Title:	Impact Assessment (IA)
The Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010	**IA No:** FoodSA 0018
Lead department or agency: Food Standards Agency	**Date:** 01/08/2010
Other departments or agencies:	**Stage:** Final
	Source of intervention: EU
	Type of measure: Secondary legislation
	Contact for enquiries: Joseph Nicholas, 020 7276 8462

Summary: Intervention and Options

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

1. Procedures for sampling and analysing animal feed were laid down in several Directives which date back over thirty years and had been amended on numerous occasions. They have been consolidated in a single directly applicable European Regulation. It is therefore necessary to revoke existing legislation and provide for the administration and application of the Regulation.
2. Setting maximum permitted levels for undesirable substances -- chiefly environmental contaminants -- is an important safeguard for animal and human health. These levels are reviewed by the European Food Safety Authority in the light of advances in scientific knowledge and experience of the actual presence of these contaminants in feed, and amendments made from time to time.

What are the policy objectives and the intended effects?

1. To replace existing national measures on sampling and analysis; to delete 17 harmonised methods of analysis to allow for greater flexibility by laboratories; to make changes to the Agriculture Act 1970 to bring certain definitions into line with those in the European Regulation; to lay down the qualifications for analysts and the form of the certificate on which analytical results are declared.
2. To extend the range of ingredients subject to maximum permitted levels for arsenic; to relax the levels for arsenic in certain ingredients; to reduce the levels for theobromine; to consolidate the existing entries for certain alkaloid-containing or toxic weed seeds.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

1. Do nothing. This would mean retaining existing procedures for sampling and analysis, which would unlawfully duplicate the rules in the European Regulation, and retaining the existing maximum permitted levels for certain undesirable substances, which would forego the new safeguards for animal and human health.
2. Make a Statutory Instrument to provide for the administration of European Regulation 152/2009/EC of 27 January 2009 and for the transposition of Commission Directive 2009/141/EC of 23 November 2009. This is the preferred option because it would harmonise methods of analysis with other Member States, transpose the revised levels for various undesirable substances, and be commensurate with the UK's obligations under the Treaty.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 01/2015
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	No

Ministerial Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister: Anne Milton ..... Date: 8th August 2010.....

Summary: Analysis and Evidence

Policy Option 1

Description:

Price Base Year 2009	PV Base Year n/a	Time Period Years n/a	Net Benefit (Present Value (PV)) (£m)		
			Low: n/a	**High:** n/a	**Best Estimate: £11k**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	n/a		n/a	**n/a**
High	n/a		n/a	**n/a**
Best Estimate	£11,100		n/a	**n/a**

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

1. European Regulation 152/2009 primarily consolidates existing sampling and analysis methods and procedures, and introduces only two new methods of analysis. In consequence, no new costs are expected to be incurred by feed businesses, enforcement authorities, and analytical laboratories apart from one-off reading and familiarisation costs of £10,400.

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

There may be some additional costs for both business and local authorities associated with the extended and in some cases tightened maximum permitted levels introduced by Directive 2009/141, but in the absence of data on current levels of testing to ensure compliance with the existing levels it is not possible to quantify this.

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

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

None -- see the non-monetised benefits below.

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

European Regulation 152/2009 deletes 17 harmonised Community methods of analysis. This may allow for greater flexibility in analytical work by enforcement authorities and laboratories because they may choose to avail themselves of other methods which are just as valid.

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

Feed businesses, laboratories and local authority enforcement officers will need to read and familiarise themselves with the consolidated methods and procedures for sampling and analysis. It has been assumed that it will take one hour for individual employees to familiarise themselves with Regulation 152/2009 and an additional 5 to 10 minutes of reading time for Directive 2009/141.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	**AB savings:**	**Net:**	**Policy cost savings:**	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/09/2010		
Which organisation(s) will enforce the policy?			Local authorities		
What is the annual change in enforcement cost (£m)?			n/a		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** n/a	**Non-traded:** n/a	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** n/a	**Benefits:** n/a	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro** 0	**< 20** 0	**Small** 0	**Medium** 0	**Large** 0
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	13
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	14
Small firms Small Firms Impact Test guidance	No	14
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	14
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	15

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	Consultation version of the Impact Assessment: http://www.food.gov.uk/consultations/consulteng/2010/feedregulations2010eng
2	
3	
4	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	0.0011									
Annual recurring cost	n/a									
Total annual costs	0.011									
Transition benefits	n/a									
Annual recurring benefits	n/a									
Total annual benefits	n/a									

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office Excel Worksheet

Evidence Base (for summary sheets)

1. Problem under Consideration

European Regulation 152/2009 on sampling and analysis

1.1 The methods and procedures for the sampling and analysis of animal feed were laid down in a number of Commission Directives which date back over thirty years and which had been amended and extended on numerous occasions. These Directives have been replaced by a single measure -- Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed -- which brings their provisions together into one comprehensive document. The Regulation also deletes a number of harmonised Community methods of analysis, either because they are considered to be no longer valid or because it is restrictive to specify the analytical method to be used when there is a range of satisfactory alternatives available.

Commission Directive 2009/141 amending the maximum permitted levels for certain undesirable substances

1.2 Feed materials may be susceptible to contamination by various substances. For the most part, these are naturally occurring environmental contaminants (such as arsenic, fluorine and mercury) which cannot be wholly avoided, or process contaminants which may potentially be introduced into the feed during or as a consequence of its treatment, manufacture and storage. (Examples of this latter type of contaminant are dioxins and mycotoxins such as aflatoxin B1.) At excessive levels, such substances may have health implications for animal health and/or the health of human consumers of animal products (i.e., milk, meat and eggs). To protect the feed and food chains, it is therefore necessary to set statutory maximum permitted levels (MPLs) for these substances and to review them periodically in the light of experience of their actual presence in feed, their effects on animal health and advances in scientific knowledge.

