food hygiene. The FSA in Scotland considered it was more transparent to keep this aspect of food law separate and have not proposed consolidation at this juncture.

3. Consultation

Within Government

- 3.1 FSA in Scotland has kept Scottish Government colleagues in Public Health, Health Protection Team, Food and Drink and Rural Communities, and the Agricultural Services Division fully updated on policy and regulatory developments and through consultations, information letters and workshops held in 2012 and 2013 and comments have been fed in throughout this process.
- 3.2 FSA in Scotland has also worked closely with the Better Regulation and Industry Engagement Team on the development of the Business and Regulatory Impact Assessment (BRIA) and with solicitors in Scottish Government Legal Directorate in the drafting of this Scottish Statutory Instrument (SSI).

Public Consultation

Across the UK

- 3.3 Throughout 2012 and 2013, FSA has consulted on the development of the EU Regulations and draft implementing instruments with stakeholders from; trade associations, industry, consumer bodies, public analysts (laboratories) and Local Authorities. FSA has issued regular update letters throughout the negotiation stages of the EU Regulations and has held UK wide industry, trade association and local authority stakeholder meetings.
- 3.4 In March 2013, a UK wide technical experts workshop took place on testing and sampling methods for sprouted seeds. At this meeting, there was representation from all four Public Analysts from across Scotland and from the Scottish E.coli reference laboratory.
- 3.5 During the UK consultation in September 2013, comments were received from food businesses (micro-large) in England expressing concerns about the micro criteria requirements in the EU Regulations and the requirement for businesses to carry out tests both on the seeds intended for sprouting and on the seeds once sprouted. Concerns raised were on the costs to the business of the time it would take to sample the seeds and sprouts, the cost of the seeds used, the destroying of seeds, cost of transporting the sample to a lab and the cost incurred of analysis of samples by an accredited lab. Responses also indicated that the familiarisation and approval estimates were too low and should be revised. The costs to industry are discussed in more detail in section 4 (Options).
- 3.6 Feedback from industry and enforcement authorities indicated that some of the larger businesses had already well-established sampling and testing regimes in place and therefore could demonstrate compliance with the new microbiological criteria. However, as part of the consultation, the FSA received limited information on the

associated costs (number of hours required for testing, the number of samples and the cost of sampling) of the new STEC testing requirement. Again, this is outlined in section 4.

- 3.7 All responses received from industry stakeholders and enforcement authorities across the UK stated that the FSA had underestimated the costs of familiarisation to the new legislation and the costs incurred with approval. The public analysts who responded also agreed that the costs to accreditation of laboratories had been underestimated. All estimated costs have been considered by the FSA and the initial costs have been revised accordingly. The summary of UK responses will be published on the FSA website.

In Scotland

- 3.8 In September 2013, the FSA in Scotland conducted a six week consultation on the draft SSI on the Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013 to provide for the enforcement of EU Regulations No 208/2013, No 209/2013, No 210/2013 and No 211/2013 on sprouts and seeds intended for sprouting and on the partial BRIA. Whilst initial information from business representatives and local authorities indicated there were no businesses in scope in Scotland, following further requests for information, one micro producer (i.e. with less than 10 employees) of sprouted seeds located in Scotland was identified that will be affected by the Regulations. This particular business was included in the list of interested parties as part of the consultation exercise.
- 3.9 FSA in Scotland received two responses on the above mentioned consultation; one from a Scottish Local Authority and the other from a Scottish Public Analyst. The Local Authority who commented was responsible for the approval process for 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 Analyst comments were on the costs of becoming an accredited laboratory and for carrying out the validation method and work. Further details are contained in section 4 (Options), section 5 (Scottish Firms Impact Test) and section 11 (Summary costs and benefits table). All comments received will be considered and published in the summary of consultation responses on the FSA website.

4. Options

- 4.1 The options considered are:

Option 1: Do nothing – do not provide for the execution and enforcement of the EU Regulations on sprouts and seeds intended for sprouting.

Option 2: Provide for the execution and enforcement of the EU Regulations and provide the legislative framework for the requirements to be enforced under UK law.

