

www.food.gov.uk



**FINAL  
BUSINESS AND REGULATORY IMPACT ASSESSMENT**

**The Feed (Hygiene and Enforcement) and Animal Feed  
(Scotland) Amendment Regulations 2013**

**File No:** SHARP/FSAS  
**Date:** November 2013  
**Stage:** Final  
**Source of intervention:** EU  
**Contact for enquiries:** Karen Robertson  
**Phone No:** 01224 288362  
**Email:** [karen.robertson@foodstandards.gsi.gov.uk](mailto:karen.robertson@foodstandards.gsi.gov.uk)

## **1. Title of Proposal**

- 1.1 The Feed (Hygiene and Enforcement) and Animal Feed (Scotland) Amendment Regulations 2013.
- 1.2 The above instrument provides for the enforcement of Commission Regulation (EU) No 225/2012 of the European Parliament and of the Council amending Annex II of Regulation (EC) No 183/2005 as regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof.

## **2. Purpose and Intended Effect**

### Objectives

- 2.1 The policy objectives are set out below. These are all legal requirements, laid down in the Annex to Regulation 225/2012:
  - closer monitoring of feed business operators engaged in the production and processing of certain fats and oils for use in animal feed, through the approval rather than the registration of their establishments;
  - a requirement for businesses to maintain the physical separation of certain fats and oils intended for feed use from those intended for other uses and to label them accordingly;
  - a risk-based programme of monitoring (i.e. sampling and analysis) of certain fats and oils and finished feeds which contain them, for the potential presence of dioxins and dioxin-like polychlorinated biphenyls (PCBs); and
  - a requirement for the reporting by laboratories of results showing non-compliance with the maximum permitted levels for dioxins and dioxin-like PCBs.

### Approval

- 2.2 Hitherto, feed business operators engaged in the production and processing of fats and oils for use in animal feed have been required only to register under Regulation 183/2005 on Feed Hygiene (the Feed Hygiene Regulation). Registration requires an establishment to be placed on a list by the competent authority (in Great Britain, the designated competent authority for this purpose is the local authority, the trading standards department of which is responsible for any follow-up inspections which may be made). Approval requires the prior inspection of an establishment by the competent authority (which in Great Britain is again the trading standards department of a local authority) to ensure that it has in place the equipment and procedures necessary for the safe handling of higher-risk materials and is capable of undertaking its activities to the standards required. The Commission considers that the risks associated with certain of these fats and oils are such that establishments engaged in their production and processing should be approved rather than registered under Regulation 183/2005.

- 2.3 The approval requirement applies to businesses processing certain crude vegetable oils and their derivatives, those producing fatty acids from oleochemicals, businesses blending fats, and those manufacturing biofuels where the by-products of that manufacturing process are sent for feed use. Fat blending is defined so as to cover the mixing of crude oils, refined oils, animal fats, oils recovered from the food industry, "and/or any products derived thereof". However, businesses engaged in the manufacture and processing of oils of marine origin will be exempt from the requirement for their activities to be approved.
- 2.4 Approval of feed business establishments also requires the payment of a fee to cover the costs of an inspection by the competent authority. This requirement is set out in Article 27 of EU Regulation 882/2004 of 29 April 2004 on official controls (the Official Feed and Food Controls Regulation), and the issues to be taken into account when calculating the level of the fee payable are laid down in Annex VI of the same measure. These include the salaries of staff involved in official controls, the costs of their equipment, training and travel, and the costs of laboratory sampling and analysis.
- 2.5 When the Feed Hygiene Regulation came into force in January 2006, a flat-rate fee of £451 was set for an establishment both manufacturing certain additive and premixture products and placing them on the market. A flat-rate fee of £226 was set for an establishment placing products on the market only. Although it is acknowledged that flat-rate fees could be inequitable for some businesses, because the actual costs of approval are likely to vary from establishment to establishment depending on the risk status of their actual activities and the complexity of their procedures, flat-rate fees were set for ease and simplicity, and to avoid potentially wide disparities in the charges levelled by different local authorities.
- 2.6 The levels of the fees were arrived at on the basis of information on costs then provided by local authority interests. These are one-off payments. Another inspection would be required, and a repeat fee payable, only if the establishment were to subsequently vary its activity or to come under the control of another feed business operator (i.e. if there was a change in the nature of the business or its ownership).

### Separation and Labelling

- 2.7 Establishments engaged in the production and processing of fats and oils of vegetable origin for use in animal feed which also engage in the manufacture or processing of fats and oils for other uses, such as oleochemicals and biofuels, will be required to maintain strict physical separation between these materials at all stages of their processing and use, and to ensure that they are stored and transported in dedicated containers where possible. Where this is not possible, then the containers must be thoroughly cleaned between uses. It will also be necessary for the label (or other document) which accompanies each batch or consignment of the fats and oils covered by this requirement to clearly indicate whether they are intended for feed or non-feed uses, with the additional proviso that a batch or consignment once labelled for a non-feed use must not subsequently be redirected back into the feed chain or its label altered. This is intended to help prevent future contamination incidents and to ensure that in future there can be no accidental mixing of feed with non-feed materials. We have been unable to obtain information from industry about the costs arising from the requirement of separation and labelling.

## Testing

2.8 Feed business operators engaged in the production and processing of certain fats and oils of vegetable and marine origin for use in animal feed, and feed compounders who incorporate certain of these fats and oils in their finished feeds, will be required to undertake sampling and analysis for the presence of dioxins and dioxin-like PCBs. The prescribed volume and frequency of this sampling and analysis is risk-based, depending on the nature of the materials, with those judged to be of a higher risk (such as crude coconut oil and fish oils) subject to more testing. The requirement to test is waived for feed business operators who can demonstrate that material received by them has previously been subject to analysis and declared as compliant at an earlier stage of its production and use, in which case the material will fall to be monitored in accordance with the HACCP (Hazard Analysis and Critical Control Points) plan which all businesses are required to have in place under the Feed Hygiene Regulation.

