ANNEXE B

Title: Package of EU Regulations on sprouts and seeds intended for sprouting: Regulations (EU) No 208/2013, 209/2013, 210/2013 and 211/2013	Impact Assessment (IA)
IA No: FOODSA IA0122	**Date: 23/08/2013**
Lead department or agency: Food Standards Agency	**Stage:** Consultation
Other departments or agencies:	**Source of intervention:** EU
	Type of measure: Secondary legislation
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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**
-£0.02m	£0.00m	£0.00m	No	NA

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 potential 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, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

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: -£0.02**

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	£0.02		£0.00	**£0.02**

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

Industry: one-off familiarisation cost £1,187 (PV); one-off cost of approval: £1,187 (PV);
Local authorities: one-off cost of familiarisation £18,341 (PV); one-off cost of approval £1,458

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

Industry: ongoing cost of micro criteria testing
Official control laboratories: one-off cost of accreditation

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: familiarisation will require 2hrs; approval will require 2hrs; costs of import control and traceability requirements are negligible.

Local Authorities: familiarisation will require 2hrs; approval will require 3hrs

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: £0.00	**Benefits: £0.00**	**Net: £0.00**	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 are 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[3] 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 of imported sprouts and seeds intended for sprouting 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 microbiological testing of a batch of seeds. The proposals which were finally agreed 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 reasonable 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 required to take advantage of the derogation contained in the Regulation from to requirement to pre-test the seeds. 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[4] 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[5] introduced are:

- ***Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) 852/2004*[6]*.*** 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] The European Commission's guidance document on HACCP notes "HACCP is science-based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing."

[4] 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

[5] 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[7].*** 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 Regulation introduces requirements for STEC testing which sets out the requirements to show compliance with the criteria for absence of six specific serotypes. There are already requirements for Salmonella testing, which are retained, and as the sprouts are considered to be 'ready-to-eat' foods, the listeria criteria will also apply. The legislation introduces a requirement for preliminary testing of seeds for sprouting and sets out the frequency for testing sprouts. The required preliminary testing will mean that there will be added costs for the testing of seeds.

- ***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, plus batch identification and dates of dispatch.

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 them.

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 and UK Government'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 revised, 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. Infraction fines are calculated as a percentage of GDP which would be for the UK between £10 million and £12 million.

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

17. 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, as all of these sectors of the industry will need to ensure that they comply with the Commission Regulations. Consultation with industry has indicated that there are 23 food businesses which will require approval. These are included in the list of interested parties as part of the consultation exercise**.**

[7] 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.

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

Consultation Question 1

We invite stakeholders to comment on whether we have managed to identify (included in the list of interested parties as part of the consultation exercise) all businesses in the UK. If not, please tell us in which country those businesses are located and the number of employees per business.

Official Control Laboratories

18. Under Option 2, any official control laboratories (OCLs) which would be designated to carry out the STEC testing would need to acquire accreditation for that process. Out of the 17 OCLs in England, we understand that only two will be carrying out this function. Other laboratories that carry out commercial testing may choose to become accredited for STEC testing but we are unable to provide an estimate of the potential costs due to the nature of the accreditation process. Table 2 below shows the number of OCLs in the UK, by country.

Table 2: Number of Official control laboratories by UK country

	England	Wales	Scotland	NI	UK
No. OCL labs	17	6	4	3	30

Consultation Question 2

We invite stakeholders to comment on whether our assessment that only designated OCLs would need to get accredited for STEC testing (not commercial laboratories) is correct.

Local Authorities

19. Local Authorities are responsible for the approval of sprouted seeds businesses under the new requirements; we are currently aware of 23 businesses which will require approval. 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

20. There will be potential consumer health benefits from more stringent controls of sprouted seeds production and import because these additional controls will 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

21. 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 would potentially be a higher risk of a future outbreak of E. coli. It 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)

22. 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 that is responsible for familiarisation and that it will take one business manager per business two hours to familiarise themselves and disseminate the information to other key staff. The median hourly wage rate of a business manager is £25.78[1], which yields a total one-off cost of familiarisation of £51.56 per business. Multiplying this with the total number of businesses affected by the Regulations (23) generates a total one off cost to the food industry of £1,187. 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
England	258	206	155	155	206	980
Wales	0	0	0	0	0	0
Scotland	52	0	0	0	0	52
NI	103	52	0	0	0	155
Total	413	258	155	155	206	1,187

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.[2] The total one-off familiarisation cost to UK industry in this proposal is £1,187 which yields an equivalent annual cost of £138 over a ten year period. Table 5 below shows the EAC for UK.

[1] 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.

[2] 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:

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

Table 5: Equivalent Annual Costs of Familiarisation to UK Industry (£)

	England	Wales	Scotland	NI	Total
EAC	114	0	6	18	138

Consultation Question 3

We invite stakeholders to comment on whether our estimate that it will take two hours for familiarisation of the Regulation seems reasonable. If not, please explain why and provide information and sufficiently detailed data so that we can monetise this cost more robustly.