Sectors and groups affected

Industry

4.2 All food businesses that undertake activities from primary production of sprouted seeds/seeds for sprouting (including, distributors, importers and retailers) up until the point of sale to the final consumer will be affected, as all of these sectors will need to ensure that they comply with the Commission Regulations. Three Local Authorities in Scotland had made FSA in Scotland aware of micro to small sized restaurants and takeaways producing sprouts from seed on their premises for use as a food ingredient in their restaurants and/or takeaways. The Local Authorities concerned had questioned whether or not these businesses, producing small quantities of sprouted seeds for immediate consumption on the premises, should meet the new requirements for approval. However, confirmation was provided by the Commission that the exemption contained in Regulation (EC) No 852/2004, Article 1(2)(c) applies so the direct supply of small quantities of sprouts to the final consumer is not within the remit of the Regulations. Apart from those exempt under the small quantities provision, the new requirements will affect all sprout and seed producers but this BRIA mainly focusses on the sprout producers as we anticipate the impact will be greatest on those businesses. Engagement with Industry indicated that there are 23 food businesses in the UK (one of which is located in Scotland) that will be affected by the Regulations. Responses to the consultation indicated that there are no further businesses in Scotland. Table 1 below shows the number of businesses affected by UK country and firm size.

Table 1: Businesses affected by UK country and firm size

Country	Micro	Small	Medium	Large	Unknown	Total
Scotland	1					1
England	5	4	3	3	4	19
Wales						0
Ni	2	1				3
Total	8	5	3	3	4	23

Official Control Laboratories

4.3 Under Option 2, all official control laboratories (OCLs) which would be designated to carry out the STEC testing would need to get accredited for that process. At present it is uncertain whether all of the 30 OCLs in the UK (4 in Scotland, 17 in England, 6 in Wales and 3 in Northern Ireland) would gain accreditation. However, the FSA is aware of four OCLs in total that are considering accreditation - two of these are located in Scotland whilst the remaining two are located in England. Other laboratories that carry out commercial testing may choose to become accredited for STEC testing. As part of the consultation we were however unable to identify any commercial labs that would get accreditation and we have therefore based costs to labs on the four OCLs that we have identified in the UK. Table 2 below shows the number of OCLs affected by the changes.

Table 2: Number of Official control laboratories affected

	Scotland	England	Wales	Ni	UK
No. OCL labs	2	2	0	0	4

Local Authorities

4.4 Local Authorities (LAs) are responsible for the approval of sprouted seeds businesses under the new requirements. Table 3 below shows the number of LAs by UK country.

Table 3: Number of Local Authorities affected by UK country

	Scotland	England	Wales	NI	UK
Number LAs	32	354	22	26	434

Consumers

4.5 There may be potential consumer health benefits from more stringent controls of sprouted seeds production and import because these additional controls could reduce the risk of an outbreak stemming from the consumption of sprouted seeds.

Benefits

Option 1: Do Nothing – do not implement the new Regulations on sprouted seeds

4.6 The benefits from this option would include no familiarisation costs to business and enforcement authorities. In addition there would be no further associated costs with the approval of the business. The business would also not have the costs incurred from regular sampling.

Option 2: Provide for the execution and enforcement of the EU Regulations and provide the legislative framework for the requirements to be enforced under UK law.

4.7 The benefits from this option are:

- Increased consumer confidence in the safety of sprouted seeds could lead to an increased demand for sprouted seeds.
- Improved public health protection will reduce the potential health risk to consumers.
- A long term improvement in compliance levels enabling enforcement authorities to free up resources and target other food safety activities.

4.8 There may be consumer health benefits from more stringent controls of sprouted seeds production and import as these additional controls could reduce the likelihood of an outbreak stemming from the consumption of sprouted seeds. The May 2011 outbreak of STEC resulted in over 3,000 cases of illness and approximately 40 deaths, internationally. It is however very difficult to monetise the benefits resulting from the introduction of the new controls as we cannot be certain about the impact of the Regulation in terms of reducing the risk of a future outbreak.

4.9 Option 2 is the preferred option as enforcement powers would be provided to the directly applicable EU Regulations and the UK would meet EU obligations. This option also provides appropriate action to address a known public health risk and therefore public health will be protected.

Costs

Option 1: Do Nothing – do not implement the new Regulations on sprouted seeds

4.10 Doing nothing would mean failing to respect the provisions of the package of EU Regulations, which apply directly in all Member States. This would be a breach of the UK's obligations as an EU Member State and could attract infraction proceedings from the Commission, which could result in the imposition by the European Court of Justice of unlimited daily fines on the UK for which Scottish Ministers would be liable.