2. Rationale for Intervention

European Regulation 152/2009 on sampling and analysis

2.1 Deletion of certain harmonised Community methods of analysis will allow laboratories greater flexibility because they will in future be able to use any method which they consider suitable for the analyte in question. If the existing legislation which transposed the Directives that Regulation 152/2009 has replaced -- the Feed (Sampling and Analysis) Regulations 1999 -- was not revoked, therefore, laboratories would be required to continue using the deleted methods at potential costs to themselves, feed businesses and enforcement authorities.

2.2 The new legislation will provide for the administration in England of the European Regulation. It will also re-enact the qualifications required by analysts and lay down the form of the certificate in which analytical results are to be declared, because these provisions are contained in the national legislation which is to be revoked. Additionally, some consequential amendments to primary legislation -- the Agriculture Act 1970 -- will be necessary, firstly to bring certain of the definitions therein relating to sampling and analysis into line with those in the Regulation, and secondly to disapply those provisions of the Act which cover territory now occupied by the Regulation.

Commission Directive 2009/141 amending the maximum permitted levels for certain undesirable substances

2.3 Maximum permitted levels for undesirable substances in animal feed are laid down in the Annex to European Parliament and Council Directive 2002/32/EC of 7 May 2002 on undesirable substances in animal feed. Commission Directive 2009/141/EC of 23 November 2009 amends certain of the entries in the earlier measure by extending and in some cases tightening the range of maximum permitted levels for arsenic, theobromine and certain alkaloid-containing and toxic weed seeds. For these amended levels to be applicable in England, transposition of the Commission Directive into national law is required.

3. Policy Objective

European Regulation 152/2009 on sampling and analysis

3.1 Regulation 152/2009 primarily consolidates existing sampling and analysis methods and procedures, which are set down in a number of separate Directives. Some of these measures date back to the 1970s and have been subject to several amendments over the past three decades, which has made the legislation increasingly complex and fragmented. The Commission had therefore been under pressure from Member States to consolidate and rationalise sampling and analysis legislation.

3.2 In addition, a number of the analytical procedures set down in the Directives had been shown to be unsatisfactory in use by official feed control laboratories, and therefore needed to be either revised or withdrawn. Some methods also needed to be withdrawn either because the analyte in question was no longer subject to EU legislation or because a number of other equally validated analytical methods had become available for it.

3.3 Another measure, European Regulation 882/2004 on Official Feed and Food Controls, has also led to the adoption by official feed control laboratories of a less restrictive approach to sampling and analysis work. Laboratories are required to use harmonised EU methods, where such methods exist; where they do not, laboratories are free to use any method which is considered fit for its purpose or has been developed according to scientific protocols. The quality criteria for the acceptance of alternative methods is set down in Annex III to Regulation 882/2004. This is the so-called "criteria approach", which has been widely adopted for food analytical methodology and is now being extended to cover feed analysis as well.

3.4 The UK was one of the main protagonists for the adoption of the "criteria approach". It was in particular concerned to ensure that laboratories should be free to use the most recent and appropriate methods of analysis, and not be constrained by methods which had been adopted many years previously and no longer reflected modern analytical practice. The UK and other Member States considered that it was not sustainable to retain methods which had been shown to be analytically deficient in use or for which there were satisfactory alternatives. The UK and other Member States therefore supported the Commission's proposals to delete a number of methods of analysis.

3.5 Methods of analysis for the following 17 analytes have been removed:

- aflatoxin B1, ascorbic and dehydroascorbic acids, avoparcin, calcium, flavophospholipol, hydrocyanic acid, magnesium, monensin sodium, pepsin activity, pepsin (hydrochloric acid soluble crude protein), potassium, sodium, spiramycin, tylosin, urease activity (of products derived from soya), virginiamycin, and zinc bacitracin.

3.6 Methods of analysis for the following 32 analytes have been retained:

- amino acids other than tryptophan, amprolium, ash insoluble in hydrochloric acid, carbonates, chlorine from chlorides, constituents of animal origin, copper, crude ash, crude fibre, crude oils and fats, crude protein, diclazuril, dioxins and dioxin-like PCBs, gossypol (free and total), halofuginone, iron, lactose, lasalocid sodium, manganese, methyl benzoquate, moisture, olaquindox, robenidine, starch, sugar, phosphorus, tryptophan, urea, vitamin A, vitamin E, volatile nitrogenous bases, and zinc.

3.7 Regulation 152/2009 also introduces two new methods of analysis, one for carbadox (a veterinary substance) and one for calculating the energy value of poultry feed. It also specifies procedures for the taking of samples and the preparation of samples for analysis. However, the Commission has indicated that the current procedures for taking samples are to be subject to further discussion in a technical working group, and amendments to them are therefore likely in the near future.

3.8 Finally, the Regulation introduces a requirement that a product intended for animal feed should be considered non-compliant if the analytical result exceeds the maximum permitted level specified in Directive 2002/32 on undesirable substances once account has been taken of expanded measurement uncertainty and correction for recovery. (Measurement uncertainty and correction for recovery are two statistical techniques applied to analytical results to determine the likely true value of the result compared to the observed value.) This procedure is common in food contaminant legislation and is entirely consistent with the “beyond reasonable doubt” approach of UK national legislation, although it

cannot be applied in all cases (e.g. it is not applicable to analysis by microscopy). This approach was well supported by the UK and other Member States.

