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|---|---|--|--|--|
| Title: The Approval of Establishments Producing and Processing Certain Fats and Oils, and the Testing of Fats and Oils of Vegetable and Marine Origin for Dioxins and Dioxin-Like PCBs IA No: FOODSA0049 Lead department or agency: Food Standards Agency Other departments or agencies: None | Impact Assessment (IA) | | | |
| | Date: 29 May 2013 | | | |
| | Stage: Consultation | | | |
| | Source of intervention: EU | | | |
| | Type of measure: Secondary legislation | | | |
| Contact for enquiries: Joseph Nicholas, Animal Feed and Animal By-Products Branch, Hygiene and Microbiology Division, Food Standards Agency | | | | |
| Summary: Intervention and Options | | | RPC Opinion: RPC Opinion Status | |

| Cost of Preferred (or more likely) Option | | | |
|---|----------------------------|--|---|
| Total Net Present Value | Business Net Present Value | Net cost to business per year (EANCB on 2009 prices) | In scope of One-In, Measure qualifies as One-Out? |
| N/A | N/A | £54,490 | No |

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

There was a feed contamination incident in Germany in December 2010-January 2011, in which fatty acids of vegetable origin for use in pig and poultry feed were mixed with fats derived from industrial use containing high levels of dioxins. The incident, 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 subsequently introduced an amendment to Regulation 183/2005 on feed hygiene to require the approval of establishments producing or processing fats and oils and laying down conditions for the control of dioxins and dioxin-like PCBs in them.

What are the policy objectives and the intended effects?

Producers and processors of certain fats and oils for animal feed use will now require to be approved rather than registered under Regulation 183/2005. Approval requires a prior physical inspection of an establishment's premises and equipment to ensure it is capable of undertaking their activities to the required standards and the payment of a fee to the competent authority for this. Producers and processors of fats and oils for use in animal feed will also be required to undertake sampling and analysis of these materials to ensure that levels of any undesirable substances which may be present do not exceed the maxima laid down in animal feed legislation.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

- **Option 1:** do nothing. However, this would not help prevent possible future contamination incidents of the kind referred to earlier.
- **Option 2:** allow self-regulation by the feed industry. However, this would mean that there was no prior inspection of premises and equipment to verify that they met the required standards and would breach EU legislation.
- **Option 3:** approval of establishments producing or processing fats and oils for feed use with 100% testing of all consignments, with fees for approvals at increased levels.
- **Option 4:** as per option 3, but with fees for approvals at their existing levels.
- **Option 5:** approval of establishments and risk-based testing of certain types of fats and oils, plus fees for approvals at increased levels.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** March 2014

| | | | | | |
|--|---------------------|-----------------------|-----------------------|---------------------------|---------------------|
| Does implementation go beyond minimum EU requirements? | | | No | | |
| Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base. | Micro Yes | < 20 Yes | Small Yes | Medium Yes | Large Yes |
| What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent) | | | Traded: N/A | Non-traded: N/A | |

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Chief Executive:



Date:

18/6/13

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing

FULL ECONOMIC ASSESSMENT

| Price Base Year 2012 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£) | | |
|-------------------------|----------------------|-------------------------|--------------------------------------|----------|-------------------|
| | | | Low: £0 | High: £0 | Best Estimate: £0 |

| COSTS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---------------|--|---|-------------------------------|
| Low | £0 | £0 | £0 |
| High | £0 | £0 | £0 |
| Best Estimate | £0 | £0 | £0 |

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

There are no costs associated with this policy, as this is the baseline against which all other proposed policies are compared.

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

There are no costs associated with this policy, as this is the baseline against which all other proposed policies are compared.

| BENEFITS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---------------|--|---|----------------------------------|
| Low | £0 | £0 | £0 |
| High | £0 | £0 | £0 |
| Best Estimate | £0 | £0 | £0 |

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

There are no benefits associated with this policy, as this is the baseline against which all other proposed policies are compared.

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

There are no benefits associated with this policy, as this is the baseline against which all other proposed policies are compared.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

In the absence of the implementation of this policy, the United Kingdom faces the risk of infraction proceedings by the European Commission, which could result in the issuance of unlimited daily fines. Otherwise, there are no further assumptions, sensitivities or risks associated with the implementation of this policy.