## Reporting of Non-Compliance

2.9 Article 20 of EU Regulation 178/2002 on the general principles of food law (which includes feed law) requires feed business operators to notify the competent authorities of any breaches of feed safety requirements (for example, breaches of the maximum permitted levels for undesirable substances such as dioxins and dioxin-like PCBs) relating to products which they have supplied or have in their possession. Feed business operators will now be required to instruct laboratories undertaking analyses on their behalf to notify the competent authorities as well as themselves of any breaches identified as a result of the mandatory testing programme. This also applies where an operator in one Member State sends material for testing to a laboratory in another Member State; the laboratory must be instructed to notify non-compliant results to the competent authority of that other Member State. The intention is to improve transparency and speed of reporting throughout the feed chain.

## Background

2.10 There was a feed contamination incident in Germany in December 2010-January 2011, in which fatty acids of vegetable origin (a type of processed oil) for use in pig and poultry feed were found to have been mixed with fats derived from an industrial use which contained high levels of dioxins. The incident, which is thought to have been attributable to fraud or negligence, led to the temporary quarantine of several hundred farms in Germany and the recall of many pork and egg products, some of which had been sent to other Member States. The Commission considered that this incident exposed a need to require the formal sampling and analysis of these materials prior to use, and to strengthen the controls on establishments producing or processing fats and oils to ensure that they have the correct procedures and equipment in place for the safe handling of the materials.

## Rationale for Government Intervention

2.11 In late December 2010, notification was received via the Commission's Rapid Alert System for Food and Feed that, following routine testing in Germany the previous month, about 500 tonnes of fatty acids of vegetable origin had been found to be contaminated with dioxins and PCBs above the legally permitted maxima. Dioxins

and dioxin-like substances, such as certain polychlorinated biphenyls (PCBs), are a range of chemical compounds generated as by-products of certain industrial processes and which can remain in the environment for many years as persistent organic pollutants (POPs). They are highly toxic and possibly carcinogenic even at comparatively low concentrations, and exposure to these chemicals thus represents a significant risk to animal and human health.

- 2.12 By the time the test results were received, the contaminated fats had been sold on to 25 feed manufacturers for use in compound feed for pigs and poultry, and the resulting feed distributed to 50 farms across northern Germany. Subsequent investigation suggested that many more farms could be affected, and that small quantities of the feed had also been sent to farms in Denmark and France. At the height of the German authorities' management of the incident, 4,760 livestock farms were quarantined and the meat, milk and eggs from them were allowed into the human food chain only if they were shown through positive testing to comply with the maximum permitted levels for dioxins laid down in EU feed legislation. The number of farms restricted was subsequently greatly reduced; but these actions, and action taken to remove and dispose of non-compliant feed and food products, entailed significant costs to industry and taxpayers from testing for dioxins, disposal of contaminated products, loss of business, reputational damage, and financial assistance to affected livestock farmers and other feed industry sectors.
- 2.13 Further investigation subsequently indicated that the contamination was attributable to a batch of fatty acids sourced originally from a company in the Netherlands, which advised that these acids had been derived from the production of biofuels and were both intended and labelled for technical uses only (i.e. not for feed and food use). It therefore appeared that the contaminated fats had been diverted, either fraudulently or negligently, into the feed and food chains in Germany.
- 2.14 The German authorities came forward in late January 2011 with a ten-point "action plan" for enhanced controls over establishments processing and using fats and oils of vegetable origin and for the monitoring and reporting of levels of contaminants in these materials. The plan was presented for discussion at European level, although some parts of it were clearly addressed to internal German problems and their relevance to other Member States was questionable (for example, the plan envisaged the introduction of a positive list of feed materials permitted for use in animal feed, the physical segregation of production lines, a requirement for producers to take out liability insurance, and increased monitoring for dioxins and frequency of inspections). The Commission, the UK and several other Member States considered that some of these proposed controls were variously not proportionate to the actual risks, too costly for business to implement, or had been considered previously in other circumstances and already rejected (for example, a positive list of feed materials cannot itself guard against contamination; physical segregation of production lines could entail the expensive duplication of equipment; and the European insurance industry has already said that it views the potential risks of contamination of materials intended for use in animal feed as unlimited and therefore uninsurable).
- 2.15 The Commission's view was that discussion of any new controls on the producing and processing of fats and oils should be deferred until it had the opportunity to consider the matter and draw up a proposal of its own. A working paper outlining its suggestions was first tabled for discussion in March 2011, and subsequently went

through a number of iterations. The chief elements, which in part replicated those in the German “action plan” were as follows:

- the approval rather than the registration of establishments producing and processing fats and oils;
- requirements for the transport and storage of these fats and oils;
- requirements for 100% monitoring of these materials and the feed products which incorporated them for the presence of contaminants above the legally permitted maxima; and
- a requirement for laboratories which undertook sampling and analysis of these fats and oils to report breaches of the permitted maxima to the competent authority.

2.16 The UK supported the general thrust of the draft measure, but considered that the proposal for 100% monitoring of all fats and oils irrespective of their source or potential use (including use for non-feed purposes such as oleochemicals and biofuels) and for the testing of all compound feed which included these fats and oils would be disproportionate. Formal negotiations on the draft measure, presented as an amendment to Regulation 183/2005 of 12 January 2005 on Feed Hygiene (the Feed Hygiene Regulation), commenced in the second half of 2011 and led to some compromises on the monitoring requirements by the Commission. In particular, it agreed to drop the proposal to test fats and oils intended for non-feed uses, to waive a requirement for feed business operators to test those incoming fats and oils which could be shown to have been tested at an earlier stage in the supply chain, and to focus testing on the highest risk materials. The compromise measure was adopted by qualified majority vote at the Standing Committee on the Food Chain and Animal Health on 21 November 2011, with the UK voting in favour. The measure was subsequently adopted by the Commission and published in the Official Journal as Commission Regulation (EU) No 225/2012 of 15 March 2012. It applied in Member States from 16 September 2012.

2.17 Intervention to update EU legislation is also in accordance with the Scottish Government's National Performance Framework target and will contribute to Scotland's growth and productivity targets by reducing the regulatory burden on affected Scottish businesses. This will help to make Scotland an attractive place for doing business in Europe and contribute to realising our full economic potential.

