

EXECUTIVE NOTE

THE OFFICIAL FEED AND FOOD CONTROLS (SCOTLAND) REGULATIONS 2009 (SSI 2009/446)

This instrument revokes and replaces the Official Feed and Food Controls (Scotland) Regulations 2007 (SSI 2007 No. 522). It also revokes the Food (Chilli, Chilli Products, Curcuma and Palm Oil) (Emergency Control) (Scotland) Regulations 2005 and the Official Feed and Food Controls (Scotland) Amendment Regulations 2008 (which amended SSI 2007 No. 522). The instrument gives effect in Scotland, to those elements of Regulation 882/2004 and Regulation 669/2009 for which a domestic legal basis is needed. The instrument is subject to negative resolution procedure, and does not amend primary legislation.

Policy objectives

The instrument will revoke and remake with changes the Official Feed and Food Controls (Scotland) Regulations 2007 (SSI No. 522). The new elements of the instrument provide for the execution and enforcement of new rules on official controls of high-risk feed and food of non-POAO imported from third countries.

Background

This instrument provides for the execution and enforcement, in Scotland of the feed and food elements of Regulation (EC) No. 882/2004 on official feed and food, animal health and animal welfare controls (“Regulation 882/2004”) and Regulation (EC) No.669/2009 implementing Regulation (EC) No. 882/2004 of the European Parliament and of the council as regards the increased level of official controls on imports of certain feed of non- animal origin and amending Decision 2006/504 (“Regulation 669/2009”). It designates the competent authorities and creates relevant offences and penalties. In particular, it provides for the execution and enforcement of new rules on official controls of high-risk feed and food of non-animal origin (non-POAO) from third countries, which are imported into the Community. Regulation 882/2004 aims to ensure consistency and effectiveness of official controls performed to ensure the verification of compliance with feed and food legislation (as well as animal health and welfare), across the EU. Therefore, it aims to provide a greater degree of food safety and consumer protection. In line with the provisions of Article 15(5) of Regulation 882/2004, the Commission has developed EU-harmonised rules for import controls on “high risk” feed and food of non-animal origin. These rules will be applied by means of Regulation 669/2009, which will apply from 25 January 2010.

Consultation

An 8 week consultation was issued to interested parties on the 14 September 2009. This was issued on the basis that in 2007 the Commission Working Document setting out implementing rules was subject to a full 12 week public consultation. The consultees included Local Authorities and businesses. The deadline for responses was the 6 November. We received no responses.

Regulatory Impact Assessment (RIA)

A Regulatory Impact Assessment has been prepared to accompany these Regulations and mainly relates to the new provisions for import controls on “high-risk” non- POAO. There are currently no designated points of entry in Scotland and costs to Scottish Business and Local Authorities are therefore considered negligible. However, as part of the consultation process businesses and Local Authorities in Scotland were invited to comment on any costs which they may have incurred. There were no comments received from Scottish importers or businesses trading the in identified high risk non POAO as to the likely impact on their business.

Food Standards Agency Scotland

December 2009

Summary: Intervention & Options

Department /Agency: Food Standards Agency	Title: Regulatory Impact Assessment of THE OFFICIAL FEED AND FOOD CONTROLS (SCOTLAND) REGULATIONS 2009	
Stage: Final	Version: 2	Date: 16 December 2009
Related Publications: Regulation (EC) 882/2004 on official controls at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:165:0001:01:EN:PDF and annex 1 of Reg 669/2009 at http://eur-		

Available to view or download at:

<http://www.food.gov.uk/consultations/>

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

Certain imported food and feed of non-animal origin represent a known or emerging risk to animal and human health, which consumers are usually unable to observe. Government intervention is necessary to address this unobservable risk to health. In particular, the introduction of European Commission measures in Regulation (EC) 669/2009, made under Regulation (EC) 882/2004 to increase the levels of risk-based official controls on these products means that domestic legislation must be made to protect consumer health.

What are the policy objectives and the intended effects?

The policy objectives are to:

- increase consumer protection through increased levels of risk-based Official Controls on imported products of non-animal origin
- ensure that appropriate legal measures, in line with EU legislation, are put in place for feed and food law enforcement authorities in Scotland

What policy options have been considered? Please justify any preferred option.

1. Do nothing. This would retain the status quo in the UK in terms of the import control arrangements for products of non-animal origin, including the current financing arrangements for such controls.
2. Implement the detailed rules set out in Regulation (EC) 669/2009 made under Regulation (EC) 882/2004.

Option 2 is preferred. This option will ensure that the UK is compliant with EC legislation and will ensure an increased level of protection for consumers.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

2013 - envisaged to be part of EU proposed review

Ministerial/CEO Sign-off For consultation stage Impact Assessments:

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 Minister/Chief Executive*:

..... Date:

* for Regulatory Impact Assessments undertaken by non-ministerial departments/agencies and NOT

1. Reason for intervention

1.1 Certain imported food and feed of non-animal origin (non- POAO) represent a known or emerging risk to animal and human health which consumers are usually unable to observe. Food businesses are unable to credibly inform consumers how far food safety risks have been minimised. This implies a need for government intervention to address this information asymmetry and the unobservable risk to health. In particular, the introduction of European Commission measures to increase the levels of risk-based Official Controls on these products on arrival at Designated Points of Entry into the UK are required to protect consumer health.

2. Intended effect

2.1 The principal purpose of introducing this SSI and replacing SSI 2008/218 is to apply better enforcement of the rules set out in Regulation (EC) 882/2004 and therefore increase consumer protection against risks associated with non-POAO. This will be achieved by giving effect to the provisions in Regulation (EC) 669/2009 implementing Regulation (EC) 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504 EC. This applies from 25 January 2010.

