Title: Package of EU Regulations on sprouts and seeds intended for sprouting: Regulations (EU) No 208/2013, 209/2013, 210/2013 and 211/2013 **IA No:** FOODSA IA0122 **Lead department or agency:** Food Standards Agency **Other departments or agencies:**	**Impact Assessment (IA)** **Date: 23/08/2013** **Stage:** Final **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries:** Liz Stretton – 0207 276 8357 SIconsolidation_england@foodstandards.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
-£14.18m	£1.63m	£1.49m	No	In/Out/zero net cost

What is the problem under consideration? Why is government intervention necessary?

Investigations into outbreaks of E. coli O104:H4 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 by food business operators (FBOs) in this sector. Government intervention is required to ensure that the necessary controls focussing on good agricultural and hygiene practices are put in place in the sector to ensure that public health is protected.

What are the policy objectives and the intended effects?

The objective of the package of Regulations is to ensure public health protection through the introduction of specific hygiene controls in the sprouts and seeds for the sprouting sector and corresponding enforcement. These are intended to ensure 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;
- seeds and sprouts can be traced to the producer in the event of a problem through enhanced traceability regulations; and
- the risk of unsafe products entering the food chain is reduced by introducing specific microbiological criteria.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing: Do not introduce the new requirements on sprouted seeds. This would mean that the current controls which require the registration of such businesses remain in place with the continued risk to public health. This would also mean that the UK was in non-compliance with EU law.

Option 2: Preferred Option: Support introduction of proportionate requirements for sprouts and seeds for the production of sprouts and provide for their enforcement. These EU Regulations would apply directly and the FSA will introduce a Statutory Instrument to ensure appropriate and adequate enforcement powers are available.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 12/2018

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

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

Signed by the responsible Minister: Jane Ellison Date: 22.11.13

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing: Do not introduce the new requirements on sprouted seeds

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: N/A**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	N/A		N/A	**N/A**

Description and scale of key monetised costs by 'main affected groups'

There are no costs associated with this option; this is the baseline against which all other options are appraised.

Other key non-monetised costs by 'main affected groups'

There are no costs associated with this option; this is the baseline against which all other options are appraised.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	N/A		N/A	**N/A**

Description and scale of key monetised benefits by 'main affected groups'

There are no benefits associated with this option; this is the baseline against which all other options are appraised.

Other key non-monetised benefits by 'main affected groups'

There are no benefits associated with this option; this is the baseline against which all other options are appraised.

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

Assumption is that the proposed policy changes are not introduced

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: N/A	**Benefits: N/A**	**Net: N/A**	No	IN/OUT/Zero net cost

Summary: Analysis & Evidence — Policy Option 2

Description: Support introduction of proportionate requirements for sprouts and seeds for the production of sprouts and provide for their enforcement

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: -£14.18**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	1.	Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0.04		£1.63	**£14.18**

Description and scale of key monetised costs by 'main affected groups'

Industry: one-off familiarisation cost £11,446 (PV 10 years); one-off cost of approval: £1,392 (PV 10 years); micro-criteria testing: £14,022,300 (PV 10 years).
Enforcement: one-off familiarisation: £17,777 (PV 10 years); one-off cost of approval: £8,214 (PV 10 years).
Official Control Laboratories: one-off plus ongoing: accreditation: £114,175 (PV 10 years).

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0.00		£0.00	**£0.00**

Description and scale of key monetised benefits by 'main affected groups'

None, we have been unable to monetise any potential health benefits to consumers from more stringent requirements on sprouted seeds

Other key non-monetised benefits by 'main affected groups'

- 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.

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

Industry: Costs of micro-criteria testing have been extrapolated to industry based on the average costs provided by only two firms in the industry, due to lack of other evidence.

Laboratories: costs of accreditation have been extrapolated to industry based on the costs provided by only one laboratory in the industry, due to lack of other evidence.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: £1.63	**Benefits: £0.00**	**Net: £1.63**	No	**IN/OUT/Zero net cos**

Evidence Base (for summary sheets)

Problem under consideration and rationale for intervention

1. Investigation into the outbreaks of Shiga toxin-producing E.coli (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 sprout and seeds for sprouting production.

2. The Advisory Committee on the Microbiological Safety of Food (ACMSF) reported that consumption of sprouts has 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.

Policy objective

3. 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 provision for the Regulations' enforcement.

Background

4. In May 2011 a major outbreak of STEC[1] occurred in Germany and France (both EU member States) 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 bacteria[2] that may contaminate seeds and sprouts (this opinion was replaced with a revised publication 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.