BUSINESS ASSESSMENT (Option 1)

| Direct impact on business (Equivalent Annual) £: | | | In scope of OIOO? | Measure qualifies as |
|--|--------------|---------|-------------------|----------------------|
| Costs: £0 | Benefits: £0 | Net: £0 | No | NA |

Summary: Analysis & Evidence

Policy Option 2

Description: Self-regulation by the feed industry

FULL ECONOMIC ASSESSMENT

| Price Base Year 2012 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£) | | |
|-------------------------|----------------------|-------------------------|--------------------------------------|---------------|------------------------|
| | | | Low: Unknown | High: Unknown | Best Estimate: Unknown |

| COSTS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---------------|--|---|-------------------------------|
| Low | £Unknown | £Unknown | £Unknown |
| High | £Unknown | £Unknown | £Unknown |
| Best Estimate | £Unknown | £Unknown | £Unknown |

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

As producers and processors would have complete freedom over the frequency and nature of the regime for testing for the presence of dioxins and dioxin-like PCBs, it is not possible to determine what the additional costs would be to the affected groups. Please see "Other key non-monetised costs" below for a discussion of potential costs.

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

As the blenders and processors would have complete freedom over the frequency and nature of the regime for testing for the presence of dioxins, it is not possible to determine what the additional costs would be for the affected groups. Potential costs incurred could involve additional transportation and storage costs, aimed at preventing any contamination, and the additional cost of testing for the presence of dioxins and dioxin-like PCBs. However, all of these additional costs would be entirely voluntary.

| BENEFITS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---------------|--|---|----------------------------------|
| Low | £Unknown | £Unknown | £Unknown |
| High | £Unknown | £Unknown | £Unknown |
| Best Estimate | £Unknown | £Unknown | £Unknown |

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

It is not possible to determine the scale of monetised benefits, as the level of benefits achieved would be dependent on the level of testing applied by both the producers and processors for fats and oils, and the feed compounders. For a discussion of potential "Other key non-monetised benefits", please see the box below.

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

There may be some human and animal health benefits arising from additional testing of feeds and oils by the relevant feed business operators. In addition to this, there could be benefits to the farming industry due to a reduction in the likelihood of product recalls following a potential dioxin or PCB contamination incident. Due to the voluntary nature of this proposal, it is not possible to say how large these benefits may be.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

This policy falls short of the requirements of EU Regulation 225/2012. Therefore, if the UK were to pursue this policy it would be subject to infraction proceedings by the European Commission, which could result in unlimited daily fines. In addition to this, it is uncertain whether this policy would be capable of delivering the reduction in the risk of a dioxin contamination incident, given that compliance with the policy would be voluntary.

BUSINESS ASSESSMENT (Option 2)

| | | | | |
|---|---------------------------|----------------------|--------------------------|-----------------------------|
| Direct impact on business (Equivalent Annual) £: | | | In scope of OIOO? | Measure qualifies as |
| Costs: £Unknown | Benefits: £Unknown | Net: £Unknown | No | N/A |

Summary: Analysis & Evidence

Policy Option 3

Description: Approval of establishments and 100% testing of fats and oils, plus increased fees for approvals

FULL ECONOMIC ASSESSMENT

| | | | | | |
|-------------------------|----------------------|-------------------------|--------------------------------------|---------------|------------------------|
| Price Base Year 2012 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£) | | |
| | | | Low: Unknown | High: Unknown | Best Estimate: Unknown |

| COSTS (£) | Total Transition (Constant Price) | Year(s) | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---------------|--------------------------------------|---------|---|-------------------------------|
| Low | £7,800 | 1 | N/A | £28,994,184 |
| High | £8,400 | | N/A | £28,994,784 |
| Best Estimate | £8,100 | | £3,367,500 | £28,994,484 |

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

Industry sources have indicated that the additional undiscounted annual costs to the fat blending sector could be around £300,000. For the suppliers of crude, unblended, unprocessed oils, this figure stands at £67,500.

As part of this consultation, the FSA wishes to seek the views of industry on the accuracy of these provisional cost estimates.