3. Background

3.1 The Scottish Statutory Instrument (SSI) which is the subject of this Regulatory Impact Assessment (RIA) replaces the Official Feed and Food Controls (Scotland) Amendment Regulations 2008 which in turn replaced the Official Feed and Food Controls (Scotland) Regulations 2007 and the Official Feed and Food Controls (Scotland) Regulations 2005. This RIA, therefore, focuses only on those measures that are being introduced for the first time in the 2009 Regulations.

Regulation (EC) 882/2004 on official controls

3.2 Regulation 882/2004 sets out requirements for the authorities in EU Member States that have responsibility for monitoring and verifying compliance with, and enforcement of, feed and food law (and animal health and animal welfare rules), i.e. the 'competent authorities' responsible for organising and undertaking 'official controls'. These include requirements for official controls of non-POAO feed and food from third countries that is imported into the Community. These are set out at Articles 15 to 25. For products which represent a known or emerging risk ('high-risk'), a framework is established under which importers will be required to pre-notify the relevant authorities of the arrival of such consignments and will have to present these products at specific points that have been designated specially to carry out the necessary controls. Article 15(5) of the Regulation empowers the Commission to establish the list of these 'high-risk' products and to detail the frequency and nature of the controls that must take place. It also allows for the possibility of establishing a system of fees for these controls. Implementation of this framework will bring arrangements for 'high-risk' non-POAO more into line with those for products of animal origin (POAO).

3.3 A risk assessment for Regulation 882/2004 as a whole was included in the associated regulatory impact assessment.¹ This concluded that the new arrangements would contribute towards a reduction in food-borne disease, a reduction in contamination incidents and to increased consumer protection, and to a reduction in the costs associated with these. It would also lead, in turn, to increased consumer confidence in food produced within the Community and in imported food. With regard to the provisions on imports of non-POAO, by filling a gap in the current EU harmonised legislation, it was considered that these

¹ The RIA developed during negotiations of the EU Regulation is available at: www.food.gov.uk/multimedia/pdfs/offcriaapr04.pdf

would help to improve public health protection by ensuring better targeting of controls and more effective management of risks.

Commission Regulation (EC) No 669/2009 on an increased level of controls on imports of certain feed and food of non-animal origin

3.4 The European Commission has now developed rules to implement the provisions of Article 15(5) of Regulation 882/2004. These rules will be applied by means of Commission Regulation (EC) 669/2009 which is directly applicable in the Member States (i.e. its provisions are in themselves the law in Member States). Regulation 669/2009 was published in the Official Journal of the European Union on 25 July and will enter into force on 25 January 2010.

The Regulation is available at:

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:194:0011:0021:EN:PDF>

The Regulation introduces new obligations for both feed and food business operators and the competent authorities in Member States. The main elements are:

- **List of 'high-risk' products** – Annex I of the Regulation lists the 'high-risk' non-POAO that will be subject to an increased level of import controls. It also specifies the frequency and nature of the checks that must be carried out. The list will be compiled with regard to sources of information including on RASFF notifications, reports and information received from third countries and scientific assessments. The list will be reviewed on a quarterly basis.
- **Standard documentation for prior notification** – Feed and food business operators responsible for importing products listed in Annex I will be required to pre-notify the enforcement ('competent') authorities of the arrival of by means of standard documentation using a Common Entry Document (CED). This will bring procedures into line with those for POAO imports for which a Common Veterinary Entry Document (CVED) is used.
- **Designated points at which controls should be undertaken** – It a requirement that 'high-risk' non-POAO must be imported via points of entry designated by Member States. These designated points must meet minimum requirements as regards facilities and equipment for unloading and storing consignments and for the competent authority carrying out the controls.
- **Controls at designated points of entry** – The appropriate documentary, identity and physical checks may be carried out at the designated point of entry before release into free circulation.
- **Fees** – The Regulation includes mandatory fees for official controls of 'high-risk' non-POAO. The relevant competent authority may recover up to full costs of the checks carried out from the feed or food business operator. Again, this is in line with the system of fees for POAO imports.

The draft Official Feed and Food Controls (Scotland) Regulations 2009

3.5 The SSI gives effect in Scotland to those elements of both EU Regulation 882/2004 and EC Regulation 669/2009 for which a domestic legal basis is needed. The provisions of the SSI will enable the competent authorities to meet their obligations under these Regulations with respect to the organisation and enforcement of new rules on checks (official controls) and set out the obligation for feed and food businesses under the new legislation. An explanation of the provisions of the 2009 Regulations is outlined in the consultation letter.

3.6 The SSI revokes and replaces the Official Feed and Food Controls (Scotland) Amendment Regulations 2008 (SSI 2008/218) which, in turn, revoked and replaced the Official Feed and Food Controls (Scotland) Regulations 2007 (SSI 2007/522) which, in turn, revoked and replaced the Official Feed and Food Controls (Scotland) Regulations 2005 (SSI 2005/616). These previous SSIs gave effect, in Scotland, to aspects of the feed and food elements of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules (Official Journal L191, 28.5.2004, 1-52) that applied from 1 January 2007 and from 1 January 2006 respectively.

3.7 The Regulations apply to Scotland only. England, Wales and Northern Ireland are making separate but parallel legislation.

Options

4.1 Two options have been considered.

- **Option 1** - Do nothing. This would retain the status quo in the UK in terms of the import control arrangements for non-POAO,
- **Option 2** – Introduce the Official Feed and Food Controls (Scotland) Regulations 2009 to give effect in Scotland to the increased level of official controls on imports of certain feed and food of non-animal origin set out in Commission Regulation (EC) 669/2009 which was made under the power provided in Regulation (EC) 882/2004.