There would also be a missed opportunity to take appropriate action to address a known public health risk.

Option 2: Provide for the execution and enforcement of the EU Regulations and provide the legislative framework for the requirements to be enforced under UK law.

Costs to Industry

Familiarisation Costs (One-Off Cost)

4.11 There will be a one-off cost to Industry from reading and familiarising themselves with the new Regulations. Familiarisation costs can be quantified by multiplying the time it takes for familiarisation by the wage rate of the person carrying it out. It is our assumption that it will be the business manager (wage rate of £25.78⁶) that is responsible for familiarisation and that it will take, on average, one business manager per business two hours to familiarise themselves and disseminate the information to other key staff.

4.12 During the consultation, no comments were received from the food business operator of the business in Scotland, which will be affected by the Regulations, but this assumption, concerning familiarisation costs, was challenged by their Local Authority, who felt that this may take more than two hours as it depends on the technical expertise of the business. However, no alternative figures were provided so we have kept the initial assumptions for Scotland. One large producer in England provided revised figures, stating that familiarisation of the Regulations had taken them 50 working days. This business was one of the businesses that assisted the FSA in understanding the impact of the new requirements. The figures provided by this firm have been taken into account in the final calculations for England. For this business we multiply 400 hours (assuming 50 working days of 8 hours each) by the wage rate, which gives a total familiarisation cost to this business of £10,312. For all other businesses in the UK, we keep the initial assumptions, as we did not receive any new information during consultation, multiply the wage rate by the number of hours required (2), and then again by the remaining number of businesses affected by the Regulations (22), which generates a total one off cost to the remaining food industry of £1,134. Table 4 below shows the familiarisation cost by location and firm size.

Table 4: Familiarisation Cost to UK industry, by UK country and firm size

Country	Micro	Small	Medium	Large	Unknown	Total
Scotland	£52					£52
England	£258	£206	£155	£10,415	£206	£11,240
Wales						0
NI	£103	£52				£155
Total	£412	£258	£155	£10,415	£206	£11,446

Costs Associated with Approval (One-Off Cost)

4.13 The new Regulations require affected FBOs to apply for and be granted an approval. An approval is granted after an on-site visit by the LA which will ensure that the establishment is compliant with the relevant hygiene rules. There is no direct cost of the

⁶ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/reference-tables.html?edition=tcm%3A77-280149>. Median hourly wage rate of a ‘production managers and directors’ was used, £19.83, plus 30% overheads, totalling £25.78.

approval (e.g. cost of any certificate), but there will be a time cost to the business since the visit will take up time that the manager otherwise could have spent on business activities.

4.14 Time costs can be monetised by multiplying the wage rate of the manager with the time required for the manager to be present at the inspection. We have limited knowledge about the time required but we have made the assumption that an on-site visit will take approximately two hours and that it will be the business manager that will be present for the LA visit. This assumption is made on the basis that information will be forwarded to the LA prior to the inspection visit and that this information is similar to that which businesses need to provide in order to be registered. During consultation, no comments were received from the single food business operator of the business in Scotland but their LA disagreed with the cost assumption and suggested four hours as being a more reasonable estimate. One large business in England responded that the approval visit would take them one full working day. These responses have been taken into account in the final calculations.

4.15 For the Scottish business, we multiply the wage rate of the manager by the number of hours required (4), which generates a total approval cost to that business of £103. For the large business in England that provided us with new estimates, we multiply the wage rate of a business manager (£25.78, see paragraph 4.11) by the hours required (8), which generates a total one-off cost of approval to that business of £206. For all other businesses we keep the initial assumptions, as no other businesses challenged these, and therefore multiply the wage rate of the manager by the total hours required (2) and the number of remaining businesses (21), which generates a total cost of approval to the remaining sector of £1,083. Table 5 below shows the cost of approval by UK country and firm size.