### Devolution

2.18 The Feed (Hygiene and Enforcement) and Animal Feed (Scotland) Amendment Regulations 2013 will apply in Scotland only. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

## **3. Consultation**

### Within Government

3.1 FSA in Scotland consulted Scottish Government colleagues in the Rural and Environment and Health Directorates, Health Protection team and Agricultural Services Division on the drafting of information letters on the EU Regulations and on the consultations on the draft Instrument and Business Regulatory Impact Assessment. No adverse comments have been received.

- 3.2 The Food Standards Agency (FSA) has worked closely with the trading standards departments of local authorities to identify any feed businesses that may be affected by the requirements of EU Regulation 225/2012.
- 3.3 FSA in Scotland has also worked closely with the Better Regulation and Industry Engagement Team on the development of the Business and Regulatory Impact Assessment (BRIA) and with solicitors in Scottish Government Legal Directorate in the drafting of this Scottish Statutory Instrument (SSI).

### Public Consultation

- 3.4 The FSA consulted for 12 weeks from June to August 2013, on the draft Feed (Hygiene and Enforcement) and Animal Feed (Scotland) Amendments Regulations 2013 providing for the enforcement of EU Regulation 225/2012 as regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived.
- 3.5 During the UK consultation in June 2013, FSA in Scotland wrote to stakeholders to confirm whether there were any businesses carrying out activities requiring approval within the new Annex of EU Regulation 225/2012. During the consultation, UK trade bodies, such as Fats and Oils Association and Agricultural Industries Confederation (AIC) and Scottish Local Authorities confirmed there were no establishments in Scotland involved in activities such as the processing of crude vegetable oil or fat blending products intended for animal feed requiring further approval.

### **Fish Oil Processors in Scotland**

- 3.6 However during the June 2013 consultation, FSA in Scotland identified that there were four small to medium sized businesses processing fish oils for use in animal feed who are subject to the dioxin and dioxin like PCB testing requirements within EU Regulation 225/2012 and one business who handled and stored fish oils imported from Norway.
- 3.7 As a result FSA in Scotland carried out a face to face meeting with one Scottish small sized business (with 35-40 employees) producing approximately 42 tonnes of fish oils daily from herring, mackerel (seasonal) and salmon (all year). This business supplies the agricultural animal feed sector, the aquaculture fish feed/meal sector and the pet food sector and has subsidiary establishments in England and Ireland.
- 3.8 During our discussions with this business they explained that they were fully aware of Regulation 225/2012 and had been meeting the dioxin monitoring requirements since 2010, prior to the EU Regulation coming into force. Before the German incident in 2010, testing took place once every 6 months. Following the German incident, testing increased to monthly and also analysis of 100% of batches of fish oils became a mandatory requirement with the Feed Materials Assurance Scheme standard. The cost to this specific business in 2013 is currently £450 for every composite sample tested and an additional £55 to ship the sample to the laboratory in Germany.

## **4. Options**

4.1 At consultation, the options considered were:

**Option 1:** Do nothing.

**Option 2:** Self-Regulation by the Feed Industry.

**Option 3:** 100% Sampling and Analysis of All Fats and Oils plus Increased Fees for Approvals.

**Option 4:** 100% Sampling and Analysis of All Fats and Oils and for Approval Fees to be Retained at their Existing Levels.

**Option 5:** Risk-Based Sampling and Analysis of Certain Fats and Oils plus Increased Fees for Approvals.

**Option 6:** Risk-Based Sampling and Analysis of Certain Fats and Oils and for Approval Fees to be Retained at their Existing Levels.

4.2 Option 6 was the preferred option. Both respondents to the consultation agreed with this decision and, following consultation, this option was selected.

### **Description of Option Selected following Consultation**

4.3 Approval of establishments producing or processing certain fats and oils requires the physical inspection of them by the competent authorities, as laid down in Regulation 183/2005 on feed hygiene. These inspections are to ensure that these establishments have the appropriate equipment and procedures in place and meet the required standards. Inspections can also highlight any gaps or oversights in the supply and production chains which have the potential to compromise their integrity, and provide an opportunity for competent authorities to give advice which may prevent an operator inadvertently breaching feed law, with possible financial costs and other costs too (for example, to the reputation of the business). Approval also helps ensure the physical separation of fats and oils for feed use from those intended for non-feed use (where a business deals in both); ensures that they are labelled accordingly and that materials intended for non-feed use are not subsequently relabelled; and requires the payment of a fee to the competent authority for the inspection work undertaken. During the consultation, clarification was sought from stakeholders on whether or not there were any establishments in Scotland engaged in both these activities. FSA in Scotland received confirmation, at the face-to-face BRIA meeting with a fish oil processor, that there are no such establishments.

4.4 The terms of EU Regulation 882/2004 require that the competent authority recoup the costs of inspection and other control work from the feed business operator, which should mean that increases in costs over time should be reflected in increased fees payable by the operator. However, the fact that the levels of the fees for approvals have not been updated to take account of increased costs to competent authorities since they were set seven years ago is not in itself a justification for updating them now. In addition, leaving the levels of the fees unchanged would be consistent with the government's policy of minimising or reducing the administrative burdens on business, and also with the current economic conditions which business in general currently faces.

- 4.5 The charging of a flat-rate fee for approvals could be inequitable for some businesses, as the actual costs of approval are likely to vary greatly from establishment to establishment depending on the risk status of their actual activities and the complexity of their procedures. However, the FSA considers that the current flat-rate fees are perhaps just as good an estimate of the costs as any uprating of them might be.
- 4.6 Risk-based sampling and analysis of fats and oils of vegetable and marine origin is in line with the requirements for monitoring laid down in Regulation 225/2012. These requirements are specific to the nature of the materials concerned, with those judged to be of a higher risk (such as crude coconut oil and fish oils) subject to more testing. The Regulation also allows for the requirement to test to be waived in those cases where a business can demonstrate that consignments it has received have been subject to analysis and declared as compliant at an earlier stage of their production and processing, thus permitting a more focused allocation of time, effort and other resources.