Costs and benefits of options

Sectors and groups affected

Competent authorities

5.1 The draft Regulation is concerned with the role of the enforcement (competent) authorities responsible for organising and undertaking official feed and food controls on non-POAO imported from outside the Community. In the UK, this responsibility is held centrally but, in practice, day to day responsibility for the official control function is divided between central and local Government. In Great Britain, feed and food law enforcement services of local and port health authorities undertake such controls. In Northern Ireland, district councils are responsible for import controls of non-POAO food whilst the Department of Agriculture and Rural Development has responsibility as regards non-POAO feed.

Feed and food businesses

5.2 There are approximately 140,000 feed businesses in the UK. This includes importers as well as producers of feed materials, manufacturers of additives and premixtures, manufacturers of compound feedingstuffs, distributors, retailers and farms. With regard to food, there are approximately 600,000 establishments which again includes importers but also slaughterhouses, cutting plants, manufacturers, processors, packers, distributors and wholesalers, retailers, and restaurants and caterers. As regards these specific proposals it is estimated that approximately 600 importers may be directly affected (this is based on the number of businesses that imported feed and food from outside the Community during 2006 that was subject to emergency safeguard measures under Regulation 178/2002²).

Consumers

5.3 The measures proposed in the draft Regulations will contribute towards the overall expected benefits of the application of Regulation (EC) 882/2004, i.e. a reduction in food-borne disease, a reduction in contamination incidents and increased consumer protection. In addition, the costs for undertaking official controls for non-POAO that present a known or emerging risk to public or animal health that, in effect, currently fall to the taxpayer will fall in future to the feed and food industry and, potentially, the consumer of the particular food.

Analysis of costs and benefits

² Source: HM Revenue & Customs uktradeinfo website www.uktradeinfo.com

Benefits

Option 1

5.4 This option will maintain the *status quo* and will, therefore, not generate any incremental benefit.

Option 2

5.5 The UK supported the establishment of a new framework for import controls on 'high-risk' non-POAO imports during the negotiations on Regulation 882/2004 as it was considered that this would help to improve public health protection by ensuring better targeting of controls and more effective management of risks. The implementing rules will give effect to this framework.

5.6 In addition, it is anticipated that this option will contribute towards a more harmonised EC market - the introduction of mandatory fees across the Community for these controls will help to ensure some consistency with import controls for POAO towards ensuring that trade is less distorted by variations in practices between Member States. The costs of official controls carried out on non-POAO that may be included on the list of 'high-risk' products under the Commission Regulation are currently funded through general and local taxation. Under the new measures, these costs will be transferred to the feed and food industry.

5.7 This option will also be of benefit to industry in that it will introduce some transparency to the process of presenting consignments for official control through the ports. For example, in planning delivery schedules for trade, food business operators will be able to consider their obligations and the likely period required for carrying out controls on Annex I products before release for free circulation.

5.8 Table 1 below details the number of incidents recorded on the Food Standards Agency Incidents database relating to products listed in Annex I of Commission Regulation (EC) 669/2009.³ There is uncertainty over the scale and type of food-borne illness caused by imported non-POAO in the UK. It is expected that the increased level of official controls under this option will reduce the number of incidents in future years, but it is not possible to estimate by what proportion and the scale of any associated cost savings. Similarly, the number of recalls of contaminated non-POAO and associated costs are also uncertain, and therefore it is not possible to quantify the potential benefits from any reduction. However, it is acknowledged that the costs associated with large scale recalls can be significant and therefore any reduction in recalls of this nature is likely to result in substantial cost savings.⁴

Feed and food	Country of Origin	Hazard	Number of Incidents	Other Details
Groundnuts	Argentina	Aflatoxins		No incidents
Groundnuts	Brazil	Aflatoxins	1	
Trace elements	China	Cadmium and lead		No incidents
Groundnuts	Ghana	Aflatoxins	5	
Spices	India	Aflatoxins	3	
Groundnuts	India	Aflatoxins	11	
Melon seeds	Nigeria	Aflatoxins	3	
Dried fruit	Uzbekistan	Ochratoxin A		No incidents
Chilli	All third	Sudan dyes	5	

³ Table 1 identifies only those incidents where a country of origin was recorded in addition to the hazard and type of product. Therefore incidents that may have been a result of high risk non-POAO but where the country of origin was not identified at the time of recording are not included in the table. As a result the figures in the table may be an underestimate.

⁴ For example see Jaffee (2005, p. 34) on the cost of destroyed stock from the Sudan I recall in the UK in February 2005 (<http://siteresources.worldbank.org/INTRANETTRADE/Resources/Topics/Standards/IndiaSpices.pdf>)

	countries			
Groundnuts	Vietnam	Aflatoxins		No incidents
Basmati rice	Pakistan	Aflatoxins		No incidents
Mangos	Dominican Republic	Pesticide residues		No incidents
Bananas	Dominican Republic	Pesticide residues		No incidents
Vegetables	Turkey	Pesticide residues		No incidents
Pears	Turkey	Pesticide residues		No incidents
Vegetables	Thailand	Pesticide residues		No incidents
Total:			28	

Source: FSA Incidents Database

There will also be a saving to competent authorities from no longer funding the current level of testing. Under the new Regulation the costs of controls will be charged to business, which is a transfer of the costs from government to business. There will also be a reduced level of testing for Sudan dyes compared to the current situation where 100% of relevant consignments are tested⁵. Data from the FSA's Imported Food Survey indicates that around 2% of non-POAO imports were subject to physical checks at port in 2007/08. Therefore to estimate these savings, 2% of the total number of consignments for most products, and 100% for those tested for Sudan dyes, are multiplied by the cost of official controls (calculated in the same way as the costs, which is explained in detail in the section below) and the results are shown in table 2 below.