Table 5: Costs Associated with Approval to UK industry, by UK country and firm size

Country	Micro	Small	Medium	Large	Unknown	Total
Scotland	£103					£103
England	£258	£206	£155	£309	£206	£1,134
Wales						0
NI	£103	£52				£155
Total	£464	£258	£155	£309	£206	£1,392

Costs Associated with Import Control (Negligible)

4.16 The new Regulations require that the import of sprouts or seeds intended for sprouting for human consumption be accompanied by a declaration that the sprouts or seeds were produced according to adequate hygiene and manufacturing practices. The import declaration must be signed by an official inspector in the country exporting the product and must follow the sprouts or seeds through the food chain. Since the obligation to provide a certificate sits with the exporting producer, it is our assumption that any costs to UK food businesses associated with this requirement will be negligible and we have therefore not monetised this cost. If a third country refuses to implement the certification system, food business operators in the UK may have to seek alternative suppliers of their consignments of seeds. We are not aware of this being an issue at the moment.

Costs Associated with Traceability Requirements (Negligible)

4.17 The new Regulations require FBOs to keep records of the names and addresses of the businesses they receive sprouts or seeds from, and the businesses they sell sprouts and seeds to. It is our assumption that any costs to food businesses associated with this requirement will be negligible since there are already measures in place which require FBOs to have in place systems in order for them to be able to demonstrate traceability. The new measures clarify the information which FBOs will be required to keep in order to demonstrate this. We have therefore not monetised this cost. Traceability is already a requirement under Regulation (EC) No 178/2002, so FBOs should already have systems in place to demonstrate traceability. It is also in food businesses' own interests for commercial reasons to ensure that good traceability systems are in place. The assumption that costs associated with traceability requirements will be negligible was accepted at consultation.

Costs to Business Associated with the Micro-Criteria Tests (Ongoing)

4.18 Unless the business was able to take up the derogation which would mean that they did not have to conduct the preliminary testing, the micro criteria requirements in the new Regulations require food business operators to carry out tests both on the seeds intended for sprouting and again once the seeds have been sprouted. The first set of tests is a preliminary test on the seeds. Only once this test has generated a result showing absence of the six STEC serotypes, can the seeds be sprouted. The second set of tests is carried out on the sprouts 48 hours after sprouting. Both sets of samples taken by the food operator need to be analysed by an accredited laboratory. This means that there will be costs to the food business operator, both in terms of the time it would take to sample seeds and sprouts, the costs of seeds used in the tests that subsequently would have to be destroyed, costs of transporting samples to laboratories, and for the actual cost paid to the accredited laboratory for analysing the samples. Feedback from stakeholders indicates some businesses already have well established sampling and testing regimes that will help to demonstrate compliance with the new microbiological criteria. In some cases sampling regimes will need to be refined so costs will be lower than if completely new regime needs to be developed and introduced.

4.19 Currently we have limited information about these costs to individual businesses within the industry. These costs would be dependent on the number of samples tested annually by businesses, which will in turn be dependent on firm production volumes. We asked questions about costs associated with the new requirement of STEC testing at consultation. No comments were received from the FBO of the Scottish business. However, two businesses provided us with information about such costs.

4.20 Out of the two businesses that provided us with costs, one business responded that the time required for testing would be 210 hours per annum; that 150 samples would have to be tested at a cost of £180 per sample (i.e. a total per annum cost of £27,000). In addition they would incur unknown costs for the transportation of samples to an accredited laboratory, as well as unknown costs associated with the destroying of the seeds used for the STEC testing. The second business that provided us with costs associated with the micro-criteria responded that they would need to spend 48 hours for sampling the seeds that needed to be tested. In addition they would incur total annual costs of £106,000 for the STEC testing (based on a cost of testing for STEC of £200 per sample), as well as transport costs of approximately £1,000 per annum for transporting the samples to an accredited

laboratory. This business also suggested that it would incur costs associated with the destroying of the seeds used for testing, but did not specify how much this cost would be.

4.21 We are aware that the costs estimates provided by these two businesses in England for STEC testing are unlikely to be representative for the sector as a whole. We can however use this information to calculate an indicative cost to industry for STEC testing, assuming an average cost based on these two firms, and then extrapolate average costs to the industry as a whole. This would mean that businesses would spend around 129⁷ hours per annum sampling the seeds that needs to be tested; spend approximately £1,000 on transporting the samples to an accredited lab (assuming the only response provided is representative for the sector); and £66,500⁸ per annum to get the samples tested by the laboratory.