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

There are other non-monetised costs associated with Policy Option 3. Familiarisation costs for the Competent Authorities (in this case local authorities) are thought to be negligible. There will be a potential cost of reporting any dioxin breach, which would fall upon Official Control Laboratories (OCLs). In addition, the producers and processors of fats and oils would be required to label the intended purpose of any processed oils and fats. Those oil and fat producers who also produce bio-diesel would be required to invest in sufficient equipment to keep the production of these materials separate.

| BENEFITS (£) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---------------|--------------------------------------|-------|---|----------------------------------|
| Low | £7,800 | N/A | N/A | £28,994,184 |
| High | £8,400 | | N/A | £28,994,784 |
| Best Estimate | £8,100 | | £3,367,500 | £28,994,484 |

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

We do not currently have information on the monetised human and animal health benefits of this policy. **As part of this consultation, we wish to seek information on the likelihood of a dioxin/dioxin-like PCB contamination in the UK.**

There would be additional benefits to local authorities from the collection of increased levels of fees for the approval of feed business operators -- this would be the same figure as the costs to businesses outlined above.

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

In recent history, there has been no evidence of the contamination of the UK feed chain with dioxins and/or dioxin-like PCBs. However, in mitigating the likelihood of such an incident, this policy would reduce the human and livestock costs likely to be associated with such an incident. Additionally, this policy should also reduce any farm quarantine costs, and costs associated with confiscated produce, which may result from a dioxin contamination incident.

| | | |
|--|--------------------------|------|
| Key assumptions/sensitivities/risks | Discount rate (%) | 3.5% |
|--|--------------------------|------|

Producers and processors of fats and oils are already likely to have in place the procedures and equipment to undertake the monitoring required by the EU Regulation and will not therefore be disadvantaged by it. However, this policy would amount to gold-plating the requirements of the EU Regulation and divert resources (time, effort, finance) into the retesting of material which had already been found to be compliant. The volume of material to be retested could also overwhelm the capacity of laboratories to undertake such work.

BUSINESS ASSESSMENT (Option 3)

| | | | | |
|---|----------------------|-----------------|--------------------------|-----------------------------|
| Direct impact on business (Equivalent Annual) £: | | | In scope of OIOO? | Measure qualifies as |
| Costs: £3,114,083 | Benefits: N/A | Net: N/A | Yes | IN |

Summary: Analysis & Evidence

Policy Option 4

Description: Approval of establishments and 100% testing of fats and oils, with no increase in fees for approvals

FULL ECONOMIC ASSESSMENT

| Price Base Year 2012 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£) | | |
|----------------------|-------------------|----------------------|--------------------------------------|-------------------|----------------------------|
| | | | Low: Unavailable | High: Unavailable | Best Estimate: Unavailable |

| COSTS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---------------|---|--|----------------------------|
| Low | £5,412 | N/A | £28,991,796 |
| High | £5,412 | N/A | £28,991,796 |
| Best Estimate | £5,412 | £3,367,500 | £28,991,796 |

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

Industry sources have indicated that the additional undiscounted annual costs to the fat blending sector could be around £300,000. For the suppliers of crude, unblended, unprocessed oils, this figure stands at £67,500. However, both discounted total costs, and transition costs are lower in policy option 4 than they are for policy option 3. This is because we have assumed that current fee levels are retained for approvals.

As part of this consultation, the FSA wishes to seek the views of industry on the accuracy of these provisional cost estimates.

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

There are other non-monetised costs associated with Policy Option 4. Familiarisation costs for the Competent Authorities (in this case local authorities) are thought to be negligible. There will be a potential cost of reporting any dioxin breach, which would fall upon Official Control Laboratories (OCLs). In addition, the producers and processors of fats and oils would be required to label the intended purpose of any processed oils and fats. Those oil and fat producers who also produce bio-diesel would be required to invest in sufficient equipment to keep the production of these materials separate.

| BENEFITS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---------------|---|--|-------------------------------|
| Low | £5,412 | N/A | £28,991,796 |
| High | £5,412 | N/A | £28,991,796 |
| Best Estimate | £5,412 | £3,367,500 | £28,991,796 |

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

We do not currently have information on the monetised benefits of this policy. **As part of this consultation, we wish to seek information on the likelihood of a dioxin/dioxin-like PCB contamination in the UK.**

There will be additional benefits to Local Authorities who will collect an increased amount of revenue for testing and approvals – this should be the same amount as the costs to businesses outlined above.