Table 2. Summary of Quantified Annual Benefits			
Costs / Hazards / Products	Upper Bound	Lower Bound	Best Estimate
Savings to Competent Authority			
Total Sample Cost (Preparation, Sampling and Analysis)			
<i>Aflatoxins</i>			
Groundnuts for food	£8,265	£7,476	£7,870
Groundnuts for feed	£9,410	£8,986	£9,198
Melon seeds and derived products	-	-	-
Spices	£10,509	£7,451	£8,980
<i>Cadmium & Lead</i>			
Trace Elements	£6,482	£4,596	£5,539
<i>Ochratoxin A</i>			
Dried vine fruit	-	-	-
<i>Pesticide Residues</i>			
Peppers, courgettes and tomatoes	£33,424	£19,713	£26,568
Mangos, yard long beans, melon bitter, lauki, peppers and aubergines	£1,923	£1,310	£1,617
Pears	-	-	-
<i>Sudan Dyes</i>			
Chilli, chilli products, curcuma and palm	£686,448	£637,060	£661,754

⁵ Article 2(3) of Commission Decision 2005/402/EC on emergency measures regarding chilli, chilli products, curcuma and palm oil. Official Journal L 135, 28.5.2005, 34–36 requires that each **consignment** is accompanied by an analytical report. This means that each consignment is subject to 100 per cent testing. Much of this may currently be carried out in the country of origin, not in the UK. Port officials are required to check the analytical report for 100% of consignments. It is assumed that the total cost of the current process is similar to the cost of the future process, and in future a smaller proportion of products will require testing. If the current process, including checks in third countries, is less costly this will overestimate the savings from the change.

oil			
TOTAL ANNUAL COST	£756,462	£686,591	£721,526

Note that the precise figures are shown in the table to enable the calculations to be replicated, but these are estimates and should be treated as indicative only. Products where 2% would be less than one consignment are omitted and a ‘-’ is displayed.

Costs

Option 1

5.9 There are no incremental costs to the do nothing option. However, doing nothing would not increase the level of consumer protection for ‘high-risk’ products as sought and would leave the UK in breach of an EU obligation to fully apply a directly applicable Commission Regulation. There is also a risk of challenge from the European Commission following inspection by its Food and Veterinary Office of UK enforcement arrangements and their compliance with the requirements of Regulation (EC) 882/2004. In view of this, the FSA considers Option 1 non-viable.

Option 2

5.10 The requirement for feed and food businesses to pre-notify the relevant authorities of the arrival of non-POAO identified as presenting a known or emerging risk will be made using a Common Entry Document (CED). Completion of the CED and complying with the resulting inspections will represent an information (administrative) obligation for industry. In addition, this new Regulation requires feed and food business operators to pay the competent authority on demand for expenses arising from the increased level of official controls provided for in Commission Regulation (EC) 669/2009. It is important to note, however, that this will apply only in cases where there is a known or emerging risk to public health i.e. for 'high-risk' products.

Table 3. Summary of Quantified Annual Costs			
Costs / Hazards / Products	Upper Bound	Lower Bound	Best Estimate
Costs to Industry			
Total Sample Cost (Preparation, Sampling and Analysis)			
<u>Aflatoxins</u>			
Groundnuts for food	£98,322	£88,935	£93,628
Groundnuts for feed	£111,952	£106,898	£109,425
Melon seeds and derived products	£623	£442	£533
Spices	£263,035	£186,488	£224,761
<u>Cadmium & Lead</u>			
Trace Elements	£163,306	£115,781	£139,544
<u>Ochratoxin A</u>			
Dried vine fruit	£1,247	£884	£1,065
<u>Pesticide Residues</u>			
Peppers, courgettes and tomatoes	£785,905	£467,855	£626,880
Mangos, yard long beans, melon bitter, lauki, peppers and aubergines	£40,204	£27,383	£33,793
Pears	£638	£187	£413
<u>Sudan Dyes</u>			
Chilli, chilli products, curcuma and palm oil	£137,147	£127,279	£132,213
Container Storage Costs			
Ambient containers storage cost	£194,549	£46,286	£120,417
Refrigerated container storage cost	£2,649,243	£820,902	£1,735,073
Administrative Costs			
Completion of Part 1 of Common Entry Document (including presentation to Competent Authority)	£169,550	£169,550	£169,550
One-off familiarisation costs	£18,564	£9,282	£13,923
Total Annual Cost to Industry	£4,615,720	£2,158,870	£3,387,295
Costs to Competent Authority			
Administrative Costs			
Reporting number and size of consignments to EC	£67,820	£67,820	£67,820
Cost of updating list of designated Points of Entry	£48	£32	£40
One-off familiarisation costs	£2,359	£1,180	£1,770
Total Annual Cost to Competent Authority	£67,868	£67,852	£67,860
TOTAL ANNUAL COST	£4,683,589	£2,226,722	£3,455,156

Note that the precise figures are shown in the table to enable the calculations to be replicated, but these are estimates and should be treated as indicative only.

5.11 We would like to draw your attention to the figures stated in Table 3. The costs are based on UK figures. There are currently no designated points of entry in Scotland and costs to Scottish Business and Local Authorities are therefore considered negligible. However, as part of the consultation process businesses and Local Authorities in Scotland were invited to comment on any costs which they may have incurred. There were no comments received from any Scottish importers or businesses trading the identified high risk non POAO as to the likely impact on their business.

5.12 Specific data for imports of some products on the list of high risk products, including Basmati rice⁶, into the UK in 2008 are not available because HMRC (and UKBA) imports data do not identify them specifically, or because there were no imports recorded in that category, and so it is not possible to estimate the level of imports from the data available.