Commission Directive 2009/141 amending the maximum permitted levels for certain undesirable substances

3.9 The European Food Safety Authority (EFSA) was charged a number of years ago with responsibility for reviewing the MPLs for undesirable substances to determine whether these levels were still appropriate in the light of advances in scientific knowledge and experience of the actual presence of these undesirable substances in feed and their effects on animal and human health. This was because many of these MPLs had never been re-examined since they were first laid down in legislation many years previously. The results of the EFSA's reviews are published in a series of Opinions which are then considered by the Commission for submission to the Standing Committee on the Food Chain and Animal Health. If appropriate, the EFSA's conclusions are framed as an amending measure to Annex I of Directive 2002/32 on undesirable substances -- i.e. the list of maximum permitted levels (MPLs) laid down in the base Directive on undesirable substances. The amending measure is then subject to a debate and a vote in the Standing Committee prior to adoption.

3.10 The amendments made by Commission Directive 2009/141 are a result of the EFSA's review process, and are as follows:

- arsenic -- new limits are being introduced for feed additives, which have not hitherto been subject to MPLs for arsenic. (Feed additives -- e.g. vitamins, trace elements, binders, preservatives -- are substances added to feed to, among other things, favourably affect its characteristics, or the characteristics of animal products, or to satisfy the animals' nutritional needs.) The existing limits for various products of marine origin, such as seaweed and fishmeal, and for feedingstuffs intended for fish, are being raised (with the proviso that their content of inorganic arsenic -- the more toxic form -- must remain below a specified level);
- theobromine -- the existing, higher limit for this alkaloid substance in feed for cattle is being removed (so that the level for bovines will in future be the same as for other farmed livestock). New, lower limits will be introduced for feed for pigs and feed for dogs, rabbits and horses;
- alkaloid-containing and toxic weed seeds -- existing entries are being consolidated, bringing various different species of plants together beneath a reduced number of headings.

3.11 Theobromine is a substance similar to caffeine, and is toxic to many non-human species (e.g. dogs and horses). The alkaloids in question are naturally occurring organic compounds which can have an adverse effect on farmed livestock.

4. Description of Options

4.1 There would appear to be two options available:

- Option 1: do nothing. Existing national measures on methods and procedures for the sampling and analysis of feed would therefore be retained, as would the existing maximum permitted levels for arsenic, theobromine and certain alkaloid-containing or toxic weed seeds; or
- Option 2: make Regulations to provide for the administration of European Regulation 152/2009/EC and the transposition of Commission Directive 2009/141/EC.

Option 1: do nothing

4.2 This would mean that the 17 methods of analysis which the Regulation has deleted must continue to be used in England, which could have cost implications for laboratories because they would be unable to use other methods of analysis which are equally capable of producing valid results. In addition, the two new methods of analysis introduced by the Regulation would not be enforceable in England. Doing nothing would also require that feed businesses abide by the existing maximum permitted levels for the undesirable substances covered by Directive 2009/141, which in the case of arsenic would mean foregoing the relaxations it introduces. This could have cost implications for feed businesses, which would be unable to use ingredients from sources which breach the existing limits.

4.3 Doing nothing could also give rise to the possibility of infraction proceedings against the UK by the Commission under Article 258 of the Treaty on the Functioning of the EU. This could lead to action

against the UK in the European Court of Justice and, if the action was successful, potentially unlimited daily fines.

Option 2: provide for the administration of European Regulation 152/2009 and the transposition of Commission Directive 2009/141

4.4 This is would ensure that UK methods and procedures for sampling and analysis of feed are harmonised with those of other Member States and delete 17 previously harmonised methods of analysis, thus freeing laboratories to use any method which is considered fit for its purpose or has been developed according to scientific protocols. This option would also transpose the extended and in some cases tightened range of maximum permitted levels for arsenic, theobromine and certain alkaloid-containing and toxic weed seeds, thus providing updated safeguards for animal and human health.

4.5 Option 2 is therefore the preferred option. It is also commensurate with the UK's legal obligations under the Treaty to apply EU legislation in its territory.

5. Costs and Benefits of Each Option

Option 1 -- do nothing

5.1 There are no incremental costs and benefits associated with doing nothing, because it is the baseline against which the other option is compared.

Option 2 -- provide for the administration of European Regulation 152/2009 and the transposition of Commission Directive 2009/141

European Regulation 152/2009 on sampling and analysis

5.2 The Regulation is primarily consolidatory, and the potential benefits to be derived from consolidation are likely to be small. However, the Regulation also deletes 17 methods of analysis, which could have some benefits for feed businesses, enforcement authorities and analytical laboratories as they will then be free to use any other procedures which can be applied to the analyte in question and they consider will be equally effective. However, it has not been possible to quantify the potential benefits of this, as there is no requirement to collect data on the methods of analysis actually used by laboratories and any quantification would therefore be a matter of speculation.

5.3 Because the Regulation is primarily consolidatory, costs are likely to be limited to one-off reading and familiarisation costs for local authority trading standards officers, analytical laboratories and feed business operators. It is assumed for this purpose that familiarisation for local authority trading standards officers will occupy an hour. To quantify the familiarisation costs for them, an hourly wage rate for a trading standards officer of £20.25[2] has been applied, which has been multiplied by the 148 local authorities in England with trading standards responsibilities and the one hour reading time. This equates to a one-off familiarisation cost for local authorities in England of £2,997.