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

In recent history, there has been no evidence of the contamination of the UK feed chain with dioxins and/or dioxin-like PCBs. However, in mitigating the likelihood of such an incident, this policy would reduce the human and livestock costs likely to be associated with such an incident. Additionally, this policy should also reduce any farm quarantine costs, and costs associated with confiscated produce, which may result from a dioxin contamination incident.

| | | |
|-------------------------------------|-------------------|------|
| Key assumptions/sensitivities/risks | Discount rate (%) | 3.5% |
|-------------------------------------|-------------------|------|

Producers and processors of fats and oils are already likely to have in place the procedures and equipment to undertake the monitoring required by the EU Regulation, and will not therefore be disadvantaged by it. However, this policy would amount to gold-plating the requirements of the EU Regulation and divert resources (time, effort, finance) into the retesting of material which had already been found to be compliant. The volume of material to be retested could also overwhelm the capacity of laboratories to undertake such work.

BUSINESS ASSESSMENT (Option 4)

| | | | | |
|--|---------------|----------|-------------------|----------------------|
| Direct impact on business (Equivalent Annual) £: | | | In scope of OIOO? | Measure qualifies as |
| Costs: £3,113,794 | Benefits: N/A | Net: N/A | Yes | IN |

Summary: Analysis & Evidence

Policy Option 5

Description: Approval of establishments and risk-based testing of certain types of fats and oils, plus increased fees for approvals

FULL ECONOMIC ASSESSMENT

| Price Base Year 2012 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£) | | |
|-------------------------|----------------------|-------------------------|--------------------------------------|-------------------|----------------------------|
| | | | Low: Unavailable | High: Unavailable | Best Estimate: Unavailable |

| COSTS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---------------|--|---|-------------------------------|
| Low | £7,800 | N/A | £507,046 |
| High | £8,400 | N/A | £507,646 |
| Best Estimate | £8,100 | £58,000 | £507,346 |

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

Industry sources have indicated that the costs for Policy Option 5 are much lower than those for policy options 3 & 4. The annual average undiscounted cost of testing for firms producing vegetable fats and oils is £47,000. For firms producing fats and oils of marine origin, the figure is £11,000.

As part of this consultation, the FSA wishes to seek the views of industry on the accuracy of these provisional cost estimates.

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

There are other non-monetised costs associated with Policy Option 5 Familiarisation costs for the Competent Authorities (in this case local authorities) are thought to be negligible. There will be a potential cost of reporting any dioxin breach, which would fall upon Official Control Laboratories (OCLs). In addition, the producers and processors of fats and oils would be required to label the intended purpose of any processed oils and fats. Those oil and fat producers who also produce bio-diesel would be required to invest in sufficient equipment to keep the production of these materials separate.

| BENEFITS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---------------|--|---|----------------------------------|
| Low | £7,800 | N/A | £507,046 |
| High | £8,400 | N/A | £507,646 |
| Best Estimate | £8,100 | £58,000 | £507,346 |

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

We do not currently have information on the monetised benefits of this policy. **As part of this consultation, we wish to seek information on the likelihood of a dioxin/dioxin-like PCB contamination in the UK.**

There will be additional benefits to Local Authorities who will collect an increased amount of revenue for testing and approvals -- this should be the same amount as the costs to businesses outlined above.

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

In recent history, there has been no evidence of the contamination of the UK feed chain with dioxins and/or dioxin-like PCBs. However, in mitigating the likelihood of such an incident, this policy would reduce the human and livestock costs likely to be associated with such an incident. Additionally, this policy should also reduce any farm quarantine costs, and costs associated with confiscated produce, which may result from a dioxin contamination incident.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

Producers and processors of fats and oils are already likely to have in place the procedures and equipment to undertake the monitoring required by the EU Regulation, and will not therefore be disadvantaged by it. This policy would concentrate monitoring effort on the higher-risk material, and would therefore be proportionate to the impacts on the feed chain.