5.13 The costs associated with Option 2 that have been possible to quantify are summarised in Table 3 above. There is uncertainty regarding a number of factors that influence the cost estimates, therefore all figures are presented using ranges with an 'upper bound' indicating the maximum value a cost is estimated as likely to be, and a 'lower bound' indicating the minimum value anticipated. A best estimate of each cost is obtained by taking the mid-point of the range. Overall annual costs are estimated to fall in the range of £2.2m to £4.7m, with a best estimate of £3.5m. In addition there will be one-off familiarisation costs to competent authorities and businesses of between £10,000 and £21,000. Details of the calculations are given in paragraphs 5.14 – 5.36.

Annual Costs

Costs to competent authorities

5.14 Mandatory levels of testing for high risk non-POAO will increase the overall level of official controls for products listed in Annex I of Commission Regulation (EC) 669/2009. The cost of these official controls will, however, be charged to the relevant businesses and therefore will not represent an on-going cost increase to competent authorities.

Costs to businesses

5.15 It is estimated that businesses importing high risk non-POAO will face three on-going annual costs. The first relates to charges levied by competent authorities for official controls. The second is a result of additional storage costs at the Designated Point of Entry for consignments that are detained in order to carry out official controls. The third refers to the cost of stock that is damaged during the official control sampling process, and would therefore have to be disposed of as a result.

Charges for official controls

5.16 Charges for official controls per consignment consist of three components – additional document checks and administering charges required by the regulations, the time and logistical costs of sampling the contents of consignments, and the cost of laboratory analysis. Stakeholder consultation responses suggest that it would take competent authorities 1 hour on average per consignment to record the receipt and details of additional documents (including the CED), process data for quarterly returns, and administer accounts and invoices in relation to charging businesses for official controls. Applying an

⁶ HMRC and UKBA data differentiate rice under CN code 1006 30 as being semi milled, wholly milled, round grain, medium grain, long grain etc. but none of the sub divisions under 1006 30 identify basmati rice. This is explained in footnote (1), Part A of Annex I of Commission Regulation (EC) No 669/2009 which states that "Where only certain products under any code are required to be examined and no specific subdivision under this code exists in goods nomenclature, the code is marked "Ex" (for example Ex 2007 99 97: only products containing hazelnuts should be included)."

hourly wage for a Port Health Official (PHO), the estimated cost of additional document checks and administering official control charges is around £20.70 per consignment.⁷

5.17 Stakeholder consultation responses indicate that it would take a PHO on average a total of 45 minutes per sample to determine the correct method of sampling required and notify the appropriate laboratory, identify and examine the consignment in question, issue a detention notice, and prepare the sample paperwork. Depending on the size and nature of the consignment it is estimated that it would take on average 1 – 3 hours per consignment to conduct the physical sample. Applying a PHO hourly wage to these times results in estimated time costs of sampling in the range of £36 - £78 per sample. In addition, stakeholder consultation suggests that transporting each sample to a relevant laboratory would on average incur a cost of £20, as well as costs of consumables of £10 to £20 per sample. In total the time and logistical costs of sampling are estimated to be in the range of £66 - £118 per consignment.

5.18 Costs of laboratory analysis per sample vary depending on the nature of the hazard being tested for, and also the turnaround time of the results. The range of average analytical cost estimates obtained through stakeholder consultation are detailed in Table 4 below. No specific analytical costs were obtained in relation to testing melon seeds and derived products (aflatoxins), spices (aflatoxins), trace elements (cadmium and lead) and dried vine fruit (ochratoxin A), therefore we assign the average of the ranges of testing costs given in Table 4 to consignments of these specific products.

Product / Hazard	Lower Bound	Upper Bound
Chilli and chilli products (Sudan dyes)	£576	-
Groundnuts for food (Aflatoxins)	£400	-
Groundnuts for feed (Aflatoxins)	£1,000	-
Pesticide residues (General)	£100	£500
Pesticide Residues: Multiresidue methods based on CG-MS and LC-MS	£450	£650
Pesticide Residues: Methomyl and oxamyl	£147	£325
Pesticide Residues: Amitraz	£205	£285
Pesticide Residues: Organophosphorus	£234	£400
Average overall	£355	£485

Notes: Where a '-' is displayed, the lower bound value was used in both upper and lower bound estimates of the overall cost of analytical testing.

5.19 The number and contents of future consignments imported in to the UK are uncertain; therefore we assume that imports of high risk non-POAO in 2008 remain unchanged in future years. Based on this assumption Table 5 summarises the estimated proportion of consignments of high risk non-POAO that will be subject to official controls under Option 2. These figures are obtained by applying the proportion of consignments that are required to be tested according to Annex I of Commission Regulation (EC) 669/2009 to the total number of consignments of high risk non-POAO imported into the UK in 2008 (see Table 6 below for totals).

Hazard	Type of Imported non-POAO	Estimated Number To Be Tested
Aflatoxins	Groundnuts for food	183
	Groundnuts for feed	98
	Melon seeds and derived products	1
	Spices	422
Cadmium & Lead	Trace Elements	262
Ochratoxin A	Dried vine fruit	2

⁷ Wage rate obtained from the Annual Survey of Household Earnings 2008 (<http://www.statistics.gov.uk/statbase/product.asp?vlnk=15187>). Average hourly wage for an Environmental Health Officer (used as a proxy for a Port Health Official) is £19.62 (including 30% uplift for overheads).