5.4 Analysts and analytical laboratories will also be required to familiarise themselves with the consolidated Regulation. It is estimated that it will take individual analysts 20 hours to familiarise themselves with the consolidated measure. A cost per laboratory has been calculated by applying an hourly wage rate for an analyst of £23.53[3], which has been multiplied by the 20 hours of reading time; this equates to a familiarisation cost per laboratory of £470.60. The familiarisation cost for the industry has been calculated by multiplying the familiarisation cost per laboratory by the number of laboratories in England, of which there are 11; this results in a one-off familiarisation cost for laboratories in England of £5,177.

[2] Wage rate obtained from The Annual Survey of Household Earnings (2009) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of 'Inspectors of factories, utilities and trading standards' (£15.58 plus 30% overheads as per SCM methodology)

[3] Wage rate obtained from The Annual Survey of Household Earnings (2009) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of 'Science and technology professionals' (£18.10 plus 30% overheads as per SCM methodology)

5.5 Feed businesses will also need to read and familiarise themselves with the consolidated methods and procedures. The number of feed businesses has been retrieved from the IDBR[4] and the number of businesses affected calculated by using the Standard Industrial Classification (SIC) codes 10.91 (businesses that manufacture prepared feeds for farm animals) and 10.92 (businesses that manufacture prepared pet foods), which gives a total of 325 firms in England. It has been assumed that it will take one hour for individual employees to familiarise themselves with the document; an hourly wage rate of £23.54[2] per employee has been applied; this equates to a cost per business of £23.54. However, this familiarisation cost will not be applicable to all businesses in the feed industry, as it has been assumed that only the larger businesses are likely to have in-house staff who will need to familiarise themselves with the content of the EC Regulation, whereas smaller businesses will outsource their sampling and analysis work and therefore will not be affected. It has therefore been assumed that approximately 117 business (between 25% and 33%) will need to read the Regulation. To quantify the familiarisation costs for businesses, the cost per business has been multiplied by the number of firms potentially affected by the Regulation, which in the UK equates to a one-off familiarisation cost for industry of £2,764[5].

5.6 Table 1 below summarises the one-off costs of familiarisation for the devolved administrations and the whole of the UK. For England, this equates to £10,400 (rounded).

Table 1: Familiarisation costs per category

	England	**Wales**	**Scotland**	**NI**	**UK**
Local Authorities	£2,998	£446	£648	£527	£4,618
Laboratory costs	£5,177	£1,412	£1,882	£941	£9,412
Business costs	£2,218	£102	£136	£307	£2,764
Total Familiarisation costs	**£10,392**	**£1,960**	**£2,667**	**£1,775**	**£16,794**
Rounded	**£10,400**	**£2,000**	**£2,700**	**£1,800**	**£16,800**

Note: Totals may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads in line with SCM methodology, which means that the wage rates reported in the text are approximate to two decimal places and when grossed may result in rounding errors.

Commission Directive 2009/141 amending the maximum permitted levels for certain undesirable substances

5.7 The extended limits relating to arsenic are likely to be of benefit to feed businesses because they increase the existing limits for this substance in products of marine origin, such as seaweed and fishmeal, and in feed for fish. This could in future allow businesses using products of marine origin, or manufacturing feed for fish, to obtain ingredients from sources which are currently excluded from the supply chain because their arsenic loading exceeds the statutory maxima. Feed businesses using materials which might potentially contain traces of certain weed seeds such as Indian mustard might also benefit from the deletion of the specific entry for this plant. However, it has not been possible to quantify the potential benefits of these changes, as data on the actual presence of these contaminants and thus the extent to which such materials or sources of supply might be excluded are not available, and any quantification would therefore be a matter of speculation.

5.8 The tightened maximum permitted levels for theobromine and certain alkaloid-containing and toxic weed seeds could impose some constraints on the sources of supply of feed materials which potentially contain or are contaminated with these substances. However, it has not been possible to quantify the potential costs of these constraints because data on the actual presence of these contaminants in feed supplies are not available and any quantification would therefore be a matter of speculation.

5.9 As with Regulation 152/2009, it has been assumed that only one-off familiarisation costs will apply for the Directive. To quantify the costs for industry of familiarisation with its content, it has been

[4] UK Business: Activity, Size and Location 2009 http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=933

[5] Assumption that between 101 (25%) and 134 (33%) of large businesses would be affected, giving a midpoint (average) of 117 businesses. This is then multiplied by a cost per business of £25.53.

assumed that interested parties will spend on average between 5 and 10 minutes reading and understanding the document[6]. Local authorities will need to read the document, and the same wage rate of £20.25[7] for a trading standards officer has been used as for Regulation 152/2009 on sampling and analysis; as before, 148 local authorities in England will need to read the document. The cost per local authority is therefore £2.53, which is derived by multiplying the average reading time by the hourly wage rate. Multiplying the cost per local authority by the number of local authorities in England results in a familiarisation cost for local authorities of £375.

5.10 Analysts and analytical laboratories will also need to read and familiarise themselves with the content of the Directive and, as for local authorities, it has been assumed that it will take between 5 and 10 minutes for them to familiarise themselves with the amended MPLs. To quantify the familiarisation costs, a cost per laboratory has been calculated by applying an hourly wage rate to an analyst of £23.53[8], which is multiplied by the average of the 5 to 10 minutes of reading time; this equates to a familiarisation cost per laboratory of £2.94. The familiarisation cost for the industry has been calculated by multiplying the familiarisation cost per laboratory by the number of laboratories in England, of which there are 11; this results in a one-off familiarisation cost for laboratories in England of £32.35.