5. 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.

6. These proposals were discussed at a number of Working Group meetings during 2012. During the discussions, 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 raised 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.

7. 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.

[1] The specific strain identified was O104:H4.

[2] http://www.efsa.europa.eu/en/efsajournal/doc/3138.pdf

8. The requirement at Article 5 of Regulation (EC) 852/2004 for food safety procedures based on HACCP principles does not apply to primary production. The UK recognises that implementation of HACCP-based systems at primary production is not generally feasible. However, given the nature of the products, it would be expected that FBOs in the sprout sector should have in place well developed food safety controls to prevent contamination and stakeholder feedback indicated that this was the case with UK FBOs in this sector.

9. 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.

10. In agreeing Regulation (EU) 209/2013, amending microbiological criteria, the UK were successful in securing amendments to the requirement for preliminary testing of a batch of seeds as this reflected the approach already taken by 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.

11. The UK made the case that 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 difficulties[3] 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

12. The four EU Regulations[4] introduced are:

- ***Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) 852/2004*[5]*.*** 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.

[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 on1 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.)

- ***Commission Regulation (EU) No 209/2013 amending Regulation (EC) 2073/2005 as regards microbiological criteria for sprouts[6].*** 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. 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.

- ***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.

13. Further details on the requirements introduced by Regulation (EU) 209/2013 can be found at Annex 1 to this IA.

14. The FSA will be producing guidance which will assist FBOs and enforcers on the implementation of the Regulations to respond to issues arising from the practical application of the Regulations.

Options considered

15. **Option 1 - Do nothing – do not implement the new Regulations on sprouted seeds**. This option carries with it a potentially higher risk of an E. coli outbreak as it does not introduce the additional safeguards in Option 2. There would be a potential risk of damaging the FSA's reputation if there was a perception that the UK was not taking appropriate action to address a known public health risk. Also although the EU Regulations are directly applicable, current enforcement provision in England would not be reviewed, so adequate enforcement powers for the UK as whole would not exist, resulting in there being no means of enforcing FBOs to comply with the new requirements and finally a failure to meet EU obligations, potentially leading to infraction proceedings against the UK.

16. **Option 2 - Preferred option is 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**. This is the preferred Option as it provides for enforcement of the necessary additional public health protection and fulfils EU obligations.

Sectors and groups affected

Industry

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 of the industry will need to ensure that they comply with the relevant Commission Regulations. Engagement with industry indicated that there are 23 food businesses which will require approval under Regulation 210/2013. These were included in the list of interested parties as part of the

[6] 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.

consultation exercise. Responses to the consultation indicated that the 23 businesses identified may be an underestimate as they do not include businesses producing home sprouting kits, production in schools as well as production for food service in certain local restaurants. We have subsequently received confirmation from 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 are 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 Impact Assessment mainly focusses on the sprout producers as we anticipate the impact will be greatest on those businesses. All costs and benefits in this impact assessment are therefore based on the assumption that there are 23 firms in the market.

Table 1: Businesses affected, by UK country and firm size

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

Official Control Laboratories

17. 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. From information received from the OCLs, the FSA is aware of 4 OCLs in total that are looking to become accredited, two of these are located in England, whilst the remaining two are located Scotland. 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 4 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

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

Local Authorities

18. Local Authorities 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

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

Consumers

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

Option Appraisal

Option 1 - Do nothing – Do not implement the new Regulations on sprouted seeds

Costs and Benefits

20. There are no quantified costs or benefits associated with this option; it is the baseline against which costs and benefits identified in the policy option (option 2) will be appraised. However, if the UK does not provide for enforcement of the EU Regulations there could be a higher risk of a potential future outbreak of E. coli. The UK would also fail to meet requirements of EU law and the Commission could open infraction procedures against the UK which could result in unknown costs.

Option 2 - Preferred option is 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

Costs

Costs to Industry

Familiarisation Costs (One-Off Cost)

21. 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 £25.78[7]) that is responsible for familiarisation and that it will on average take one business manager per business two hours to familiarise themselves and disseminate the information to other key staff.

22. At consultation these assumptions were challenged by four businesses, who believed that familiarisation may take longer for small businesses that may not have the necessary expertise in-house. However, only one business (a large one) provided us with 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. We have taken the numbers provided by this firm into account in our final calculations. 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, we keep the initial assumptions (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. Summing up across all businesses generates a total one-off cost to the whole sector of £11,446. 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

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

23. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (EACs) by dividing the one-off cost by an annuity factor.[8] The total one-off familiarisation cost to UK industry in this

[7] Wage rate obtained from Annual Survey of Hours and Earnings 2012, http://www.ons.gov.uk/ons/publications/re-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.