## **Sectors and groups affected**

### Industry

- 4.7 The Interdepartmental Business Register (IDBR) 2012 contains a list of all UK VAT-registered businesses in the UK. SIC<sup>1</sup> Code 1091 contains all businesses involved in the manufacture of prepared feeds for farm animals. Last year there were 245 feed manufacturing companies operating within the UK; of these, 15 operate in Scotland, with a further 185 in England, 10 in Wales and 35 in Northern Ireland.
- 4.8 Information from the feed industry is that there are 21 firms in the UK of varying sizes operating in the fats and oils sector (importers and brokers, crushers and refiners, and feed fat blenders) but none of these are located in Scotland. The industry further estimates that the number of likely new entrants to the fats and oils sector (and therefore requiring to be approved before they can legally commence operations) is probably five or less per year. We have assumed it will take 1 hour per business for familiarisation and that an approval visit would take approximately 2 hours per business.

### Laboratories

- 4.9 Laboratories undertaking the analysis will be required to notify the competent authority of any breaches identified as a result of the mandatory testing programme. Since this potentially could be done via an email or a phone call, we envisage that these costs will be minimal.

### Enforcement

- 4.10 Feed businesses operating in the fats and oils sector will require approval. Approval requires the local authority to carry out an inspection visit to ensure that the feed business establishment has in place the appropriate equipment and procedures prior to the commencement of its operations. The cost of the inspection is recharged to the feed business operator, although enforcement authorities will incur costs from the

---

<sup>1</sup>Standard Industrial Classification codes –these are used in the UK for classifying business establishments. Further information on SIC codes can be found at <http://www.ons.gov.uk/ons/guide-method/classifications/current-standard-classifications/standard-industrial-classification/sic-2007-summary-of-structure.xls>

need to familiarise themselves with the changes in the legislation. We have assumed it will take 1 hour per competent authority for familiarisation.

## Consumers

4.11 This measure is intended to reduce the risk of dioxins and dioxin-like PCBs entering the animal feed chain. This will have health benefits for the human consumers of animal products (milk, meat and eggs), will enhance consumer confidence in the UK food chain, and potentially aid British food exporters. It may be further assumed that the requirement for risk-based testing of certain fats and oils of vegetable and marine origin will, over time, lead to the identification of the most prevalent geographical sources of dioxins and dioxin-like PCBs in these materials, and thus the eventual exclusion from the feed chain of fats and oils from those sources. This would in turn reduce the likelihood of future feed contamination incidents, because it would mean that such material did not enter the feed chain in the first place. We have been unable to monetise any benefits in terms of consumer health from the new requirements.

## **Benefits**

### **Option 1: Do Nothing**

4.12 There were no benefits associated with this option, as there would have been no change to the existing position.

### **Option 2: Self-Regulation by the Feed Industry**

4.13 As with doing nothing, there were no benefits associated with this option because it would not have required industry to undertake any more or less sampling and analysing than it does already under its existing HACCP plans and as part of its normal “due diligence” procedures to warrant that its materials and products are fit for their intended purpose.

### **Option 3: 100% Sampling and Analysis of All Fats and Oils plus Increased Fees for Approvals**

4.14 The benefits associated with this option would have accrued largely to the human consumers of animal products (meat, milk and eggs) from the assurance that the feed consumed by the animals did not contain excess levels of dioxins and dioxin-like PCBs and therefore that their produce was safe to eat, although there was also the possibility, raised earlier, that 100% testing could have led to delays in uncovering and reporting non-compliant results, with the possible consequence that contaminated product had already entered the feed supply chain. Irrespective of this, few (if any) benefits would have been derived by the feed industry, which would have had to bear the costs of monitoring for dioxins and dioxin-like PCBs at every stage of the use of certain fats and oils. Local authorities would have been reimbursed for the inspection work necessary before an establishment could be approved to undertake its activities, but the apparent benefit of the higher fee would have been cancelled out by the cost of the work involved.

### **Option 4: 100% Sampling and Analysis of All Fats and Oils and for Approval Fees to be Retained at their Existing Levels**

4.15 The benefits from this option are the same as those for option 3.

**Option 5: Risk-Based Sampling and Analysis of Certain Fats and Oils plus Increased Fees for Approvals**

4.16 The benefits associated with this option would also have accrued to the human consumers of animal products (meat, milk and eggs) from the assurance that the feed consumed by the animals did not contain excess levels of dioxins and dioxin-like PCBs and therefore that their produce was safe to eat; and to feed compounders. Feed compounders, who are the end users of certain fats and oils of vegetable and marine origin, would also have benefited from the fact that the costs of monitoring for dioxins and dioxin-like PCBs would have fallen mainly on their suppliers (i.e. the producers and processors of these fats and oils) rather than themselves. Local authorities would have been reimbursed for the inspection work necessary before an establishment could be approved to undertake its activities, but the apparent benefit of the higher fee would have been cancelled out by the cost of the work involved.

**Option 6: Risk-Based Sampling and Analysis of Certain Fats and Oils and for Approval Fees to be Retained at their Existing Levels**

4.17 The benefits to the feed industry, to national and local government authorities, and to animal and public health are difficult to monetise, although they can be weighed against the potentially very large costs which could result from a future dioxin contamination incident. There are two recent incidents which can be cited as illustrative of these potential costs, in Ireland in December 2008, and the German incident discussed in earlier paragraphs. Avoidance of such costs is of clear benefit to the industry, enforcement authorities, and the wider public.

**Costs**

**Option 1: Do Nothing**

4.18 There could have been severe costs associated with doing nothing, because it could have left open the potential for future incidents of the kind which occurred in Germany in December 2010-January 2011 or that which occurred in Ireland in December 2008. Both had serious cost impacts on the feed and food chains, and associated sectors.