4.22 If we assume that it would be a production manager carrying out the sampling, at a wage rate of £25.78 (see paragraph 4.11), this generates a total cost per business and per annum for sampling of £3,328⁹. Summing up over all costs results in a total cost per business and per annum for the micro-criteria testing of £70,828¹⁰. Multiplying this with the total number of firms generates a total cost to industry of £1,629,044¹¹. To note is that this cost does not include the cost of destroyal of seeds as we do not have any information about such costs. Table 6 below shows the costs to industry of micro-criteria testing, assuming that the average costs of the two businesses providing information is representative for the whole sector. These costs should however be treated with caution, and only as an indicative estimate, as it is unlikely that the costs on which this estimate is based are representative for all businesses within the sector.

Table 6: Indicative Costs of the Micro-Criteria Testing

Country	Micro	Small	Medium	Large	Unkown	Total
Scotland	£70,828	0	0	0	0	£70,828
England	£354,140	£283,312	£212,484	£212,484	£283,312	£1,345,732
Wales	0	0	0	0	0	0
NI	£141,656	£70,828	0	0	0	£212,484
Total	£566,624	£354,140	£212,484	£212,484	£283,312	£1,629,044

Costs to Local Authorities

Familiarisation (One-Off Cost)

4.23 There will be a one-off cost to LAs from reading and familiarising themselves with the new Regulations. Familiarisation costs can be quantified by multiplying the time it takes for familiarisation by the wage rate of the official carrying it out. It is for the Local Authority to decide whether it will be the responsibility of an Environmental Health Officer (EHO, wage rate of £21.13¹²) or a Trading Standards Officer (TSO, wage rate of

⁷ $(210+48)/2=129$

⁸ $(27k+106k)/2=66,500$

⁹ $25.8*129*=3,328$

¹⁰ $3,328+1,000+66,500=70,828$

¹¹ $70,828*23=1,629,049$

¹² Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/reference-tables.html?edition=tcn%3A77-280149>. Median hourly wage rate of a 'health and safety officers' was used, £16.25, plus 30% overheads, totalling £21.13.

£18.55¹³) to carry out the approval visits. We have therefore based our calculations of familiarisation costs on the average of the two wage rates (£19.84). It is our assumption that it will take one EHO/TSO per LA two hours to familiarise themselves and disseminate the information to other key staff.

4.24 These assumptions were however challenged at consultation by the LA of the producer in Scotland. This LA stated that one officer familiarisation required 7 hours work, as a group was formed with other sprouting seed approved premises as well as contact with FSA for familiarisation and that other officers have spent an estimated 6 hours familiarising with the new legislation. One LA in England responded estimating that it had spent 19 hours on familiarisation. We have therefore revised our estimates in line with these responses. To calculate the familiarisation cost to the Scottish LA, we multiply the wage rate by the hours required (13), which generates a total cost of familiarisation to that LA of £258. For the English LA, we therefore multiply the number of hours required (19) by the average wage rate of an EHO/TSO, generating a total cost of familiarisation to that LA of £377. For all other LAs we have kept the initial assumptions as these were not challenged by any of the other LAs at consultation. To monetise the familiarisation costs to these LAs we multiply the wage rate by the number of hours required (2) and then again by the number of remaining LAs (432). Table 7 below shows the familiarisation cost to LAs by UK location.

Table 7: Costs of Familiarisation to Local Authorities by UK Country

	Scotland	England	Wales	NI	Total
Familiarisation Cost	£1,488	£14,384	£873	£1,030	£17,777

Costs Associated with Approval (One-Off Cost)

4.25 The new Regulations require that food businesses are approved to ensure that they are compliant with food hygiene legislation. It is LAs that are responsible for the approval of businesses and LAs will therefore incur a one-off cost per business that requires approval. It is for the Local Authority to decide whether it will be the responsibility of an EHO or a TSO to carry out the approval visits. We have therefore based our calculations of familiarisation costs on the average of the two wage rates (£19.84, see paragraph 4.23). We envisage that it will take the EHO three hours per business that requires approval (this includes travel time). This assumption was however challenged at consultation by one LA in Scotland and two in England.