[8] The annuity factor is essentially the sum of the discount factors across the time period over which the policy is appraised. The equivalent annual cost formula is as follows:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^{j} \left(\frac{1}{1+r_i} \right)$$

proposal is £11,446 which yields an equivalent annual cost of £1,330 over a ten year period. Table 5 below shows the EAC for UK.

Table 5: Equivalent Annual Costs of Familiarisation to UK Industry

	England	Wales	Scotland	NI	Total
EAC	1,306	0	6	18	1,330

Costs Associated with Approval (One-Off Cost)

24. 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 Local Authority which will ensure that the establishment is compliant with the relevant hygiene rules. There is no direct cost of the 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.

25. 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 Local Authority prior to the inspection visit and that this information is similar to that which businesses need to provide in order to be registered. At consultation two businesses challenged this assumption. One large business responded that the approval visit would take them one full working day; whilst one micro sized business responded that it would take it 4 hours for the approval visit. We have taken these responses into account in our final calculations.

26. For the large business that provided us with new estimates, we multiply the wage rate of a business manager (£25.78, see paragraph 22) by the hours required (8), which generates a total one-off cost of approval to that business of £206. For the micro business that provided us with new estimates, 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 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. Summing up approval costs across all businesses in the sector then generates a total approval cost to industry of £1,392. Table 6 below shows the cost of approval by UK country and firm size.

Table 6: Costs Associated with Approval to UK industry, by UK country and firm size

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

27. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (see Paragraph 23 above). The total one-off approval cost under this proposal is £1,392, which generates an EAC of £162 to UK industry. Table 7 below shows this EAC by UK country and firm size.

Table 7: Equivalent Annual Costs of Approval to UK Industry

	England	Wales	Scotland	NI	Total
EAC	132	0	12	18	162

Costs Associated with Import Control (Negligible)

28. 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. The assumption of negligible costs associated with import control was broadly accepted by consultation responses.

29. 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)

30. The new Regulations require food business operators 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 would 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 food business operators 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)

31. 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 a laboratory that can show their protocol is robust. 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 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.

32. 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. However, only two businesses provided us with information about such costs.

33. 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.

34. 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.

35. We are aware that the costs estimates provided by these two businesses 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 129[9] 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 £66,500[10] per annum to get the samples tested by the laboratory.

36. If we assume that it would be a production manager carrying out the sampling, at a wage rate of £25.78 (see paragraph 21), this generates a total cost per business and per annum for sampling of £3,328[11]. Summing up over all costs results in a total cost per business and per annum for the micro-criteria testing of £70,828[12]. Multiplying this with the total number of firms generates a total cost to industry of £1,629,044[13]. 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 8 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 8: Indicative Costs of the Micro-Criteria Testing

Country	Micro	Small	Medium	Large	Unkown	Total
England	354,140	283,312	212,484	212,484	283,312	1,345,732
Wales	0	0	0	0	0	0
Scotland	70,828	0	0	0	0	70,828
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)

37. There will be a one-off cost to Local Authorities 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 £21.13[14]) or a Trading Standards Officer (TSO, wage rate of £18.55[15]) 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.

38. These assumptions were however challenged at consultation by two local authorities. Out of these two LAs, one LA estimated it had spent 19 hours on familiarisation. This LA was one of the LAs that assisted FSA in understanding the industry and those 19 hours included a visit by the LA to the FSA

[9] (210+48)/2=129

[10] (27k+106k)/2=66,500

[11] 25.8*129*=3,328

[12] 3,328+1,000+66,500=70,828

[13] 70,828*23=1,629,049

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

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

in London. The other LA responded that the proposals required their officers to spend in total 13 hours on familiarisation. We have therefore revised our estimates in line with these responses. To calculate the familiarisation cost to the first 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 the second LA we multiply the wage rate by the hours required (13), which generates a total cost of familiarisation to that LA of £258. For all other LAs we keep 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), which generates a total familiarisation cost of £17,142. Summing up across all LAs results in a total one-off familiarisation cost to LAs in the UK of £17,777. Table 9 below shows the familiarisation cost to LAs by UK location.