4.19 The Irish incident arose from the use of contaminated oils as a source of heat to dry surplus bread products prior to their entry to the animal feed chain, and resulted in the recall of all pork and pork products produced in the four months September 2008-December 2008. According to the Irish authorities' subsequent report, the incident "cost the Irish taxpayer in excess of €100 million (£83.4m) from the financial assistance facility made available to the industry ... not to mention the cost to industry of providing contingency supplies to their customers, the costs of lost business, and the consequent damage to reputations" The Report of the Inter-Agency Review Group on the Dioxin Contamination Incident in Ireland in December 2008, Department of Agriculture, Food and the Marine, December 2009, is available online at

<http://www.agriculture.gov.ie/media/migration/publications/2010/DioxinReport211209revised190110.pdf>

4.20 The final costs of the German dioxin incident are not available, although in January 2011 the president of the German Farmers' Association (Deutscher Bauernverband), Gerd Sonnleitner, was reported as claiming that these could also amount to €100 million (£83.4m). At that point during the German authorities' management of the incident, 4,760 livestock farms had been placed under restriction and the meat, milk and eggs from them were being allowed into the human food chain only if they could be shown through positive testing to be compliant with the maximum permitted levels for dioxins laid down in EU feed legislation. The number of farms restricted was subsequently greatly reduced; but these actions, and action taken to remove and dispose of non-compliant feed and food products, would also have resulted in costs to industry and taxpayers from testing for dioxins, disposal of contaminated products, loss of business, reputational damage, and financial assistance to affected livestock farmers and other feed industry sectors.

4.21 For these reasons and the risk of costly infraction proceedings, the Do Nothing option was not supported.

### **Option 2: Self-Regulation by the Feed Industry**

4.22 Self-regulation could have had some costs for business which produce, process or use certain fats and oils of vegetable and marine origin. However, the exact costs would depend on the nature and frequency of the testing for dioxins and dioxin-like PCBs undertaken and the range of materials selected for testing. Self-regulation could have given rise to a risk that the testing did not meet the specific requirements laid down in Regulation 225/2012, and therefore that potentially contaminated consignments of fats and oils were not detected prior to their entry into the feed chain, with consequences similar to those outlined in paragraphs 4.19-4.20 above.

4.23 Nevertheless, in response to previous high-profile instances of contamination, UK feed compounders established in July 2012 their own voluntary two-year programme to monitor dioxins and dioxin-like PCBs. This programme is being run under the auspices of the Universal Feed Assurance Scheme (UFAS) operated by the Agricultural Industries Confederation (AIC) which is the main trade association which groups together merchants, millers, feed compounders, firms which transport animal feed, and associated sectors. This voluntary programme aims to take 108 samples per year (216 samples in total) from all compound feed mills subscribing to UFAS, for which AIC negotiated a bulk rate with the participating laboratory of £425 per sample. The total cost of the programme is therefore £45,900 per year, over and above the costs associated with testing under HACCP. The industry has reported that testing during the first twelve months of the programme found no non-compliances.

4.24 However, this voluntary programme applies only to the feed materials used, and the finished feeds produced, by compound feed mills, which are at the end of the chain for the use of fats and oils in feed; in consequence, it does not address all the requirements for the testing of certain fats and oils set out in Regulation 225/2012. For this reason, and also for the reasons set out in the two preceding paragraphs above, the Self-Regulation by the Feed Industry option was not supported.

### **Option 3: 100% Sampling and Analysis of All Fats and Oils plus Increased Fees for Approvals**

- 4.25 The costs associated with this option would have fallen on the producers and processors of certain fats and oils, and on the feed compounders who incorporate certain fats and oils of vegetable and marine origin in the finished feeds they produce.
- 4.26 The proposal as originally tabled by the Commission would have required 100% sampling and analysis of all fats and oils of vegetable and marine origin at every stage of their use, both incoming and outgoing, wherever sourced and whatever their intended use and irrespective of whether they had been tested at an earlier stage in the supply chain. Under this option, the costs of testing for dioxins and dioxin-like PCBs would have fallen on not just the producers and processors of these fats and oils but also on the feed compounders who incorporate them in their finished feeds. As previously explained, this proposal for 100% sampling and analysis of fats and oils of vegetable and marine origin at all stages of their production and supply was removed during negotiations on the draft measure, but the UK feed industry nevertheless undertook some calculations of the potential costs to it of this level of monitoring.
- 4.27 The annual cost to producers and processors of testing incoming and outgoing fats and oils of vegetable origin was calculated by the fat blending sector at around £300,000, with an additional annual cost of £67,500 to the suppliers of crude (unblended, unprocessed) oils. For these businesses, there could also have been one-off capital costs associated with the construction of the additional, separate storage tank facilities to hold outgoing consignments of fats and oils until the formal results of their testing were available and they could be released for free circulation. However, these potential capital costs would have been dependent on the volumes of fats and oils traded by each of the affected businesses and the times taken by laboratories to produce analytical results, and are thus difficult to quantify.
- 4.28 UK feed compounders calculated the possible costs to them of the proposal to test 1% of all batches of finished feed irrespective of whether the fats and oils used had previously been sampled and analysed. The calculations were based on the following assumptions:
- retail feed sales of 12.5 million tonnes of which around 80% may contain added fats and oils;
  - a size of 15 tonnes for each batch of finished feed sampled; and
  - a charge of £450 for each analysis undertaken by a laboratory.
- The UK compound feed industry therefore estimated that the cost to it of this testing would be around £3 million a year.
- 4.29 As context for this calculation, the following should be noted:
- annual UK production of compound feed is around 14 million tonnes;
  - the total UK feed market -- which includes direct sales of feed materials to livestock farmers -- amounts to around 20 million tonnes; and
  - the annual usage of fats and oils in the manufacture of compound feed is around 256,000 tonnes (split between crude oils (mainly soya oil) of around 150,000 tonnes and processed oils of around 106,000 tonnes).
- There are also direct sales of feed materials to livestock farmers which are thought to include fats and oils in flaked (i.e. solid) form, but information on the volume of these transactions is not collected and it is not therefore possible to quantify it (although it is thought to be small). In any case, farmers are exempt from the requirement to test

the materials they receive, in part because they lack the equipment and expertise to undertake such work.

4.30 However, the potential cost to the UK feed industry of 100% sampling and analysis would not have been proportionate to the actual risks. This is because, firstly, certain materials, such as crude coconut oil and fish oils, are likely to contain higher loadings of dioxins and dioxin-like PCBs than others, and therefore warrant more attention; secondly, it would have been a duplication of previous work for compound feed manufacturers to test feed containing fats and oils which had been tested and found compliant at an earlier stage of their production and use; and thirdly, 100% testing of lower-risk materials for dioxins and dioxin-like PCBs which are not likely to be present, or likely to be present only at insignificant levels, would not have represented an efficient allocation of resources.