5.11 Feed businesses will also need to read and familiarise themselves with the content of the Directive. The number of feed businesses has been retrieved from the IDBR[3] using the SIC codes 10.91 (businesses that manufacture prepared feeds for farm animals) and 10.92 (businesses that manufacture prepared pet foods), which gives a total of 325 firms in England. It has again been assumed that it will take between 5 and 10 minutes for individual employees to familiarise themselves with the document, and (as before) an hourly wage rate of £23.53 has been applied to the employee, which means that the cost per business is £2.94. However, this familiarisation cost will not be applicable to all businesses in the feed industry, as it has been assumed that only the larger businesses will have in-house staff who will need to familiarise themselves with the content of the Directive, whereas smaller businesses will outsource the work of sampling and analysing for the presence of undesirable substances and so will not be affected. It has therefore been assumed, as with Regulation 152/2009, that only the larger businesses (between 25% and 33%) will need to familiarise themselves with the content of the Directive. To quantify the familiarisation cost for businesses, the cost per business has been multiplied by the number of firms potentially affected by the Directive, which equates to a one-off familiarisation cost for industry in England of £277.

5.12 Table 2 below summarises the one-off costs of familiarisation for the devolved administrations and the whole of the UK. For England, this is £700 (rounded).

5.13 Consultees' responses to the benefit and cost calculations are summarised in section 8 below. However, it should be noted that all the substantive comments concerned the potential costs associated with European Regulation 152/2009 on sampling and analysis; no respondent made any comment on the potential costs associated with Commission Directive 2009/141, or on the potential benefits of both measures.

[6] Mid way point of 7.5 minutes taken.

[7] Wage rate obtained from The Annual Survey of Household Earnings (2009) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of 'Inspectors of factories, utilities and trading standards' (£15.58 plus 30% overheads as per SCM methodology)

[8] Wage rate obtained from The Annual Survey of Household Earnings (2009) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of 'Science and technology professionals' (£18.10 plus 30% overheads as per SCM methodology)

Table 2: Familiarisation costs per category

	England	Wales	Scotland	NI	UK
Number of local authorities	148	22	32	26	228
Familiarisation cost per LA	£3	£3	£3	£3	£3
Local Authorities	**£375**	**£56**	**£81**	**£66**	**£577**
Number of laboratories	11	3	4	2	20
Familiarisation cost per laboratory	£3	£3	£3	£3	£3
Laboratory costs	**£32**	**£9**	**£12**	**£6**	**£59**
Number of businesses affected[1]	94	4	6	13	117
Familiarisation cost per business	£3	£3	£3	£3	£3
Business costs	**£277**	**£13**	**£17**	**£38**	**£345**
Total Familiarisation costs	**£684**	**£77**	**£110**	**£110**	**£982**
Rounded	**£700**	**£100**	**£100**	**£100**	**£1,000**

Notes
[1] It is assumed that 25%-33% of businesses will be affected.
Totals may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads in line with SCM methodology, which means that the wage rates reported in the text are approximate to two decimal places and when grossed may result in rounding errors.

6. Administrative Burden and Policy Saving Calculations

European Regulation 152/2009 on sampling and analysis

6.1 It is thought that there are unlikely to be any new burdens or policy savings associated with the Regulation because it is primarily a consolidatory measure.

Commission Directive 2009/141 amending the maximum permitted levels for certain undesirable substances

6.2 It is thought that the Commission Directive may have some additional administrative burdens for feed businesses and enforcement authorities because the extended and in some cases tightened maximum permitted levels may require additional testing to ensure conformity with them.

6.3 Further information about the potential administrative burdens associated with both measures was sought as part of the consultation on the draft Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010, but no comments on this issue were received.

7. Consultation

7.1 Key stakeholders were kept apprised of the content of the two EU measures while they were under discussion in the Standing Committee in Brussels, although few comments were received on either. The results of the public consultation undertaken on the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 to provide for the administration of Regulation 152/2009 and the transposition of Directive 2009/141 into law in England are summarised in the remainder of this section.

7.2 Stakeholders were asked in particular to comment on the following issues:

- whether they agreed with the assumptions used in the calculations in sections 5 and 6, and if not to provide alternatives, with supporting evidence and data;

- whether there are any new administrative burdens which may be associated with the two EU measures, and to provide appropriate supporting evidence and data;
- whether the qualifications for analysts have been correctly set out, and if not whether there are any additional or alternative qualifications which should be specified;
- whether the methods of analysis set out in Regulation 152/2009 are appropriate to the work involved;
- whether there are any harmonised methods of analysis which have been deleted from Regulation 152/2009 which should be retained in national legislation, and if so why;
- whether it is appropriate to replace the methods of taking samples laid down in the Agriculture Act 1970 with their equivalents in Regulation 152/2009, and if not why the existing methods should be retained;
- whether the consequential amendments to the Feed (Hygiene and Enforcement) Regulations and the GM Feed Regulations will achieve their intended purpose;
- to provide any further information or case studies on the benefits which will result from the adoption of the two EU measures;
- whether it is appropriate to increase the current MPLs for arsenic in products of marine origin such as seaweed and fishmeal, and in feedingstuffs for fish;
- whether it is appropriate to introduce limits for arsenic in feed additives;
- whether it is appropriate to remove the existing limit for theobromine in feed for cattle;
- whether it is appropriate to introduce new, lower limits for theobromine in feed for pigs, dogs, rabbits and horses; and
- whether it is appropriate to consolidate the existing entries for certain alkaloid-containing or toxic weed seeds, and thereby to remove specific entries for certain weed seeds.