4.26 These respondents all gave examples of particular premises where approval visits had taken longer than the three hours we have assumed in this BRIA. The Scottish LA stated that an approval visit had taken officers approximately 40 hours while one LA in England estimated that an approval visit would take approximately 4.5 hours and the other indicated that it would take approximately 10 hours per approval. These responses indicate that the time required for approval may have to be revised. We have therefore revised our estimates, taking into account these responses in our calculations. Taking the average of these three estimates results in an average time required per premises of approximately 18 hours. It is unclear whether the estimated 18 hours is representative for all approval visits, but based on the consultation

¹³ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/reference-tables.html?edition=tcn%3A77-280149>. Median hourly wage rate of a 'Inspectors of standards and regulations' was used, £14.27, plus 30% overheads, totalling £18.55.

responses, we believe that our initial estimate needed an upward revision and we have therefore based our final estimate on these responses.

4.27 We can then multiply the median hourly wage rate of an EHO/TSO (£19.84, see paragraph 4.23) by the hours required (18) and the number of businesses that require approval (23, see Table 1 above). This generates a total one-off cost of approval to LAs in the UK of £8,214. Please note that this estimate may be an underestimate as more sprouted seeds producers may enter the market in the future. We have however been unable to find any historical data on entrants into, and exits from the market, and have therefore not been able to monetise any costs to potential future entrants. Table 8 below therefore shows the cost of approval by UK country, based on the 23 firms that are currently in the market.

Table 8: Costs of Approval to Local Authorities by UK Country

	Scotland	England	Wales	NI	Total
Approval Cost	£357	£6,785	N/A	\$1,071	£8,214

Costs to Laboratories

Accreditation of Official Control Laboratories One-Off and Ongoing Costs)

4.28 Under Option 2, OCLs designated to carry out the required testing will need to get accredited for STEC testing. We have received information that there may be four OCLs that will seek accreditation, two located in Scotland and two in England. Laboratories that carry out official controls testing normally have an accreditation assessment annually for all of the testing processes which they undertake. Accreditation would therefore be an additional element to this process.

4.29 At present, costs associated with accreditation are uncertain. We did however ask questions about such costs at consultation and received one response from a laboratory in Scotland which provides scientific services to Local Authorities, private businesses and government agencies. This respondent replied that accreditation would be associated with a start-up cost for the investment of necessary laboratory equipment and estimated this one-off cost to be approximately £18,000. This laboratory also estimated that accreditation would involve a time cost to laboratories which would involve at least two members of staff for a period of six weeks. It also estimated that the validation work would have to be assessed by the United Kingdom Accreditation Service (UKAS) at a cost of around £500 per annum. In addition the laboratory envisaged that accreditation may be associated with costs from the upgrading of laboratory facilities, as well as costs associated with Proficiency Tests, but at this stage the laboratory was unable to give any estimates of these potential costs.

4.30 The FSA recognise that the estimates provided by this laboratory are uncertain and may not be representative for all labs requiring accreditation, but in order to obtain an indicative estimate of costs associated with accreditation we have used the estimates provided by the laboratory in Scotland and have assumed that all OCLs in the UK would incur similar costs. For the staff time costs we have assumed a median hourly wage rate of laboratory technicians (£13¹⁴) which has been multiplied by hours

¹⁴ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/reference-tables.html?edition=tcn%3A77-280149>. Median hourly wage rate of a 'laboratory technician' was used, £10.01, plus 30% overheads, totalling £13.

required (2*6 weeks at 40 hours per week). Multiplying individual estimates by the number of OCLs in the UK affected (4) results in the following total costs contained in Table 9.

Table 9: Indicative Costs to OCLs from Accreditation

One-Off Costs	Scotland	England	Wales	NI	Total
Start-up costs	£36,000	£36,000	0	0	£72,000
Facility upgrades	n/a	n/a	n/a	n/a	n/a
Staff time costs	£12,480	£12,480	0	0	£24,960
proficiency test	n/a	n/a	n/a	n/a	n/a
Total costs	£48,480	£48,480	0	0	£96,960
Ongoing Costs	Scotland	England	Wales	NI	UK
UKAS p.a.	£1,000	£1,000	0	0	£2,000

5. Scottish Firms Impact Test

5.1 During the development of the four EU proposals in 2012, FSA in Scotland worked closely with Scottish stakeholders; Local Authorities, Scottish Government and industry to establish the impact to businesses. Although initial information from food industry representatives and local authorities indicated that there were no affected businesses in Scotland, further requests for information in early 2013, as part of ongoing discussions with local authorities, FSA in Scotland identified a Scottish business involved in Third Country (non EU) imports of seeds for sprouting and also undertaking production of sprouted seeds. This business is defined as a micro business (i.e. with less than 10 employees). Scottish Local Authorities have confirmed that there are currently no additional businesses across Scotland involved in either the production of sprouts within their Authority or the import of seeds for sprouting.