Pesticide Residues	Peppers, courgettes and tomatoes	1,464
	Mangos, yard long beans, melon bitter, lauki, peppers and aubergines	51
	Pears	1
Sudan Dyes	Chilli, chilli products, curcuma and palm oil	192
Total		2,676

Source: HM Revenue & Customs

5.20 Total estimates of the additional costs of official control charges to businesses are obtained by multiplying the overall costs per consignment explained in paragraphs 5.13 – 5.16 by the estimated number of consignments to be tested in Table 5. In total it is estimated that the costs of official controls would be in the region of £1.1m - £1.6m.

5.21 A sample that returns a laboratory analysis which deems a consignment to be non-compliant with Regulation (EC) 882/2004 will incur additional official control charges relating to costs incurred by the competent authority in terms of serving notice and the associated administrative burden. Whilst it is not possible to estimate the number of non-compliant consignments in future years, it is possible to estimate an average cost per non-compliant consignment. Consultation responses indicate that it would take a PHO 3 hours and 15 minutes to carry the necessary duties per non-compliant consignment. Applying an hourly PHO wage rate results in a cost of around £67 per consignment.⁸

Other potential non-quantifiable costs

5.22 Other competent authorities such as Trading Standards Authorities (where they are designated as the feed authority) or the designated enforcement body under the Pesticides Safety Directorate in the case of monitoring pesticide residues, may potentially be involved in conducting official controls. There may be a variation in the costs incurred by the different enforcement bodies but these cannot be quantified because the expected level of involvement of other bodies is not known. It is also not clear whether it would be more or less costly for other bodies, and this is likely to vary.

5.23 Higher costs may also be incurred for providing potential out of hours clearance particularly for highly perishable commodities at weekends; but these are not quantified because the likely timing of arrival of high-risk imports is not known. Competent Authorities may have to deal with consignments from one-off importers acting independently without an agent, and also agents who only deal with an infrequent number of food consignments. In such circumstances, it is likely that these importers will not be able to generate a CED electronically and this responsibility will fall onto officers. Competent Authorities may consider charging for this additional activity. Again, these costs cannot be quantified because the likely level of consignments from one-off importers is not known.

5.24 The DPE, or in cases where any sampling for testing checks were carried out outside the DPE, the competent authority responsible will charge for the costs of official controls. Options for how fees will be charged to feed and food businesses importing products on Annex I will be determined by local/port health authorities.

Costs of storage

5.25 Whilst consignments are detained for physical checks and awaiting laboratory results, the containers remain under official control and must therefore be stored at the DPE until the laboratory results are received. Stakeholder consultation responses indicate that, depending on the size of the container, the average cost of ambient (non-refrigerated) storage per container is £11 - £22 per day for the

⁸ Wage rate obtained from the Annual Survey of Household Earnings 2008 (<http://www.statistics.gov.uk/statbase/product.asp?vlnk=15187>). Average hourly wage for an Environmental Health Officer (used as a proxy for a Port Health Official) is £19.62 (including 30% uplift for overheads).

first 12 days, and £33 - £66 per day thereafter. Containers requiring refrigeration are estimated to cost £15.70 per day in addition to the cost per ambient container. Also, residual fumigant in containers could result in significant additional delays while surplus fumigant is removed and the container vented so that safe gas concentrations are registered before workers can safely unload containers. The cost of this delay cannot be estimated as it is not known to how many containers this would apply.

5.26 Consultation responses suggest that consignments under official control are likely to be detained for an additional 10 – 15 days on average than if no controls were carried out. Applying the costs discussed in paragraph 5.20 to these time frames, the estimated average cost per container ranges from £110 - £462 for ambient storage, and £277 - £713 for refrigerated storage.

5.27 For official control sampling to be carried out businesses will need to unload, palletise and reload part or all of the contents of each container. The number of containers per consignment of non-POAO can vary, it is therefore assumed that on average each consignment consists of 1.5 – 2 containers. It is assumed that the costs associated with unloading, palletising and reloading are in the region of £100 - £200 per container. Applying this cost to the number of containers per consignment results in a cost per consignment in the range of £150 - £400.

5.28 Applying the storage and unloading costs per container detailed in paragraphs 5.24 – 5.26 to the number of consignments in Table 5 results in total estimated additional storage costs in the range of £0.05m - £0.2m for consignments requiring ambient storage (this takes into account expected savings compared to the current position for consignments being tested for Sudan dyes, which are currently detained at a rate of 100% under emergency controls), and £0.8m - £2.7m for consignments requiring refrigerated storage.⁹

Cost of damaged stock

5.29 There is uncertainty concerning the scale and value of stock that would potentially be damaged during the sampling process for official control and therefore require to be disposed of. Therefore this cost is non-quantified in this RIA.

Designated points of entry

5.30 It is not envisaged that the designation of specific ports for ‘high-risk’ non-POAO will impose additional costs on businesses. The requirement for importers to present non-POAO for mandatory checks at designated ports (with adequate examination facilities) is already established, and there is a good geographical spread of such seaports in the UK. For example 20 points of entry are currently designated for importation of certain foodstuffs where there is a risk of contamination by aflatoxins. It seems likely that the existing designated points of entry will be appropriate for those non-POAO deemed to be ‘high-risk’ and there should be no need for shippers to re-route consignments.

Administrative burden costs

Costs to businesses

5.31 The proposed Regulation will introduce a new administrative burden on businesses through the requirement to complete a CED. Consultation responses suggest that the cost per consignment of completing the CED and passing it to the competent authority is around £25. This will be a requirement for all consignments of non-POAO, not only the proportion that will be subject to official controls. The number of non-POAO consignments to be imported in to the UK in future is uncertain, therefore we assume that imports of high risk non-POAO in 2008 remain unchanged in future years, as summarised in

⁹ It is assumed that the following non-POAO products require refrigerated storage: dried vine fruit, mangos, yard long beans, melon bitter, lauki, peppers and aubergines, and fresh, chilled or frozen vegetables.