Costs Associated with Approval (One-Off Cost)

24. The new Regulations require FBOs producing sprouts or seeds intending for sprouting 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 by the time required for the manager to be present at the inspection. At the moment we do not have any estimate of the time it will take for an approval visit. Due to this lack of evidence we make 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.

26. Multiplying the wage rate of a business manager (£25.78, see paragraph 22) with the hours required (2) and the total number of businesses affected (23) generates a total one-off cost of approval of £1,186. 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	155	206	980
Wales	0	0	0	0	0	0
Scotland	52	0	0	0	0	52
NI	103	52	0	0	0	155
Total	413	258	155	155	206	1,187

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 £1,187, which generates an EAC of £138 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	114	0	6	18	138

Consultation Question 4

We invite stakeholders to comment on whether our estimate of the time required for an approval visit (two hours) seems reasonable. If not, please explain why and provide information and sufficiently detailed data so that we can monetise these costs more robustly.

Costs Associated with Import Control

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 marketing 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.

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 and have therefore not attempted to monetise this potential cost.

Consultation Question 5

We invite stakeholders to comment on our assumption that costs associated with import control will be negligible to business. If not, please explain why and provide information and sufficiently detailed data so that we can monetise this cost more robustly.

Costs Associated with Traceability Requirements

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 as required by Regulation (EC) No 178/2002. 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. It is also in food businesses' own interests for commercial reasons to ensure that good traceability systems are in place.

Consultation Question 6

We invite stakeholders to comment on our assumption that costs associated with the traceability requirement will be negligible to business. If not, please provide information and sufficiently detailed data so that we can monetise this cost more robustly.

Costs to Business Associated with the Micro-Criteria Tests

31. 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 screening 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 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.

32. Currently we have limited information about these costs to industry. We have some indicative information from a laboratory which suggests that an STEC 'O' group screen would be around £27

per sample, but there are uncertainties around this estimate and we invite stakeholders to provide information on this.

Consultation Question 7

We invite stakeholders to comment on whether this estimate of £27 per sample seems reasonable for the testing of the six STEC serotypes. If not, please provide information and sufficiently detailed data so that we can monetise this cost with more accuracy.

33. To be able to monetise the cost to businesses per annum we also need information about how many additional samples would be required, per business in the sector, for industry to comply with the new STEC requirements. We invite stakeholders to provide information on this.

34. Related to the cost of sampling is the cost of wastage, where seeds and sprouts that are sampled for testing are rendered unmarketable and therefore have to be destroyed. We currently do not have this information and therefore invite stakeholders to provide this.

Consultation Question 8

Currently we have limited information on the costs associated with the new micro criteria requirements for STEC testing. We therefore invite stakeholders to comment on these costs. In particular we need detailed information about:

- The estimated time that will be spent, on average, per annum, for the collecting of samples required for analysis under the new STEC requirement;
- The number of kilos or tonnes of seeds you produce or import, per annum, which would fall under the requirements of the new preliminary STEC testing.
- The number of additional samples required for STEC testing, per annum;
- The cost for sending samples for STEC testing to a laboratory for analysis;
- The number of kilos or tonnes of seeds and sprouts that are tested and that would have to be destroyed, and the associated cost, per kilo/tonne, or per annum;
- Any additional costs associated with the testing for STEC.

Please provide as detailed information and evidence as possible, in order for us to be able to monetise these costs.

Costs to Local Authorities

Familiarisation (One-Off Cost)

35. 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 with the wage rate of the official carrying it out. It is our assumption that it will be the Environmental Health Officer (EHO) that is responsible for familiarisation and that it will take one EHO per LA two hours to familiarise themselves and disseminate the information to other key staff. The median hourly wage rate of an EHO is £21.13[3], which yields a total one off cost of familiarisation of £42.26 per LA. Multiplying this with the total number of LAs (434) generates a total one off cost to enforcement of £18,341. Table 8 below shows the familiarisation cost to LA by UK location.

[3] 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.

Table 8: Costs of Familiarisation to Local Authorities by UK Country (£)

	England	Wales	Scotland	NI	Total
Familiarisation	14,960	930	1,352	1,099	18,341

36. 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 £18,341, which generates an EAC of £2,131to UK enforcement. Table 9 below shows this EAC by UK country and firm size.

Table 9: Equivalent Annual Costs of Familiarisation to Local Authorities by UK Country (£)

	England	Wales	Scotland	NI	Total
EAC	1,738	108	157	128	2,131

Consultation Question 9

We invite stakeholders to comment on whether the number of hours required for familiarisation (two hours) seems reasonable. If not, please explain why and provide information and sufficiently detailed data so that we can monetise this cost more robustly.