5.2 FSA in Scotland policy and enforcement colleagues have worked closely with the business and the Scottish Local Authority concerned to provide guidance to the Scottish producer of sprouts. The Scottish Local Authority has provided FSA with comments on estimated costs to the business for sampling and testing the sprouts and familiarisation with the legislation. The Local Authority has also provided their own estimated costs for approval of this establishment and costs of their familiarisation to the legislation.

5.3 These comments will be considered in detail in the summary response table which will be published on the FSA website.

Competition Assessment

5.4 The Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013 is not expected to have any impact either directly or indirectly on competition.

5.5 Using the Office of Fair Trading (OFT) competition assessment framework, it has been established that the preferred policy option (option 2) is unlikely to have any material impact on competition.

Test Run of Business Forms

5.6 The Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013 will not introduce any new or additional forms to businesses that will be affected by the Regulation.

6. Legal Aid Impact Test

6.1 This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013.

7. Enforcement, Sanctions, and Monitoring

7.1 Enforcement of the Regulations in Scotland will be the responsibility of Local Authority Environmental Health Departments – this will be drawn from powers written within the Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013.

Sanctions

7.2 An amendment is being made to regulation 41 (offences and penalties) of the Official Feed and Food Controls (Scotland) Regulations 2009 to make it an offence for any person who imports into Scotland or places on the market any sprouts or seeds intended for sprouting which do not comply with the certification requirements of Article 3 of Commission Regulation (EU) No 211/2013 on certification requirements for imports into the EU of sprouts and seeds intended for the production of sprouts.

Monitoring

7.3 The effectiveness and impact of the Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013 will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process.

8. Implementation and delivery plan

8.1 The publication of the Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Scotland) Regulations 2013 will be communicated to stakeholders by email, letter and monthly Enforcement Report. This will be done shortly after the SSI has been published on legislation.gov.uk website.

9. Post-Implementation Review

9.1 A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulation, is expected to take place in five years, in December 2018. The effectiveness of these Regulations will also be monitored via general feedback from industry and enforcement authorities.

10. Summary and Recommendation

10.1 The Agency recommends Option 2 to provide for the execution and enforcement of the EU Regulations and provide the legislative framework for the requirements to be enforced under UK law.

10.2 Taking this option allows the Government to fulfil its obligations to implement EU law.

10.3 This option also provides appropriate action to address a known public health risk and therefore public health will be protected.

11. Summary costs and benefits table

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social - Policy and Administrative
1 Do Nothing	No familiarisation costs to business and local authorities. No approval of business premises costs or testing required.	The benefits from this option would include no familiarisation costs to the business and the Local Authority. In addition there would be no further associated costs with the approval of the business. The business would also not have the costs incurred from regular sampling.
2. Provide for the execution and enforcement of the EU Regulations and provide the legislative framework for the requirements to be enforced under UK law.	This option provides appropriate action to address a known public health risk and therefore public health will be protected. Enforcement powers would be provided to the directly applicable EU Regulations and the UK would meet EU obligations.	<p>The estimated familiarisation cost to industry (one micro business) in Scotland: £52.</p> <p>The estimated cost associated with approval to industry (one micro business) in Scotland: £103.</p> <p>Indicative costs of the micro-criteria testing: £70,828.</p> <p>The estimated cost of familiarisation to all 32 Local Authorities in Scotland: £1,488.</p> <p>The estimated cost incurred by the Local Authority in Scotland to approve the micro business: £357.</p>

		Indicative costs to OCLs from accreditation: £48,480.
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12. Declaration and publication

I have read the impact assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Minister’s Signature.....

Minister’s Title

Date.....

Contact point

Karen Robertson
Standards, Hygiene and Associated Regulatory Policy Branch
Food Standards Agency in Scotland
6th floor, St Magnus House
25 Guild Street, Aberdeen, AB11 6NJ

Tel: 01224 288362
e-mail: karen.robertson@foodstandards.gsi.gov.uk