4.31 100% testing would therefore have imposed excessive administrative and financial burdens on the affected businesses. It would also have imposed on the laboratories contracted to undertake the testing a volume of additional work for which they had not or could not develop the capacity, and which could therefore have led to delays in uncovering and reporting non-compliant results. In such cases, the delay could have been such that contaminated product had already entered the feed supply chain, with potential consequences similar to those outlined previously.

4.32 As explained previously, EU Regulation 882/2004 requires that the competent authority recoup the costs of inspection and other control work from the feed business operator. In addition to introducing fees for the approval of the affected businesses, this should also have meant that any increases in costs since 2005 should be reflected in increased fees payable by the operator. Increases in costs to local authorities in the past seven years suggested that an appropriate fee for an establishment both manufacturing and placing products on the market should now be between £650 and £700 (i.e., 10 hours' work at a rate of £65-70 per hour). For an establishment placing products on the market only, the flat-rate fee would be half of this, at between £325 and £350.

4.33 This would have meant that the total one-off costs for the approval of establishments both manufacturing and placing products on the market would be (depending on the actual hourly rate) between £13,650 and £14,700. This increase would have been consistent with the policy on full cost recovery set out in chapter 6 of the Treasury guidance document *Managing Public Money* available at [http://www.hm-treasury.gov.uk/d/mpm\\_ch6.pdf](http://www.hm-treasury.gov.uk/d/mpm_ch6.pdf). However, increasing the fee payable for approvals would have been inconsistent with the government's policy of minimising or reducing the administrative burdens on business.

4.34 For these reasons, the option of 100% Sampling and Analysis of all Fats and Oils plus Increased Fees for Approvals was not supported.

**Option 4: 100% Sampling and Analysis of All Fats and Oils and for Approval Fees to be Retained at their Existing Levels**

4.35 The costs to feed business operators of 100% sampling and analysis would have been the same as those set out in paragraphs 4.27-4.28 above.

- 4.36 The introduction of fees for the approval of the affected businesses at their existing levels could be interpretable as offsetting the costs to industry of 100% sampling and analysis, but the offset would be very minor (a saving to industry of £199 to £249 for each establishment). This saving (i.e. the difference between the existing fee and the increased fee) would be the same whether the establishment was both manufacturing and placing products on the market, or placing products on the market only. Given that there are 21 firms in the UK operating in this sector of the feed industry, the total saving to industry would be between £4,179 (assuming that all the establishments are placing products on the market only) and £5,229 (assuming that all establishments are both manufacturing and placing products on the market). This would represent 0.14% to 0.18% of the estimated total cost to feed compounders of £3 million for 100% sampling and analysis, and an even smaller fraction of a percentage once the costs to producers and processors of fats and oils have also been taken into account. Any saving from retaining the fees for approvals at their existing levels would therefore be vastly exceeded by the costs of 100% sampling and analysis.
- 4.37 There could also have been costs to local authorities, because they might not have recovered the full costs of the inspection work necessary before an establishment could be approved to undertake its activities. However, the costs to industry of 100% sampling and analysis is the principal reason why the option of 100% Sampling and Analysis of All Fats and Oils and for Approval Fees to be Retained at their Existing Levels was not supported.

#### **Option 5: Risk-Based Sampling and Analysis of Certain Fats and Oils plus Increased Fees for Approvals**

- 4.38 Regulation 225/2012, as finally adopted, contains 100% testing of certain fats and oils rather than all fats and oils. In addition, the sizes of the consignments to be tested are larger than those originally proposed by the Commission, with consequent savings to all affected businesses because the number of consignments to be tested is lower. Under this option, the costs would have fallen mainly on the producers and processors of certain fats and oils, and to a much lesser extent on the feed compounders who incorporate these fats and oils in the finished feeds they produce.
- 4.39 The producers and processors of certain fats and oils calculated that the costs to them of testing these materials will be around half of the figures set out in paragraph 4.27 because sampling will be necessary only for materials they are sourcing (incoming consignments). They will not be required to test materials they are despatching to other users (outgoing consignments).
- 4.40 The assumptions underlying the UK compound feed industry's calculation of the likely costs to it of this option are the same as those set out in paragraph 4.28 above, but the resulting costs to it are much lower - around £47,000 annually for the testing of vegetable fats and oils and around £11,000 for the testing of fats and oils of marine origin. The total cost to the compound feed industry in the UK would therefore be around £58,000 a year.
- 4.41 However, the costs to the feed industry of risk-based sampling and analysis are considerably outweighed by the implementation of measures intended to avoid a major future dioxin contamination incident that could result in very large, but

unquantifiable, costs to the feed and livestock industries, national and local government authorities, and public health.

4.42 However, the arguments against introducing fees for the approval of the affected businesses at the increased levels were the same as those set out in paragraph 28 above. For this reason, the option of Risk-Based Sampling and Analysis of Certain Fats and Oils plus Increased Fees for Approvals was not supported.

#### **Option 6: Risk-Based Sampling and Analysis of Certain Fats and Oils and for Approval Fees to be Retained at their Existing Levels**

4.43 The costs of the dioxin monitoring requirements of Regulation (EU) 225/2012 will fall mainly on the producers and processors of the higher-risk fats and oils, and to a lesser extent on the feed compounders who incorporate these fats and oils in their finished feeds.

4.44 The producers and processors of fats and oils had calculated that the annual costs to them - i.e. the fees they would pay the laboratories contracted to undertake the testing of the 100% testing of all fats and oils originally proposed by the Commission would be around £300,000 to the fat blending sector, with an additional annual cost of £67,500 to the suppliers of crude (unblended, unprocessed) oils. The producers and processors have since calculated that because sampling will be necessary only for materials they are sourcing (incoming consignments), and not for materials they are despatching to other users (outgoing consignments), the annual costs to them are around half of their original estimate - i.e. £150,000 to the fat blending sector, and £33,750 to the suppliers of crude (unblended, unprocessed) oils.

4.45 UK feed compounders undertook a similar calculation of the possible costs to them of the Commission's original proposal for testing finished feed which incorporates fats and oils, irrespective of whether these fats and oils had previously been tested and found to be compliant. This resulted in an estimated cost to feed compounders (again from the fees payable to the laboratories undertaking the testing) of around £3 million a year, based on the following assumptions:

- retail feed sales of 12.5 million tonnes of which around 80% may contain added fats and oils;
- a size of 15 tonnes for each batch of finished feed sampled; and
- a charge of £450 for each analysis undertaken by a laboratory.