7.3 There were eight responses to the public consultation. Three of these were either non-committal or made broad general expressions of welcome for the implementation of the two EU measures. One raised a series of questions about sampling procedures and the application and interpretation of MPLs for undesirable substances, but did not comment directly on the draft Regulations to implement the two EU measures. The remaining four responses, from four professional associations, were more substantive, commenting chiefly on the first, third and sixth of the above bullet points -- i.e., the potential cost calculations, the qualifications of analysts, and the methods of taking samples. One of these responses also commented on an issue not listed above, viz: the form of the certificate of analysis annexed as a Schedule to the draft Regulations. The detail of these responses is summarised in the remainder of this section.

7.4 Two of the substantive responses addressed the costs of familiarisation with the new measures. One of these responses suggested that the calculations in paragraph 5.3 underestimated the likely costs on the grounds that familiarisation would involve not one but two analysts, who would be of a more senior level; it was therefore suggested that the actual cost would be four times that calculated in paragraph 5.3 above. It was additionally claimed that technical staff would also require training in the new aspects of EC Regulation 152/2009, which could cost as much as for analysts to familiarise themselves with it. However, no arguments were provided to support the claims that training for technicians would cost as much as for analysts or why familiarisation would need to be undertaken at senior levels by two analysts per laboratory. In addition, the Regulation's primarily consolidatory nature means that -- apart from the two new methods of analysis it introduces -- the methods of analysis it lists should already be known to and in use by analysts. For that reason, it is not considered that familiarisation with the document should take longer, or cost more, than calculated in paragraph 5.3.

7.5 The other response to the costs of familiarisation with Regulation 152/2009 suggested that these would be similar to the costs of familiarisation, validation and accreditation claimed in response to a previous consultation by the Agency. The previous consultation concerned the carry-over of residues of coccidiostats into food for human consumption, but that involved then new analytical procedures with which laboratories should now be familiar. It is therefore considered very unlikely that the costs of familiarisation, validation and accreditation related to the then new analytical procedures covered by the previous consultation will recur for any or all the existing methods of analysis -- already known to and in use by analysts -- listed in paragraph 3.6 above.

7.6 One the four substantive responses also suggested that there could be costs associated with the adoption of the harmonised method for the analysis of carbadox of between £3,000 and £10,000 per laboratory, with the typical cost per laboratory being around £5,000. However, carbadox is a veterinary

medicine, the monitoring of the use of which and the analysis of any residues of which will fall to Defra's Animal Medicines Inspectorate. Although it is necessary to make legal provision for the analysis of carbadox, in practice such work will not be undertaken by analytical laboratories. In the Food Standards Agency's view, therefore, they will not need to familiarise themselves with the method nor seek accreditation for it.

7.7 One substantive response also claimed that there could be accreditation costs for the development of alternative methods of analysis to replace the 17 methods listed in paragraph 3.5 above which have been removed from Regulation 152/2009. However, it is not the case that the deletion of a method amounts to a prohibition on its continued use: deletion means only that the method is no longer regarded as a harmonised one. If the deleted method satisfies a provision in other legislation -- the "criteria approach" mentioned in paragraph 3.3 above, which covers acceptability criteria for methods where there is no harmonised rule and which is specifically referred to in regulation 6(2) of the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 -- then it remains available for use and would be regarded as valid even if it was no longer cutting edge. Whether to seek accreditation for the use of alternative methods to any or all of the 17 methods which have been removed from Regulation 152/2009 is therefore a matter of choice for analytical laboratories. Accordingly, the Agency considers that there are unlikely to be significant accreditation costs associated with the deletion of these methods of analysis.

7.8 Another substantive response suggested that the qualifications for analysts should be tightened by requiring them to not only have a master's diploma awarded by the Royal Society of Chemistry (as at present) but also to be a Chartered Chemist and to have their expertise attested by another analyst holding such a master's diploma rather than (as at present) merely another analyst. The Food Standards Agency has advised in response that tightening of the qualifications in such a manner might be premature: although it is recognised that there are inconsistencies between the qualifications for agricultural, food and public analysts, the Agency will be reviewing the qualifications for food analysts as part of a forthcoming consultation on the sampling and analysis of food. The inconsistency in qualifications will therefore be addressed in the light of that, although a question on the issue had been included in this consultation because it was felt important to gather the views of all parties with an interest in it before any substantive changes are actually made.

7.9 One of the four substantive responses also pointed to an inconsistency in the sampling procedures for feed and food, which can affect the analytical results derived from the sampling of bulk commodities at ports of import. The Agency is aware of the potential problems this can cause when it may not be known at the point of arrival whether an imported consignment is to be sent for food or feed use; however, as indicated at paragraph 3.7 above, it is understood that the Commission intends to review sampling methodologies in the near future.

7.10 Finally, one of the substantive responses also commented on the form of the certificate of analysis attached as a Schedule to the draft Regulations, requesting the re-insertion of a number of footnotes and reporting requirements which were present in the certificate in the Feeding Stuffs (Sampling and Analysis) Regulations 1999 but which were deleted from the simplified certificate in the draft Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010. The Food Standards Agency has carefully considered this request, but remains of the view that many of the deleted provisions were either administratively burdensome or superfluous to the key issues on which analysts are required to report. It has not therefore accepted some of these requests, although a number of small amendments to the draft certificate have been made in line with other requests. Provision will also be made for the certificate to be completed electronically, in line with another request.