Table 9: Costs of Familiarisation to Local Authorities by UK Country

	England	Wales	Scotland	NI	UK
Familiarisation	14,384	873	1,488	1,032	17,777

39. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (see Paragraph 23 above). The total one-off familiarisation cost to LAs under this proposal is £17,777, which generates an EAC of £2,065 to UK enforcement. Table 10 below shows this EAC by UK country.

Table 10: Equivalent Annual Costs of Familiarisation to Local Authorities by UK Country

	England	Wales	Scotland	NI	UK
EAC	1,671	101	173	120	2,065

Costs Associated with Approval (One-Off Cost)

40. The new Regulations require that food businesses are approved to ensure that they are compliant with food hygiene legislation. It is local authorities 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 37). 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 three respondents. These respondents all gave examples of particular premises where approval visits had taken longer than the three hours we have assumed in this IA. One respondent estimated that an approval visit would take approximately 4.5 hours; another that it would take approximately 10 hours per premises and the third one that it would take approximately 40 hours per premises. 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 responses we believe that our initial estimate needed an upward revision and we have therefore based our final estimate on these responses.

41. We can then multiply the median hourly wage rate of an EHO/TSO (£19.84, see paragraph 37) 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. To note is 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 11 below therefore shows the cost of approval by UK country, based on the 23 firms that are currently in the market.

Table 11: Costs of Approval to Local Authorities by UK Country

	England	Wales	Scotland	NI	Total
Approval Cost	6,785	0	357	1,071	8,214

42. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (see paragraph 23 above). The total one-off approval cost to LAs under this proposal is £8,214, which generates an EAC of £954 to UK enforcement. Table 12 below shows this EAC by UK country and firm size.

Table 12: Equivalent Annual Costs of Approval to Local Authorities by UK Country

	England	Wales	Scotland	NI	Total
EAC	788	0	41	124	954

Costs to Laboratories

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

43. Under Option 2, Official Control Laboratories (OCLs) designated to carry about the required testing will need to get accredited for STEC testing. We have received information that there will be in total four OCLs that will get accreditation, two located in England and two located in Scotland. 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.

44. At the present, costs associated with accreditation are uncertain. We did however ask questions about such costs at consultation and received one response from a laboratory providing 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 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.

45. 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 and 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 (£13[16]) which has been multiplied by hours 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:

Table 13: Indicative Costs to OCLs from Accreditation

One-Off Costs	England	Wales	Scotland	NI	UK
Start-up costs	36,000	0	36,000	0	72,000
Facility upgrades	n/a	n/a	n/a	n/a	n/a
Staff time costs	12,480	0	12,480	0	24,960
Proficiency test	n/a	n/a	n/a	n/a	n/a
Total costs	48,480	0	48,480	0	96,960
EAC by country	England	Wales	Scotland	NI	Total
EAC	5,632	0	5,632	0	11,264
Ongoing Costs	England	Wales	Scotland	NI	UK
UKAS p.a.	1,000	0	1,000	0	2,000

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

46. Since the above table includes both annual and one-off costs, Table 14 below shows the 10 year profile of total costs.

Table 14: 10 year Profile of Accreditation Costs to OCLs

COSTS	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/p.a.	PV
Start-up costs	72,000	0	0	0	0	0	0	0	0	0	72,000	8,365	72,000
Facility upgrades	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Staff time costs	24,960	0	0	0	0	0	0	0	0	0	24,960	2,900	24,960
Proficiency test	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
UKAS p.a.	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	20,000	2000	17,215
Total Costs	**98,960**	**2,000**	**2,000**	**2,000**	**2,000**	**2,000**	**2,000**	**2,000**	**2,000**	**2,000**	**116,960**	**13,264**	**114,175**

Benefits

Benefits to Consumer Health

47. 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. The most recent Salmonella outbreak in the UK (2010) resulted in 241 cases and 1 death. 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.

48. However, in order to put the cost estimates in this impact assessment in relation to potential benefits, we can use estimates of the willingness to prevent illness of different severities and death. The HSE has produced such estimates[17]. Table 15 below shows these values, uprated to 2013 values.

Table 15: Willingness to pay to prevent illness of different severity

	£2013
Minor illness (<7 days)	211
Illness (>7 days)	2,663
Permanent incapacity	256,581
Death	1,447,495

49. Using the HSE estimates we can then calculate an indicative measure of the benefit of preventing an outbreak such as the 2010 UK outbreak. We do not have details on the length of illness associated with the 2010 outbreak. However, information from Public Health England18 suggests that most salmonella infections last between 4 and 7 days. We have no information about the likelihood that infection leads to incapacity. Given this information we can calculate an indicative estimate by multiplying the number of deaths (1) by the willingness to pay (WTP) estimate for death (£1,447,495), and then the assumed number of cases of minor illness (240, i.e. 241 minus 1 death), and then summing up of the results. This then generates an indicative estimate of the benefit of preventing the 2010 outbreak of £1,498,032.

