

EXPLANATORY MEMORANDUM TO
The Food Safety, Food Hygiene and Official Controls (Sprouting Seeds)
(Wales) Regulations 2013

This Explanatory Memorandum has been prepared by the Food Standards Agency (FSA) and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Member's Declaration

In my view the Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Wales) Regulations 2013. I am satisfied that the benefits outweigh any costs.

Mark Drakeford AM

Minister for Health and Social Services, one of the Welsh Ministers

27 November 2013

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

1. Description

The Food Safety, Food Hygiene and Official Controls (Sprouting Seeds) (Wales) Regulations 2013 will provide for the enforcement in Wales of Commission Regulations 208/2013, 209/2013, 210/2013 and 211/2013, which establish measures for control for the safe supply of sprouted seeds and seeds for sprouting.

2. Matters of Special Interest to the Constitutional and Legislative Affairs Committee

None

3. Legislative Background

The Regulations are made in exercise of the powers conferred on the Welsh Ministers by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972. For the purposes of that section:

- (a) the National Assembly for Wales was designated in relation to measures relating to food (including drink) including the primary production of food by the European Communities (Designation)(No.2) Order 2005 (functions of the National Assembly for Wales were transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006); and
- (b) the Welsh Ministers were designated in relation to the veterinary and phytosanitary fields for the protection of public health by the European Communities (Designation)(No.2) Order 2008.

This instrument is subject to the negative procedure.

4. Purpose and Intended Effect of the Legislation

The objective of the Regulations is to ensure public health protection through the introduction of specific hygiene controls for 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.

5. Consultation

A six-week consultation was held from 2 September 2013 to 14 October 2013. The FSA in Wales received no responses to this consultation.

Similar consultation exercises were carried out in England, Scotland and Northern Ireland.

Comments were received from food businesses (micro-large) in England expressing concerns about the micro criteria requirements in the EU Regulations and the requirement for businesses to carry out tests both on the seeds intended for sprouting and on the seeds once sprouted. Concerns raised were about the costs to the business of the time it would take to sample the seeds and sprouts, the cost of the seeds used, the destroying of seeds, cost of transporting the sample to a laboratory and the cost incurred of analysis of samples by an accredited laboratory. Responses also indicated that the familiarisation and approval estimates were too low and should be revised.

Feedback from industry and enforcement authorities indicated that some of the larger businesses already had well-established sampling and testing regimes in place and therefore could demonstrate compliance with the new microbiological criteria. However, as part of the consultation, the FSA received limited information on the associated costs (number of hours required for testing, the number of samples and the cost of sampling) of the new requirement to test for the presence of a particular group of toxin-producing *E Coli* bacteria (known as STEC) that includes the type responsible for the 2011 outbreak in Germany, which evidence suggested was caused by sprouted seeds.

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

FSA in Scotland received two responses – one from a Scottish local authority and the other from a Scottish public analyst. The local authority that commented was responsible for the approval process for a Scottish establishment producing sprouted seeds. Their comments included estimates of costs of approval of the premises and the estimated costs of familiarisation with the legislation. The local authority also

included estimates of costs to the business. The Public Analyst’s comments were on the costs of becoming an accredited laboratory and of carrying out the validation method and work.

No responses were received in Northern Ireland.

While none of the responses across the UK required that the Regulations were altered, the final impact assessment below reflects those comments made on the cost assumptions in the consultation draft.

6. Regulatory Impact Assessment

Sectors 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 Commission Regulations. Engagement with industry indicated that there are 23 food businesses affected by the proposal. These were included in the list of interested parties as part of the 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. None of these businesses is located in Wales.

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

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. No labs in Wales are affected.

Table 2: Number of Official control laboratories affected

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

Local Authorities

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

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.

Costs

Costs to Industry

Familiarisation Costs (One-Off Cost)

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 £25.78¹) 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.

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

¹ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-280149>. Median hourly wage rate of a 'production managers and directors' was used, £19.83, plus 30% overheads, totalling £25.78.

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

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 £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)

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.

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

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

the sum of the discount factors across the time period over which the policy is appraised. The equivalent is follows:

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.

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

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)

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.

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)

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)

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

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.

Out of the two businesses that provided us with costs, one business responded that the time required for testing would be 210 hours per annum; that 150 samples would have to be tested at a cost of £180 per sample (i.e. a total per annum cost of £27,000). In addition they would incur unknown costs for the transportation of samples to an accredited laboratory, as well as unknown costs associated with the destroying of the seeds used for the STEC testing.

The second business that provided us with costs associated with the micro-criteria responded that they would need to spend 48 hours for sampling the seeds that needed to be tested. In addition they would incur total annual costs of £106,000 for the STEC testing (based on a cost of testing for STEC of £200 per sample), as well as transport costs of approximately £1,000 per annum for transporting the samples to an accredited laboratory. This business also suggested that it would incur costs associated with the destroying of the seeds used for testing, but did not specify how much this cost would be.

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 1293 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 £66,500⁴ per annum to get the samples tested by the laboratory.

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 £3,328⁵. Summing up over all costs results in a total cost per business and per annum for the micro-criteria testing of £70,828⁶. Multiplying this with the total number of firms generates a total cost to industry of £1,629,044⁷. 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.

3 $(210+48)/2=129$

4 $(27k+106k)/2=66,500$

5 $25.8*129=3,328$

6 $3,328+1,000+66,500=70,828$

7 $70,828*23=1,629,049$

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)

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 £21.13⁸) or a Trading Standards Officer (TSO, wage rate of £18.55⁹) 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.

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 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.

⁸ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-280149>. Median hourly wage rate of a 'health and safety officers' was used, £16.25, plus 30% overheads, totalling £21.13.

⁹ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-280149>. Median hourly wage rate of a 'Inspectors of standards and regulations' was used, £14.27, plus 30% overheads, totalling £18.55.

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

- a. 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)

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.

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

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)

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.

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.

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 (£13¹⁰) 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

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 Cos	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

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.

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

¹⁰ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-280149>. Median hourly wage rate of a 'laboratory technician' was used, £10.01, plus 30% overheads, totalling £13.

different severities and death. The HSE has produced such estimates¹¹. 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

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 England¹² 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.

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

As can be seen in Table 15, 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 £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.

¹¹ <http://www.food.gov.uk/multimedia/pdfs/euhygiene2004riafull.pdf>

¹² http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733816528

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

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

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.