Costs Associated with Approval (One-Off Cost)

37. 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 producing sprouts and seeds for sprouting and LAs will therefore incur a one-off cost per business that requires approval. We envisage that it will be the responsibility of an Environmental Health Officer (EHO) to carry out the inspection and that it will take the EHO three hours per business that requires approval (this includes travel time). We can then multiply the median hourly wage rate of an EHO (£21.13, see paragraph 35) by the hours required (3) 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 £1,458. Table 10 below shows the cost of approval by UK country.

Table 10: Costs of Approval to Local Authorities by UK Country (£)

	England	Wales	Scotland	NI	Total
Approval Cost	1,204	0	63	190	1,458

38. 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 £1,458, which generates an EAC of £169 to UK enforcement. Table 11 below shows this EAC by UK country and firm size.

Table 11: Equivalent Annual Costs of Approval to Local Authorities by UK Country (£)

	England	Wales	Scotland	NI	Total
EAC	140	0	7	22	169

Consultation Question 10

We invite stakeholders to comment on whether the number of hours required for an approval visit (three hours) seems reasonable. If not, please explain why and provide information and sufficiently detailed data so that we can monetise this cost more robustly. We invite stakeholders to comment and provide data on how often sprouted seed businesses start up or shut down.

Costs to Laboratories

Accreditation of Official Control Laboratories

39. Under Option 2, Official Control Laboratories designated to carry about the required testing will need to be accredited for STEC testing. Laboratories that carry out official controls testing normally have an accreditation assessment annually for all of the testing processes which they undertake. Accreditation for STEC testing would therefore be an additional element to this process. Currently the FSA does not have enough information about what extra resources in terms of time and costs that this additional element would require and we have therefore been unable to monetise the cost of accreditation of OCLs. We therefore invite stakeholders to provide information about this potential cost.

Consultation Question 11

We invite stakeholders to provide as detailed information and data as possible about this potential cost to OCLs from accreditation. In particular:

- If there is a time cost associated with accreditation; how many hours would an OCL have to set aside to get accredited, and how is that time spent?
- What additional fees are OCLs likely to incur as a result of accreditation?
- How many OCLs are likely to obtain accreditation, by UK country?

Summary of Total Costs under Option 2

40. As can be seen in Table 12 below, Option 2 generates a total cost to the UK of £22,173 (22,173, net present value). However, this total cost does not include the costs to food businesses operators (FBOs) from micro criteria testing, or the cost to Official Control Laboratories (OCLs) from accreditation. The table also does not show the 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.

Table 12: Total Costs to the UK under Option 2 (£)

	Year 0	1	2	3	4	5	6	7	8	9	Total cost	EAC	PV
FBO familiarisation	1,187	0	0	0	0	0	0	0	0	0	1,187	138	1,187
FBO approval	1,187	0	0	0	0	0	0	0	0	0	1,187	138	1,187
FBO micro criteria	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
LA familiarisation	18,341	0	0	0	0	0	0	0	0	0	18,341	2,131	18,341
LA approval	1,458	0	0	0	0	0	0	0	0	0	1,458	169	1,458
OCL accreditation	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
Total costs	**22,173**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**22,173**	**2,576**	**22,173**

Risks and Assumptions

41. 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

42. As mentioned previously in this impact assessment, the new EU requirements (approval of primary producers, micro criteria requirements, import control and traceability) contained in the legislation should not have any wider impacts. The microbiological criteria requirements set a precedent for STEC criteria which may lead to an increased appetite for setting criteria for other commodities. This is also the first time that the EU has set specific controls of this nature for primary products and for products of non-animal origin.

Summary and preferred option with description of implementation plan

43. Option 2 is the preferred option. The UK has influenced the negotiations and will implement the Commission Regulations for approval, import control, microbiological criteria and traceability for producers of sprouts. The EU Regulations applied from 1 July 2013[4] and provisions for their enforcement in England are contained in the draft SI. The UK has issued interim measures (based on good audit practices by the FBO) to allow continuing import trade from 3rd countries while work is still on-going to ensure full compliance with import certification requirements.

Specific Impact Tests

Competition Assessment

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

Small Firms Impact Test

45. For the moment we do not have information about the employment size of all firms affected by this package of regulations 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.
46. We are sending this IA to all of the relevant 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.
47. 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.

Consultation Question 12

We invite stakeholders to comment on how micro, small and medium firms are likely to be affected by this proposal, and whether the impact on those types of businesses is different from the impact on larger firms.

Sustainable development

48. 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

49. No impact on race equality is anticipated.

Gender equality issues

50. No impact on gender is anticipated.

Disability equality issues

[4] Regulation (EU) No 211/2013 came into effect on 1 April 2013 with a transitional period until 1 July 2013 when it applied.

49. 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.