50. We have, however, not used this estimate in the impact assessment as we cannot be certain of how the introduction of controls could reduce the number of cases of various types of illness in a typical outbreak (we do not even know whether the 2010 outbreak can be categorised as a typical outbreak). The estimates are hence only provided to put the costs of the measures into context.

Summary of Total Costs and Benefits under Option 2

51. As can be seen in Table 15 below, Option 2 generates a total cost to the UK of £16,446,229 (£14,175,304, net present value over a period of ten years). The total cost to business is

[17] http://www.food.gov.uk/multimedia/pdfs/euhygiene2004riafull.pdf

[18] http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733816528

£16,303,278 (£14,035,139, NPV 10 years). To note is that the costs of micro criteria testing as well as costs associated with the accreditation of OCLs are uncertain and should be treated as indicative costs. We have also been unable to monetise any potential health benefits to consumers from a strengthening of the requirements on sprouted seeds, which aim to reduce the risk of future outbreaks of E. coli, which means that the net impact of the proposal is a net cost. It should however be noted that, although it is not possible to determine the extent to which the application of additional controls would have reduced the impacts outlined in paragraphs 47 to 50, the FSA believes that observation and enforcement of these new regulations would improve protection and reduce future public health risks from this source.

Table 15: Total Costs to the UK under Option 2

COSTS	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/p.a.	PV
FBO familiarisation	11,446	0	0	0	0	0	0	0	0	0	11,446	1,330	11,446
FBO approval	1,392	0	0	0	0	0	0	0	0	0	1,392	162	1,392
FBO micro criteria	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	16,290,440	1,629,044	14,022,300
LA familiarisation	17,777	0	0	0	0	0	0	0	0	0	17,777	2,065	17,777
LA approval	8,214	0	0	0	0	0	0	0	0	0	8,214	954	8,214
OCL accreditation	98,960	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	116,960	13,264	114,175
Total Costs	**1,766,833**	**1,631,044**	**1,631,044**	**1,631,044**	**1,631,044**	**1,631,044**	**1,631,044**	**1,631,044**	**1,631,044**	**1,631,044**	**16,446,229**	**1,646,819**	**14,175,304**

BENEFITS	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/p.a.	PV
Consumer health	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

NET IMPACT	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/p.a.	PV
Total (net cost)	1,766,833	1,631,044	1,631,044	1,631,044	1,631,044	1,631,044	1,631,044	1,631,044	1,631,044	1,631,044	16,446,229	1,646,819	14,175,304
Business (net cost	1,641,882	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	1,629,044	16,303,278	1,630,536	14,035,139

Risks and Assumptions

52. Local Authorities and Industry will need to invest time to familiarise themselves with new legislation as they would be responsible respectively for enforcement and compliance.

Wider impacts

53. As mentioned previously in this impact assessment, the proposal requirements; approval of primary producers, micro criteria requirements, import control and traceability as contained in the legislation should not have any wider impacts. This sets a precedent for STEC criteria so there may be an increased appetite for setting criteria for other commodities. This is also the first time for setting specific controls for primary products and for products of non-animal origin.

Summary and preferred option with description of implementation plan

54. Option 2 is the preferred option. The UK would influence and implement the Commission legislative proposals for approval, import control, microbiological criteria and traceability for producers of sprouts. UK intervention has already achieved some results in the development of the proposals. The UK would be seen to be in compliance with EU law which is providing additional public health protection. The Regulations apply from 1 July 2013 with the exception of Regulation (EU) No 211/2013 which came into effect on 1 April 2013 with a transitional period until 1 July 2013.

Specific Impact Tests

Competition Assessment

55. The incoming measure is not expected to have any impact either directly or indirectly on competition.

Small Firms Impact Test

56. For the moment we do not have information about the employment size of all firms affected by this regulation but we believe that the majority of businesses are either micro or small (see Table 1). The whole impact assessment therefore considers the effect on small (or micro) businesses, so we have not applied the Small Firms Impact Test separately.

57. We are sending this IA to all of the businesses that we are aware of, or have had any contact with, to give them the opportunity to provide further information on the size of their businesses and the impact that these measures will have on them.