Table 6 below. Applying the cost per consignment to the number of consignments in Table 6 results in an on-going annual administrative cost to businesses of around £170,000. To estimate the impact on the Admin Burdens Baseline in 2005 prices we assume that the major component of this ongoing cost is staff time and deflate in line with wage growth over the period 2005 to 2008, as measured by the ONS Annual Survey of Hours and Earnings.¹⁰ This gives an impact on the Admin Burden Baseline of approximately £153,000.

Table 6. High Risk Non-POAO Consignments Imported into the UK in 2008		
Hazard	Type of Imported non-POAO Product	Number Imported to UK in 2008
Aflatoxins	Groundnuts for food	768
	Groundnuts for feed	413
	Melons	1
	Spices	843
Cadmium & Lead	Trace Elements	520
Ochratoxin A	Dried vine fruit	3
Pesticide Residues	Peppers, courgettes and tomatoes	3,143
	Mangos, yard long beans, melon bitter, lauki, peppers and aubergines	122
	Pears	8
Sudan Dyes	Chilli, chilli products, curcuma and palm oil	961
Total		6,782

Costs to competent authorities

5.32 The proposed Regulation will introduce two new administrative obligations on competent authorities. The first relates to the obligation to report the number and size of high risk non-POAO consignments entering the UK, the cost of which is likely to fall to Port Health Authorities (PHAs). The second refers to the time cost of updating the list of high risk non-POAO on a quarterly basis, which will fall to the Food Standards Agency. In addition there will be a one-off cost to PHAs in terms of the time required to familiarise themselves with the Official Feed and Food Controls (Scotland) Regulations 2009.

5.33 Previous stakeholder consultation responses suggest that it costs competent authorities around £10 per consignment to report the number and size of high risk non-POAO consignments arriving in the UK to the EC. The cost of reporting the number and size of consignments to the EC is therefore estimated by multiplying the number of consignments in Table 6 by £10, which equals around £68,000.

5.34 It is anticipated that it will take the FSA 30 – 45 minutes to update the list of Designated Points of Entry every quarter, or 2 – 3 hours per year. Applying a Civil Service Executive Officer hourly wage results in costs of £32 - £48 per annum.¹¹ Cost recovery may be insufficient to cover staff resource and on-going training costs due to the unpredictable nature of work (especially with regard to imported feeds). These costs are uncertain and thus difficult to quantify.

One-off Costs

5.35 In order to enforce Option 2, competent authorities (PHAs) will have to familiarise themselves with the Official Feed and Food Controls (Scotland) Regulations 2009. It is estimated that it will take one

¹⁰ Median pay for all employees in 2005 was £9.49 and in 2008 was £10.53. To adjust the ongoing administrative cost we take (9.49-10.53)/10.53 which gives 9.9%, and multiply the ongoing costs by (1-9.9%)

¹¹ Wage rate obtained from the Annual Survey of Household Earnings 2008 (<http://www.statistics.gov.uk/statbase/product.asp?vlnk=15187>). Average hourly wage for a Civil Service Executive Officer is £16.13 (including 30% uplift for overheads).

PHO 1 – 2 hours to read and understand the Regulations per PHA. At present there are 57 PHAs in the UK. Applying an hourly wage for a PHO results in familiarisation costs in the range of £1,200 - £2,400.¹² The estimated one-off setting up costs may underestimate the level of work needed to be done to establish working relationships in authorities where Port Health/ Trading Standards do not currently work together. These costs are uncertain and thus difficult to quantify.

5.36 The precise number of businesses importing high risk non-POAO at present is uncertain, therefore it is assumed that the 600 businesses described in paragraph 5.2 is representative. It is also assumed that a manager from each business will require 1 – 2 hours to read and understand the Regulations. Applying an hourly managerial wage results in familiarisation costs to businesses in the range of £9,000 - £19,000.¹³ Overall the best estimate of total familiarisation costs to businesses and competent authorities is around £16,000, which is obtained by summing the mid-points of the two ranges.

6. Consultation

Within Government

6.1 Consultation at official level with Her Majesty's Revenue and Customs has been on-going since the discussions on the Commissions proposals for a Regulation began in 2006.

Public Consultation

6.2 Following the initial discussions at EU level on the implementing rules, the Agency wrote to over 100 interested parties, including trade associations, enforcement bodies and consumer organisations, seeking initial views on the main issues. The responses from this exercise helped to inform the UK negotiating position during subsequent discussions at EU level. Enforcement stakeholders were, in general terms, very supportive of the proposals whilst industry stakeholders highlighted the need to ensure that proper risk assessments are undertaken and that consideration is given to the economic implications for the trade.

6.3 A full 12 week public consultation on a draft Commission Regulation and this RIA was undertaken between 1 March and 24 May 2007. However, it should be noted that at this time a proposed list of 'high risk' products had not been made available.

¹² Wage rate obtained from the Annual Survey of Household Earnings 2008 (<http://www.statistics.gov.uk/statbase/product.asp?vlnk=15187>). Average hourly wage for an Environmental Health Officer (used as a proxy for a Port Health Official) is £19.62 (including 30% uplift for overheads).

¹³ Wage rate obtained from the Annual Survey of Household Earnings 2008 (<http://www.statistics.gov.uk/statbase/product.asp?vlnk=15187>). Average hourly wage for a Manager in Distribution, Storage and Retail is £15.07 (including 30% uplift for overheads).