UK feed compounders subsequently calculated that a risk-based approach to sampling and analysis would generate much lower costs figures for them - around £47,000 annually for the testing of vegetable fats and oils and around £11,000 for the testing of fats and oils of marine origin. The total cost to the compound feed industry is therefore around £58,000 a year.

4.46 As context for this calculation, UK feed production statistics are as follows:

- annual UK production of compound feed is around 14 million tonnes;
- the total UK feed market -- which includes direct sales of feed materials to livestock farmers -- amounts to around 20 million tonnes; and
- the annual usage of fats and oils in the manufacture of compound feed is around 256,000 tonnes (split between crude oils (mainly soya oil) of around 150,000 tonnes and processed oils of around 106,000 tonnes).

There are also direct sales of feed materials to livestock farmers which are thought to include fats and oils in flaked (i.e., solid) form, but information on the volume of these

transactions is not collected and it is not therefore possible to quantify it (although it is thought to be small). In any case, farmers are exempt from the requirement to test the materials they receive, in part because they lack the equipment and expertise to undertake such work.

## 5. Scottish Firms Impact Test

- 5.1 Throughout 2011 and 2012, FSA in Scotland consulted with trading standards enforcement officers to request information on Scottish businesses affected by the impact of Commission Regulation (EU) 225/2012. There were no establishments in Scotland, carrying out activities such as (fat blending, processing of crude vegetable oil) requiring to be approved under the new Annex in 225/2012 amending Annex II to (EC) Regulation 183/2005 (the Feed Hygiene Regulation).
- 5.2 However FSA in Scotland identified four small to medium sized businesses producing fish oils in Scotland. These businesses have all had to comply with the dioxin monitoring requirements within the EU 225/2012. FSA in Scotland met to discuss the impact of the EU Regulation 225/2012 with one fish oil producer. The impact of increased testing and monitoring was not just a cost to this business but also a cost to other fish oil producers across Scotland and the UK. Prior to the German incident in 2010 fish oil businesses were testing on a 6 monthly basis and then under the Feed Materials Assurance Scheme revised standard they were required to test on a monthly basis which lead to a substantial increase in costs.
- 5.3 The costs to one Scottish business producing fish oils are summarised in Table 1 below. The costs of testing in 2009 were £1,800 per annum then, following the incident, the costs of testing have increased considerably to £5,600 in 2012 (excluding inflation). This increase in costs reflects the change to the standard within the Feed Materials Assurance Scheme of monthly testing being a mandatory requirement. Further information is provided in section 3 on the consultation responses and is detailed in paragraphs 3.6-3.8 on fish oil processors in Scotland.

**Table 1 Costs of testing fish oils from pre German incident 2009 to 2012**

| <b>Year</b>                                      | <b>2009</b>                                      | <b>2010</b>                                      | <b>2011</b>                                     | <b>2012</b>                                     |
|--|--|--|---|---|
| <b>Total Annual Tonnage of fish oil produced</b> | 68,000 t   | 62,000 t   | 64,000t   | 57,000t   |
| <b>Total Annual Cost of Testing</b>              | £1,800<br><i>(composite sample taken 6mthly)</i> | £2,000<br><i>(composite sample taken 6mthly)</i> | £4,800<br><i>(composite sample taken mthly)</i> | £5,600<br><i>(composite sample taken mthly)</i> |

### Competition Assessment

- 5.4 We recognise the need to ensure that businesses in Scotland are not at a competitive disadvantage as a result of Regulation 225/2012. During the negotiations in 2011 informal consultation with the UK feed industry took place, which included representation from Scottish stakeholders.

- 5.5 Using the Office of Fair Trading (OFT) competition assessment framework, it has been established that the preferred policy option (option 6) is unlikely to have any material impact on competition.

#### Test Run of Business Forms

- 5.6 The Feed (Hygiene and Enforcement) and Animal Feed (Scotland) Amendment Regulations 2013 will not introduce any new or additional forms to the businesses that will be affected by the Regulation.

### **6. Legal Aid Impact Test**

- 6.1 The amending regulations do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund as a result of the proposed amendments.

### **7. Enforcement, Sanctions, and Monitoring**

#### **Enforcement**

- 7.1 Provision for the enforcement of Regulation 183/2005 (the Feed Hygiene Regulation) is made under Parts 2, 3 and 4 of the Feed (Hygiene and Enforcement) (Scotland) Regulations 2005. These designate the competent authorities for the enforcement of the relevant Articles of the EU Regulation (chiefly the trading standards departments of local authorities) and lay down the penalties for non-compliance with it. The penalties, which are standard for breaches of animal feed legislation, are a fine and/or imprisonment for up to three months on summary conviction, or a fine and/or imprisonment for up to two years for conviction on indictment.
- 7.2 The amendments made to Regulation 183/2005 by Regulation 225/2012 extend the ambit of one Article (the requirement to obtain approval for certain activities) and insert additional requirements into Annex II (which sets out the procedures to be followed by feed businesses). However, these amendments do not themselves have penalties for non-compliance attached to them. In consequence, no amendment is required to the enforcement provisions of the Feed (Hygiene and Enforcement) (Scotland) Regulations 2005, as the existing enforcement provisions are considered to be sufficient to encompass the requirements of Regulation 225/2012.

#### **Sanctions**

- 7.3 No changes are being proposed to the criminal sanctions or civil penalties contained in the Feed (Hygiene and Enforcement) (Scotland) Regulations 2005, which are described in paragraph 7.1.

#### **Monitoring**

- 7.4 The effectiveness and impact of the 2013 amending regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process.

## 8. Implementation and delivery plan

8.1 The publication of The Feed (Hygiene and Enforcement) and Animal Feed (Scotland) Amendment Regulations 2013 will be communicated to stakeholders by email, letter and monthly Enforcement Report. This will be done shortly after the SSI has been published on legislation.gov.uk website.

## 9. Post-Implementation Review

9.1 A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulation, is expected to take place in five years, in December 2018. The effectiveness of these Regulations will also be monitored via general feedback from industry and enforcement authorities.