8. Wider Impacts

Race Equality Issues

8.1 The Agency considers that the Regulations are unlikely to have any implications for or impact on race equality issues.

Disability Equality Issues

8.2 The Agency considers that the Regulations are unlikely to have any implications for or impact on disability equality issues.

Gender Equality Issues

8.3 The Agency considers that the Regulations are unlikely to have any implications for or impact on gender equality issues.

Competition Assessment

8.4 An accurate picture of the feed sector's economic position is not available, as detailed information on the capital formation, market share, turnover and geographical location of animal feed businesses has not been collected for some years. However, it is known from data compiled by the Office for National Statistics for the Inter-Departmental Business Register that in 2009 there were 405 premises manufacturing prepared feeds for farm animals in the UK. These figures will include firms producing pet food and feed for horses as well as feed for farmed livestock, although they exclude firms producing fish meal and oil seed cake. Using regional data on the number of employees, the premises can be categorised by size as follows:

Region	Micro	Small	Medium	Large	Total
UK	250	100	50	5	405
England	201	80	40	4	325
Wales	9	4	2	0	15
Scotland	12	5	2	0	20
Northern Ireland	28	11	6	1	45

Notes: Sizes are defined by number of employees per premises as follows: Micro -- less than 10 employees; Small -- 10-49 employees; Medium -- 50-249 employees; Large -- more than 250 employees.
Distribution of premises by employee size is available only at UK level, for individual regions the UK distribution of premises by size is applied to the total number of animal feed manufacturing premises in each region.
Source: ONS Inter-Departmental Business Register (2009) SIC codes -- 10.91 Manufacture of prepared feeds for farm animals and 10.92 Manufacture of prepared pet foods.

8.5 The Food Standards Agency's assessment is that the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 will have little direct impact on competition in the UK feed industry. It will not limit the number or range of businesses operating in the sector by imposing exclusive rights to supply products or by creating a licensing scheme for them; it will not raise the costs of feed ingredients to some suppliers relative to others or alter the costs of entering or leaving the feed market; it will not limit the ability of businesses to compete by attempting to control the prices charged, to limit the scope for innovation or to restrict the ability to advertise feed products; and it will not limit incentives to compete by exempting any businesses from general competition law or by amending existing intellectual property rights.

Small Firms Impact Test

8.6 The Food Standards Agency's assessment is that those parts of the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 which concern sampling and analysis will have little direct or indirect impact on small firms. This is because small firms are more likely to outsource their sampling and analysis work and therefore will not have to invest resources in familiarising themselves with the content of EC Regulation 152/2009.

8.7 The Food Standards Agency's assessment is that those parts of the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 which concern the amended maximum permitted levels for arsenic, theobromine and certain alkaloid-containing and toxic weed seeds may have a marginal impact on small firms. This is because the increase in the level for arsenic in some products and the consolidation of the levels for weed seeds into fewer entries may entail less testing to confirm feed products' compliance with these MPLs and thus a reduction in the costs of

both testing and disposing of non-compliant product. Proportionately, small firms are more likely than larger firms to benefit from this relaxation.

Greenhouse Gas Assessment

8.8 The Agency considers that the Regulations are unlikely to have any implications for or impact on greenhouse gas emissions.

Wider Environmental Issues

8.9 The Agency considers that the Regulations are unlikely to have any implications for or impact on wider environmental issues other than those discussed under the sustainable development heading at paragraph 8.14 below.

Health and Well-Being

8.10 The Agency considers that the Regulations are unlikely to have any implications for or impact on issues concerning health and well-being.

Human Rights

8.11 The Agency considers that the Regulations are unlikely to have any implications for or impact on human rights issues.

Justice System

8.12 The Agency considers that the Regulations are unlikely to have any implications for or impact on the justice system.

Rural Proofing

8.13 The Agency considers that the Regulations are unlikely to have any particular implications for rural areas.

Sustainable Development

8.14 Impacts under the three pillars of sustainable development (environment, economy and society) have been considered in the preparation of this Impact Assessment.

- *Environment* -- the reduction in the number of harmonised methods of analysis seems unlikely to have much impact on the environment. However, the amendments to the MPLs for certain undesirable substances could have both positive and negative impacts, albeit minor, on the environment. The impacts could be negative, because the increase in the level for arsenic in certain products and the consolidation of the entries for certain alkaloid-containing and toxic weed seeds could lead to the exploitation of a wider range of sources for the feed materials likely to contain these substances, with knock-on effects on these sources. However, the impacts could also be positive, because in the longer run fewer consignments will breach the MPLs and therefore have to be disposed of outside the feed chain, which usually entails incineration, landfill or re-despatch to the country of origin, all of which have associated negative impacts.
- *Economy* -- the reduction in the number of harmonised methods of analysis and the freedom thereby granted to laboratories to use any scientifically proven method may have positive economic impacts, because this could reduce the costs of analysis for all parties (feed businesses, laboratories and enforcement authorities). Similarly, the amendments to the MPLs for certain undesirable substances could have positive economic impacts because they could reduce the frequency and cost of testing to ensure compliance with the levels, and of the quantities of materials which have to be disposed of for non-compliance.
- *Society* -- neither the reduction in the number of harmonised methods of analysis nor the amendments to the MPLs for certain undesirable substances seems likely to have any impact on social questions relating to (for example) safety at work, the rate of crime, the population's level of skills and education, or community cohesion and the provision of community services. However, the amendments to the MPLs could have some impacts on the health of both

animals and the human consumers of animal products (milk, meat and eggs), although it is difficult to quantify these because of the absence of data on the actual incidence of the undesirable substances concerned, the number of past breaches of the maximum permitted levels and any adverse health impacts which may have been attributable to same. However, it is considered that these issues will have been taken into account by the European Food Safety Authority in drawing up its recommendation for a variation in these levels, and the risk is therefore believed to be proportionate to the intended outcome.