58. Although the majority of respondents to the consultation said that they envisaged that micro and smaller businesses were likely to be greatly impacted by the legislation, we are unable either to apply an exemption from the requirements for micro businesses or apply the requirements to a lesser degree, as EU Regulations apply directly. Furthermore the risk to human health remains if food safety measures are not applied correctly regardless of the size of the business.

Sustainable development

59. This impact assessment considers the economic effects of the measure. We do not believe that there will be any significant social effects. There may be environmental impact if seeds or sprouts that are sampled for testing are rendered unmarketable and have to be destroyed but we have no evidence to quantify this.

Race equality issues

60. No impact on race equality is anticipated.

Gender equality issues

61. No impact on gender is anticipated.

Disability equality issues

62. No impact on disability is anticipated.

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SPECIFIC IMPACT TESTS

[As you develop your proposal you need to think about all of the following specific impact tests, but they may not all be relevant to your policy. Click on the relevant box to show which are. For those shown as relevant, include the heading and relevant text in the Evidence Base. **When you have completed the table, delete this paragraph but keep the following Note and the table in your IA.]**

Note: the Health and Wellbeing specific impact test is not in the list, because the whole of an FSA IA focuses on food safety in the health context.

Type of test and link to guidance **(Double click on each of the headings to follow link)**	**Click on a box for EACH row to show if the test is relevant or not:**	
	Relevant	**Not relevant**
Competition assessment	☒	☐
Small firms impact test	☒	☐
Sustainability:		
Economic impact	☒	
Social impact	☒	
Environmental impact	☒	
Carbon impact	☐	☒
Equality impact	☒	☐
Justice impact	☐	☒
Rural proofing	☐	☒
Human rights	☐	☒
Privacy impact	☐	☒
Creation of new criminal offence	☐	☒
Impact on powers of entry	☐	☒

Summary of the proposals

Annex 1:

Further detail on microbiological criteria for sprouts

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs lays down microbiological criteria for certain micro-organisms and the rules to be complied with by FBOs referred to in Article 4 of Regulation (EC) No 852/2004. Chapter 1 Annex I to the Regulation sets out the food safety criteria to be complied with by certain food categories, including sampling plans, analytical reference methods and limits for micro-organisms or their toxins and metabolites. Chapter 1 lists the food safety criteria for sprouted seeds, as regards Salmonella.

Regulation (EU) 209/2013 lays down a new criterion for establishments producing sprouted seeds for certain Shiga toxin producing E.coli (STEC) serotypes to be included alongside existing criteria for Salmonella and Listeria monocytogenes as set out below. The European Commission has indicated that the analytical method for STEC could provide positive result within 25 hours, and full results in 48 hours. Results for Salmonella would take at least 48 hours.

Certain STEC serogroups (namely O157, O26, O103, O111, O145 and O104:H4) are recognized to be those causing most of the Haemolytic Uremic Syndrome (HUS) cases occurring in the European Union. Furthermore serogroup O104:H4 caused the outbreak in May 2011 and so microbiological criteria have been introduced for these serotypes. It is possible that other STEC serogroups may also be pathogenic to humans and STEC may cause less severe forms of disease such as diarrhoea and or bloody diarrhoea or even HUS and may therefore represent a hazard for the consumers' health.

Regulation (EC) No 2073/2005 Annex 1 is amended as follows:

Chapter 1 is amended as follows:

(a) footnote 12 is deleted

(b) in row 1.18 the reference to footnote 12 is replaced by the reference to footnote 23.

(c) the following row 1.29 and the corresponding footnote 22 and 23 are added:

"1.29 Sprouts ([23])	Shiga toxin producing___*E. coli* (STEC) O157, O26, O111, O103, O145 and O104:H4	5	0	Absence in 25 grams	CEN ISO 13136 ([22])	Products placed on the market during their shelf-life

([22]) Taking into account the most recent adaptation by the European Union reference laboratory for *Escherichia coli,* including Verotoxigenic *E. coli* (VTEC), for the detection of STEC O104:H4;

([23]) Excluding sprouts that have received a treatment effective to eliminate *Salmonella* spp and STEC."

Sprouts should be considered to be ready-to-eat foods, as they can be consumed without the need for cooking or other processing, which would otherwise be effective in eliminating or reducing to an acceptable level the pathogenic micro-organisms. FBOs producing sprouts should therefore comply with the food safety criteria for ready-to-eat food laid down in the legislation, including the sampling of processing areas and equipment as part of their food safety procedures.