## 10. Summary and Recommendation

10.1 The Agency recommends Option 6 to provide for the execution and enforcement of the EU Regulations and provide the legislative framework for the requirements to be enforced under UK law.

10.2 Taking this option allows the Government to fulfil its obligations to implement EU law.

10.3 This option also provides appropriate action to address a known public health risk and therefore public health will be protected.

## 11. Summary costs and benefits table

| <p style="text-align: center;"><b>Option</b></p> | <p style="text-align: center;"><b>Total Benefits per annum</b></p> <p style="text-align: center;"><b>Economic, environmental, social</b></p> | <p style="text-align: center;"><b>Total Costs per annum</b></p> <p style="text-align: center;"><b>Economic, environmental, social</b></p> <p style="text-align: center;"><b>Policy &amp; Administrative</b></p>   |
|--|--|---|
| <p><b>Option 1</b><br/>Do nothing.</p>           | <p>With no change, there are no benefits with <b>Option 1</b></p>  | <p>The costs associated with Option 1, doing nothing, are;</p> <ul style="list-style-type: none"> <li>• No health benefits to consumers from no criteria or monitoring of oils and fats for feed</li> <li>• Increased risks of future PCB or Dioxin contamination incidents</li> <li>• Costs associated with future incidents e.g confiscation of product, migration of contamination, quarantining livestock, increased price of feed</li> </ul> |

|  |  |   |
|--|--|---|
| <p><b>Option 2</b><br/>Self-regulation by feed industry</p>  | <p>Benefits with <b>Option 2.</b></p> <ul style="list-style-type: none"> <li>• No new administrative burdens</li> <li>• Industry would remain registered and not incur the costs of approved under the feed regulations</li> <li>• Businesses would be free to decide nature, frequency of sampling and would only incur some testing costs</li> </ul> | <p>The costs associated with Option 2, self-regulation are;</p> <ul style="list-style-type: none"> <li>• Some increased costs to businesses producing, processing or using certain fats and oils of vegetable and marine origin (fish oils) depending on nature and frequency of testing for dioxins and PCBs</li> <li>• Risks that the testing does not meet the requirements within Regulation 225/2012</li> <li>• Risks that contaminated consignments of fats and oils entering the feed chain</li> </ul>   |
| <p><b>Option 3</b><br/>Approval of establishments producing/processing fats and oils, 100% sampling and analysis of all fats and oils plus fees for approvals at increased levels.</p>                   | <p>Benefits of <b>Option 3</b></p> <ul style="list-style-type: none"> <li>• Assurance that feed consumed by animals does not contain excess levels of dioxins and dioxin like PCBs</li> <li>• No benefits to feed industry from 10% sampling and analysis plus fees at increased levels</li> </ul>   | <p>The costs associated with Option 3, 100% sampling/analysis, and increased in fees for approval are;</p> <ul style="list-style-type: none"> <li>• The annual cost to UK producers and processors of testing incoming and outgoing fats and oils of vegetable origin estimated £300,000, with an additional annual cost of £67,500 to the suppliers of crude oils (unblended, unprocessed).</li> <li>• One-off increased costs for the approval of establishments manufacturing and placing products on the market, depending on actual hourly rate, estimated between £13,650 and £14,700.</li> </ul> |
| <p><b>Option 4</b><br/>Approval of establishments producing/processing fats and oils and 100% sampling and analysis of all fats and oils plus approval fees to be retained at their existing levels.</p> | <p>Benefits of <b>Option 4</b></p> <ul style="list-style-type: none"> <li>• No additional increase in approval fees</li> <li>• Assurance that feed consumed by animals does not contain excess levels of dioxins and dioxin like PCBs</li> <li>• Few benefits to feed industry from 10% sampling and analysis apart from the approval</li> </ul>       | <p>The costs associated with Option 4, 100% sampling/analysis and retaining of costs of approval fees are;</p> <ul style="list-style-type: none"> <li>• The annual cost to UK producers and processors of testing incoming and outgoing fats and oils of vegetable origin was estimated £300,000, with an additional annual cost of £67,500 to the suppliers of crude oils (unblended, unprocessed)</li> </ul>  |

|   |   |   |
|---|---|---|
|   | fees being retained at existing levels.   |   |
| <p><b>Option 5</b></p> <p>Approval of establishments producing/processing fats and oils and risk-based sampling and analysis of certain fats and oils plus fees for approval of these businesses at increased levels.</p> | <p><b>Benefits to Option 5</b></p> <ul style="list-style-type: none"> <li>• Feed compounders would benefit from the decrease costs associated with risk based sampling and analysis</li> </ul>  | <p>The costs associated with Option 5 are;</p> <ul style="list-style-type: none"> <li>• Producers/Processors costs of sampling only sourced materials (incoming consignments)</li> <li>• The total cost to the compound feed industry in the UK is estimated £58,000 a year.</li> </ul>                                     |
| <p><b>Option 6</b></p> <p>Approval of establishments producing/processing fats and oils, sampling and analysis of most high risk fats and oils plus fees for approval of these businesses at existing levels</p>          | <p><b>Benefits to Option 6</b></p> <ul style="list-style-type: none"> <li>• No additional increase in approval fees</li> <li>• Feed compounders would benefit from the decrease costs associated with risk based sampling and analysis</li> </ul> | <p>The costs associated with Option 6 are;</p> <ul style="list-style-type: none"> <li>• The total cost to the compound feed industry in the UK is estimated £58,000 a year. Estimated £47,000 annually for testing vegetable fats and oils and estimated £11,000 for fats and oils of marine origin (fish oils).</li> </ul> |

## 12. Declaration and publication

12.1 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) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

**Minister's Signature**.....

**Minister's Title** .....

**Date**.....

### **Contact point**

Karen Robertson  
Standards, Hygiene and Associated Regulatory Policy Branch  
Food Standards Agency in Scotland  
6th floor, St Magnus House  
25 Guild Street, Aberdeen, AB11 6NJ

Tel: 01224 288362

e-mail: [karen.robertson@foodstandards.gsi.gov.uk](mailto:karen.robertson@foodstandards.gsi.gov.uk)