6.4 A summary of the responses on the specific issues on which views were sought is provided at www.food.gov.uk/multimedia/pdfs/consultationresponse/highriskimportresponse.pdf. Stakeholders supported using the proposed sources of information as the basis for identifying 'high-risk' products and the level of official controls, but cautioned that the mechanism to add or remove products from the list should be transparent and flexible to avoid creating barriers to trade. The majority of respondents supported use of the Common Entry Document (CED) to facilitate prior notification and for the notification to be provided before the physical arrival of consignments into the Community. Views on the application of mandatory fees varied; some stakeholders supported the adoption of a minimum fee whilst others felt that any fees should be restricted to the actual cost incurred from the controls undertaken.

6.5 The FSA has also engaged with stakeholders throughout the development of the Commission Regulation. This included publication of regular briefings and updates on the Agency's website; consultation using the Agency's Rapidly Developing Policy system (a web-based consultation tool that can be accessed from the link below), writing to interested parties seeking their views and participation in relevant meetings and seminars.
www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/

6.6 A draft version of this Regulatory Impact Assessment (RIA) was subject to public consultation from 14 September to 6 November 2009 and respondents' views were taken into account in finalising the costs and benefits. Some respondents believed that the estimates for wages were low and where data was based on previous years these have been revised by using 2009 data where available. A few respondents commented that the assumption in Table 2 that 100 per cent of relevant consignments are tested for Sudan dyes was incorrect. A footnote has been included to explain the Agency's opinion that since Commission Decision 2005/402/EC requires that each consignment is accompanied by an analytical report each consignment is subject to 100 per cent testing. An estimate was provided by a respondent on additional costs for giving effect to the provisions in Regulation (EC) 669/2009, based on chilli this has not been included in this IA because it cannot be generalised to other products and therefore cannot be used to help estimate the total impact. Other potential non-quantifiable costs were highlighted by several respondents and have been noted. Some respondents questioned the absence of estimates on imports of Basmati rice. This is because specific data is not available and has been explained in paragraph 5.11 and table 5. A summary of the responses will be published on the Agency's website at <http://www.food.gov.uk/consultations/consulteng/2009/foodfeedregs09>.

7. Enforcement sanctions and monitoring

7.1 The new provisions in the SSI relate to the recovery of charges made to businesses by the competent authorities for official controls and related activities. These do not represent penalties as such, and there are no criminal law sanctions for non-payment. Bad debts will be pursued via normal channels and businesses that fail to pay will be sued via the courts.

8. Simplification

8.1 Import controls on 'high-risk' feed and food of non-animal origin across the EC will move towards ensuring that trade is less distorted.

9. Summary and Recommendation

9.1 The proposed measures will contribute to the protection of public and animal health in relation to feed and food. They will help to deliver a more proportionate and consistent enforcement, to improve the transparency of enforcement arrangements for stakeholders, through the wider implementation of a risk-based system and reduce the level of illegal imports. In particular the proposed measures will increase consistency and effectiveness of enforcement across the Community for businesses.

9.2 The cost to feed/food businesses will be off-set by savings for the competent authorities (and indirectly to the taxpayer). Table 2 above shows a summary of estimated savings and table 3 shows a summary of estimated costs.

10. Implementation and Review

Implementation

10.1 The measures in the Commission Regulation are directly applicable. This will be given effect, in Scotland, through the SSI which is the subject of this RIA. It is intended that the measures will come into force on or before 25 January 2010.

Review

10.2 The European Commission will undertake a review of the application of Regulation (EC) 882/2004. It is envisaged that this will take place in 2013 and will cover the official controls of non-POAO imports. The UK will feed into this and will review the application measures as part of the proposed EU review.

10.3 It is a requirement under Regulation 882/2004 for each Member State to prepare a multi-annual national control plan setting out the national control structure and the work that the enforcement authorities will undertake, including import controls for 'high-risk' non-POAO, and report annually to the Commission on its implementation. These reports will also provide a more formal means of monitoring the effectiveness of the measures proposed in the draft Regulation.

Specific Impact Tests: Checklist

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Competition Assessment

In terms of the domestic market the competition effects of Option 2 depend partly on how charges for official controls are distributed among businesses importing non-POAO. If the costs of official controls are charged to only those businesses whose high risk non-POAO consignments are selected for testing, these firms will be competitively disadvantaged in the short run compared to similar businesses whose consignments of high risk non-POAO are not selected for testing. However, in the longer run this should average out across businesses because, if each consignment has an equal chance of selection, over time each business will experience approximately the same level of testing and therefore costs. This also applies to the other costs of Option 2, such as storage costs and destroyed stock.

If charges are distributed equally among businesses importing non-POAO based on the number of consignments, then this part of the proposal will affect each business proportionately and therefore not affect competition between importers of high risk non-POAO.

Internationally, Option 2 is likely to increase the cost of importing high risk non-POAO in to the UK from 'Annex I' countries, which may in turn competitively disadvantage these countries relative to other countries that export non-POAO. However, this may in turn produce an incentive for 'Annex I' countries to reduce the risks associated with their non-POAO exports in an attempt to be removed from Annex I.

Small Firms Impact Test

The costs associated with Option 2 are on a per consignment basis and will therefore be proportionate to the number of consignments imported by businesses. Assuming small businesses import fewer consignments of non-POAO than large businesses, the costs of official controls will not be disproportionate for small firms.

The Small Business Service has been involved in the development of this Regulatory Impact Assessment.

Sustainable development

Impacts under the three pillars of sustainable development (environmental, economic and social) have been considered in the preparation of this Impact Assessment. The Agency considers Option 2 is the most sustainable of the two options because it is more proportionate to the actual risks to animal and human health.

Race equality issues

The proposed Regulation does not have an impact on race equality.

Gender equality issues

The proposed Regulation does not have an impact on gender equality.

Disability equality issues

The proposed Regulation does not have an impact on disability equality.