It is therefore considered that providing for the administration of European Regulation 152/2009 and the transposition of Directive 2009/141 is the relatively more sustainable of the two options identified in section 4 of this Impact Assessment because the positive impacts are assessed as outweighing the negative ones. It is also considered that it is more proportionate to the requirements of feed business operators, analytical laboratories and local authority trading standards departments.

Simplification

8.15 Those parts of the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 which concern sampling and analysis can be classified as a simplificatory measure because they will replace an existing regime which comprises a mixture of provisions in national legislation and other provisions which have to be located in a number of different pieces of EU legislation. Regulation 152/2009, for the administration of which the Statutory Instrument will provide, brings all these provisions together in a single, comprehensive document, which it is considered that all stakeholders -- feed businesses, enforcement authorities and analytical laboratories -- will find more user-friendly.

8.16 Those parts of the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 which concern the extended and in some cases tightened maximum permitted levels for certain undesirable substances add new entries to and thus lengthen the existing list of such levels. This may be considered counter to the spirit of simplification. Against this, however, should be set the fact that these parts of the Statutory Instrument also consolidate the existing entries for certain alkaloid-containing and toxic weed seeds, bringing various different plant species together beneath a reduced number of headings.

Enforcement

8.17 Enforcement of animal feed legislation in England is the responsibility of local authority trading standards departments. This responsibility encompasses procedures for the taking of samples to confirm the accuracy of labelling declarations for protein, fibre, and other analytical ingredients, and/or compliance with statutory upper limits for the presence of certain undesirable substances.

8.18 The Food Standards Agency provides guidance to local authorities, through the annual National Control Plan for the UK, on the number of samples to be taken and the analytes to be sampled for. However, it is not considered necessary to provide guidance to the use of the methods of analysis laid down in the Annexes to Regulation 152/2009, since these themselves set out the procedures to be followed for each of the methods of analysis concerned.

9. Summary, Preferred Option and Implementation Plan

9.1 Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed is a consolidatory measure which replaces several Commission Directives which date back over thirty years and brings their provisions together into a single, comprehensive document. It also deletes 17 harmonised methods of analysis either because they are considered to be no longer valid or because it is restrictive to specify the method of analysis to be used when there is a range of satisfactory alternatives available. As a Regulation, it is directly applicable in all EU Member States.

9.2 An important safeguard in the protection of animal and human health is the setting of maximum permitted levels for undesirable substances -- chiefly naturally occurring environmental contaminants which cannot be wholly avoided. These levels are reviewed by the European Food Safety Authority in the light of advances in scientific knowledge and experience of the actual presence of these contaminants in feed, and amendments made from time to time. Commission Directive 2009/141/EC of 23 November 2009, which is based on the latest recommendations from EFSA, extends and in some

cases tightens the range of maximum permitted levels for arsenic, theobromine and certain alkaloid-containing and toxic weed seeds.

9.3 The preferred option is to make legislation to provide for the administration of Regulation 152/2009 and to transpose the provisions of Commission Directive 2009/141. This will be achieved by the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010, which will revoke the existing national legislation which transposed the Directives the Regulation 152/2009 has replaced, make consequential amendments to primary legislation -- the Agriculture Act 1970 -- to bring certain definitions therein into line with those of the Regulation, and amend the existing entries in Schedule 5 to the Feeding Stuffs (England) Regulations 2005 (as amended) in line with the new entries for arsenic, theobromine and certain alkaloid-containing and toxic weed seeds in the Annex to Directive 2009/141.

9.4 There is no requirement in either of the two EU measures for a review to be undertaken within a fixed period of procedures for sampling and analysis or of the MPLs for the undesirable substances in question. However, procedures for sampling and analysis are revisited from time to time by the Standing Committee on the Food Chain and Animal Health, while MPLs for undesirable substances are kept under review by the European Food Safety Authority; both of these bodies will make recommendations for further amendments as considered appropriate. The Food Standards Agency would then lead for the UK in the negotiations on any proposed changes to the existing measures.

9.5 The potential costs and benefits identified in section 5 of this Impact Assessment and the additional information on potential costs and benefits in the consultation responses summarised in section 7 will be reviewed within a maximum of five years.

Annexes

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: To evaluate the practical application in England of the sampling and analysis procedures laid down in EU Regulation 152/2009.
Review objective: To formulate UK views for input to future discussions in the Standing Committee on the Food Chain and Animal Health on the appriopriateness and proportionality of these procedures.
Review approach and rationale: Feedback from analysts using the procedures laid down in the EU Regulation.
Baseline: Current methods of analysis.
Success criteria: Discussions in the Standing Committee on the Food Chain and Animal Health are influenced by the UK's views.
Monitoring information arrangements: Continuing stakeholder engagement (from formal and informal feedback and meetings with key interest groups such as analysts) will be the main tool.
Reasons for not planning a PIR: