EXECUTIVE NOTE

THE FEED (SAMPLING AND ANALYSIS AND SPECIFIED UNDESIRABLE SUBSTANCES) (SCOTLAND) REGULATIONS 2010

SSI 2010/354

The above instrument is made under powers conferred by sections 66(1), 67(5), 74A, 79(9) and 84 of the Agriculture Act 1970, section 2(2) of the European Communities Act 1972 (in so far as these Regulations cannot be made under the aforementioned powers of the Agriculture Act 1970). The instrument is subject to negative resolution procedure.

Policy Objectives

1. The Regulations will provide for the administration in Scotland of Commission Regulation (EC) No. 152/2009 of 27 January 2009, laying down the methods of sampling and analysis for the official control of animal feed ("Regulation 152/2009"). They will also transpose into law in Scotland Commission Directive 2009/141 of 23 November 2009, amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum permitted levels for arsenic, theobromine, *Datura* sp., *Ricinus communis* L., *Croton tiglium* L. and *Abrus precatorius* L. ("Directive 2009/141").

Consultation

2. The Food Standards Agency kept key stakeholders apprised of the content of both Regulation 152/2009 and Directive 2009/141 while, in draft form, they were under discussion in the Standing Committee on the Food Chain and Animal Health in Brussels. A formal public consultation on the draft Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010 ran from 22 February 2010 to 19 April 2010.

3. No responses were received to the consultation in Scotland.

Financial Effects

4. A Business and Regulatory Impact Assessment has been produced for this instrument. The likely impacts associated with Regulation 152/2009 will be limited. There will be one-off reading and familiarisation costs for local authority trading standards officers, analytical laboratories and feed business operators, although these are expected to be small because of the primarily consolidatory nature of the measure. The potential benefits are similarly likely to be small, although the deletion of some Community methods of analysis could have some benefits for feed businesses, analytical laboratories and enforcement authorities which will be free to use other procedures which they consider will be equally effective.

5. The likely impacts associated with Directive 2009/141 will similarly be limited. There will be one-off familiarisation costs for local authority trading standards officers, analytical laboratories and feed business operators. There may also be some benefits for feed businesses, particularly the increased limits for arsenic in products of marine origin and in feed for fish, which could allow feed businesses to use ingredients from sources which are currently excluded from the supply chain because their arsenic loading exceeds the current statutory maxima.

FOOD STANDARDS AGENCY SCOTLAND
1 October 2010

TRANSPOSITION TABLE

Commission Directive 2009/141 of 23 November 2009 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for arsenic, theobromine, *Datura* sp., *Ricinus communis* L., *Croton tiglium* L. and *Abrus precatorius* L. (OJ No 20, 24.11.2009, p. 20)			
Article	**Purpose**	**Implementation**	**Responsibility**
Article 1 and the Annex	To amend certain entries in Annex I to Directive 2002/32	Regulation 25	Scottish Ministers through implementing Regulations

Business and Regulatory Impact Assessment

Title of Proposal

The Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010.

Purpose and intended effect

- **Objectives**

Provide for the administration of EC Regulation 152/2009/EC of 27 January 2009 on sampling and analysis methods and procedures, by (a) replacing existing national measures which implement European Directives on methods and procedures for the sampling and analysis of feed with a single directly applicable harmonised EC Regulation; (b) deleting a number of Community methods of analysis to allow for greater flexibility in analytical work by enforcement authorities and laboratories; (c) making a number of technical changes to the Agriculture Act 1970 to bring certain definitions into line with those in the EC Regulation and (d) re-enacting, from the legislation to be revoked, the qualifications required by analysts and to lay down the form of the certificate on which analytical results are to be declared. These policy objectives are intended to ensure consistency in procedures for sampling and analysis of animal feed throughout EU Member States

Provide for the transposition of Commission Directive 2009/141/EC of 23 November 2009 which amends the list of maximum permitted levels (MPLs) laid down in the base Directive on undesirable substances. This is done by (a) extending the range of ingredients subject to maximum permitted levels for arsenic and to relax the levels of arsenic in certain ingredients; (b) reducing the current maximum permitted levels for theobromine and c) consolidating the existing entries for certain alkaloid-containing or toxic weed seeds. The policy objective is to reflect the latest advice from the European Food Safety Authority and to ensure the continued protection of animal and human health.

- **Background**

EC Regulation 152/2009 on sampling and analysis

EC 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.

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.

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.

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.

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.

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.

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 specifies procedures for the taking of samples and the preparation of samples for analysis. However, the Commission has indicated that the current procedures for the taking of samples are to be subject to further discussion in a technical working group, and amendments to them are therefore likely in the near future.

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

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. Many of these MPLs had not 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.

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.

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.

<u>Devolution</u>

The Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

- **Rationale for Government intervention**

European Regulation 152/2009 on sampling and analysis

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.

The new legislation will provide for the administration in Scotland 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

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 Scotland, transposition of the Commission Directive into national law is required.

Consultation

- **Within Government**

Officials from Scottish Government's Legal Directorate were closely involved in the drafting of the Statutory Instrument. The Chief Medical and Veterinary Officers for Scotland, and officials from the Scottish Government's Rural Affairs Directorate were kept apprised of the content of the two EU measures while they were under discussion in the Standing Committee in Brussels, and were included in the recent consultation. The Food Standards Agency consulted the Scottish Government's Better Regulation and Industry Engagement team during the preparation of the consultation and the Business and Regulatory Impact Assessment.

- **Public Consultation**

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) (Scotland) Regulations 2010 to provide for the administration of Regulation 152/2009 and the transposition of Directive 2009/141 into law in Scotland are summarised in the remainder of this section.

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.

There were no responses to the consultation in Scotland; however, consultations on parallel legislation across the UK yielded eight responses. 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.

Two of the substantive responses addressed the costs of familiarisation with the new measures. One of these responses suggested that the calculations in regarding local authorities (below) 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. 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 'Cost' section below.

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 the 'Background' section above.

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.

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 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 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) (Scotland) 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.

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.

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 above, it is understood that the Commission intends to review sampling methodologies in the near future.

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) (Scotland) Regulations 2010, and parallel legislation throughout the UK. 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.

- **Business**

Feed business and relevant trade associations were kept apprised of and invited to comment on the European measures enforced by the Regulations during the negotiating process in Brussels. They were also invited to comment on the provisions of the draft Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010 during the public consultation.

Options

Two options have been identified, the details of which have been set out below:

- 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 EC Regulation 152/2009/EC and the transposition of Commission Directive 2009/141/EC

Option 1: do nothing

This would mean that the 17 methods of analysis which the Regulation has deleted must continue to be used in Scotland, 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 Scotland. 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.

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 enforcement of European Regulation 152/2009 in national law and the transposition of Commission Directive 2009/141

This 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 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.

- **Sectors and groups affected**

Local authorities are responsible for enforcing the legislation with respect to feed safety and will be affected

Analytical laboratories carrying out sampling and analysis of animal feed will be affected

Feed businesses will be affected

- **Benefits**

Option 1 – Do nothing

The result of this option would be that the costs outlined below would not be incurred.

Option 2 – provide for the enforcement of European Regulation 152/2009 in national law and the transposition of Commission Directive 2009/141

European Regulation 152/2009 on sampling and analysis

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. 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.

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

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 is not possible to quantify the potential benefits of this as data on the extent to which such materials or sources of supply may currently be excluded are not available and would in any case be a matter of speculation. Information on potential benefits will therefore be sought as part of the public consultation on the draft Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010.

- **Costs**

Option 1 – Do nothing

The result of this option would be that the benefits outlined above would not be realised.

Option 2 – provide for the enforcement of EC Regulation 152/2009 in national law and the transposition of Commission Directive 2009/141

EC Regulation 152/2009 on sampling and analysis

As 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[1] has been applied, which has been multiplied by the 32 local authorities in Scotland with trading standards responsibilities in Scotland and the one hour reading time. This equates to a one-off familiarisation cost for local authorities in Scotland of £648.

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 to an analyst of £23.53[2], 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 Scotland, of which there are 4; this results in a one-off familiarisation cost for laboratories in Scotland of £1,882.

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 IBBR[3] and the number of businesses affected calculated by using the Standard Industrial Classification (SCI) 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 20 firms in Scotland. 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, which 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 Regulation whereas smaller businesses will outsource their sampling and analysis work and therefore will not be affected. It has therefore been assumed that between 25% and 33% of businesses 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 EC Regulation, which equates to a one-off familiarisation cost for industry in Scotland of £136.47.

Table 1 below summarises the one-off costs of familiarisation for the devolved administrations and the whole of the UK. For Scotland, this equates to £2,700 (rounded).

[1] 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 an 'Inspectors of factories, utilities and trading standards' (£20.25 including 30% overheads)

[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 an 'Science and technology professionals' (£23.53 including 30% overheads)

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

Table 1: Familiarisation costs per category

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

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

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.

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 its content, it has been assumed that anyone interested will spend on average between 5 and 10 minutes reading and understanding the document[4]. Local authorities will need to read the document and the same wage rate of £20.25[5] for a trading standards officer has been used as for Regulation 152/2009 on sampling and analysis; as before, 32 local authorities in Scotland 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 Scotland results in a familiarisation cost for local authorities of £81.

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[6], 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 Scotland, of which there are 4; this results in a one-off familiarisation cost for laboratories in Scotland of £12.

Feed businesses will also need to read and familiarise themselves with the content of the Directive.

[4] Mid way point of 7 and a half minutes taken.

[5] 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 an 'Inspectors of factories, utilities and trading standards' (£20.25 including 30% overheads)

[6] 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 an 'Science and technology professionals' (£23.53 including 30% overheads)

The number of feed businesses has been retrieved from the IBBR[3] and the number of businesses affected calculated by 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 20 firms in Scotland. It has again been assumed that it will take between 5 and 10 minutes for individual employees to familiarise themselves with the document, and an hourly wage rate of £23.53[5] 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 is therefore assumed that between 25% and 33% of businesses 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 Scotland of £17.

Table 2 below summarises the one-off costs of familiarisation for the devolved administrations and the whole of the UK. For Scotland, this equates to £100.

Table 2: Familiarisation costs per category

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

[1] It is assumed that 25%-33% of businesses will be affected

Consultees' responses to the benefit and cost calculations are summarised in the 'Consultation' section above. 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.

European Regulation 152/2009 on sampling and analysis

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

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

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.

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) (Scotland) Regulations 2010, but no comments on this issue were received.

Scottish Firms Impact Test

A consultation took place on the draft Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010 from the 22 February and 19 April 2010. A range of feed businesses likely to be affected by the Regulations were included in the consultation, and a partial Regulatory Impact Assessment was included as part of the consultation package. No responses were received to the consultation in Scotland, and the Regulations have not changed substantively in the post-consultation process.

EC Regulation 152/2009 on sampling and analysis

The Food Standards Agency's assessment is that those parts of the Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) 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.

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

The Food Standards Agency's assessment is that those parts of the Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) 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.

- **Competition Assessment**

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
Scotland	12	5	2	0	20
Wales	9	4	2	0	15
England	201	80	40	4	325
NI	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 SIC code 10.92 Manufacture of prepared pet foods.

The Food Standards Agency's assessment is that the Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) 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.

- **Test run of business forms**

The regulation will not introduce any additional forms to the businesses that will be affected by the Regulations.

Legal Aid Impact Test

The Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010 will not introduce new criminal sanctions or civil penalties; therefore, there are no legal aid implications.

Enforcement, sanctions and monitoring

Enforcement of animal feed legislation in Scotland -- which includes procedures for the sampling and analysis of feed, and the taking of samples to confirm compliance with statutory upper limits for the presence of certain undesirable substances -- is the responsibility of local authority trading standards departments.

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.

Under current legislation, the penalties for failure to comply with the requirements of the Feeding Stuffs (Scotland) Regulations 2005 (as amended) are set out in section 74A of the Agriculture Act 1970. The maximum penalty available to the courts for offences under these Regulations is a 12 month term of imprisonment and/or a fine at level 5 on the standard scale. The standard scale of fines for summary-only offences ranges from £200 at level 1 to £5,000 at level 5. No changes are being proposed to the criminal sanctions contained in existing legislation.

The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open forums, stakeholder meetings, surveys, and general enquiries from the public.

Implementation and delivery plan

The publication of the Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010 will be communicated to stakeholders through the Agency's website, FSA News, etc.

- **Post-implementation review**

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.

The potential costs and benefits identified in section 5 of this Business and Regulatory Impact Assessment and the additional information on potential costs and benefits in the consultation responses summarised in section 8 will be reviewed within a maximum of five years.

Summary and recommendation

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.

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.

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) (Scotland) 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 (Scotland) 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.

- **Summary costs and benefits table**

Option	**Total benefit per annum:** **- economic, environmental, social**	**Total cost per annum:** **- economic, environmental, social** **- policy and administrative**
1	N/A	N/A
2	Non-monetised benefits	£2,800 (one-off, reading and familiarisation costs)

Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs I am satisfied that business impact has been assessed with the support of businesses in Scotland

Signed……

Date

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