BUSINESS ASSESSMENT (Option 5)

| | | | | |
|---|---------------|----------|--------------------------|-----------------------------|
| Direct impact on business (Equivalent Annual) £: | | | In scope of OIOO? | Measure qualifies as |
| Costs: £54,490 | Benefits: N/A | Net: N/A | No | Zero net cost |

Summary: Analysis & Evidence

Policy Option 6

Description: Approval of establishments and risk-based testing of certain types of fats and oils, with no increase in fees for approvals

FULL ECONOMIC ASSESSMENT

| Price Base Year 2012 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£) | | |
|----------------------|-------------------|----------------------|--------------------------------------|-------------------|----------------------------|
| | | | Low: Unavailable | High: Unavailable | Best Estimate: Unavailable |

| COSTS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---------------|---|--|----------------------------|
| Low | £5,412 | N/A | £504,658 |
| High | £5,412 | N/A | £504,658 |
| Best Estimate | £5,412 | £58,000 | £504,658 |

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

Industry sources have indicated that the costs for Policy Option 6 are much lower than policy options 3 & 4. The annual average undiscounted cost of testing for firms producing vegetable fats and oils is £47,000. For firms producing fats and oils of marine origin, the figure is £11,000. Additionally, both discounted total costs, and transition costs, are lower than policy option 5, as we assume retention of current fee levels for approvals.

As part of this consultation, the FSA wishes to seek the views of industry on the accuracy of these provisional cost estimates.

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

There are other non-monetised costs associated with Policy Option 6 Familiarisation costs for the Competent Authorities (in this case local authorities) are thought to be negligible. There will be a potential cost of reporting any dioxin breach, which would fall upon Official Control Laboratories (OCLs). In addition, the producers and processors of fats and oils would be required to label the intended purpose of any processed oils and fats. Those oil and fat producers who also produce bio-diesel would be required to invest in sufficient equipment to keep the production of these materials separate.

| BENEFITS (£) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---------------|---|--|-------------------------------|
| Low | £5,412 | N/A | £504,658 |
| High | £5,412 | N/A | £504,658 |
| Best Estimate | £5,412 | £58,000 | £504,658 |

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

We do not currently have information on the monetised benefits of this policy. **As part of this consultation, we wish to seek information on the likelihood of a dioxin/dioxin-like PCB contamination in the UK.**

There will be additional benefits to Local Authorities who will collect an increased amount of revenue for testing and approvals – this should be the same amount as the costs to businesses outlined above.

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

In recent history, there has been no evidence of the contamination of the UK feed chain with dioxins and/or dioxin-like PCBs. However, in mitigating the likelihood of such an incident, this policy would reduce the human and livestock costs likely to be associated with such an incident. Additionally, this policy should also reduce any farm quarantine costs, and costs associated with confiscated produce, which may result from a dioxin contamination incident.

| | | |
|-------------------------------------|-------------------|------|
| Key assumptions/sensitivities/risks | Discount rate (%) | 3.5% |
|-------------------------------------|-------------------|------|

Producers and processors of fats and oils are already likely to have in place the procedures and equipment to undertake the monitoring required by the EU Regulation, and will not therefore be disadvantaged by it. This policy would concentrate monitoring effort on the higher-risk material, and would therefore be proportionate to the impacts on the feed chain.

BUSINESS ASSESSMENT (Option 6)

| | | | | |
|--|---------------|----------|-------------------|----------------------|
| Direct impact on business (Equivalent Annual) £: | | | In scope of OIOO? | Measure qualifies as |
| Costs: £54,202 | Benefits: N/A | Net: N/A | No | Zero net cost |

Evidence Base

Problem under Consideration

1. 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 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 these materials and to require their testing prior to use.

Rationale for Intervention

2. In late December 2010, notification was received via the 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 which can be generated as by-products of certain industrial processes and 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.

3. 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. Quarantine restrictions were therefore placed on all the farms concerned, on all products (feed and food) that were potentially contaminated, and on all businesses which might have handled the contaminated feed and food, thereby ensuring that nothing (feed product, animal, and animal product for human consumption) could be moved until it had been tested and found to be free of contamination.

4. 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.

5. 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.

6. The Commission in any case considered 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 their monitoring 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.

7. 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.

Policy Objectives

8. 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 testing of fats and oils, and finished feeds which contain certain of them, for the potential presence of dioxins and dioxin-like 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

9. 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 the 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.

10. The approval requirement will apply 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". Businesses engaged in the manufacture and processing of oils of marine origin will be exempt from the requirement for their activities to be approved.

11. 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 engaged in official controls, the costs of their equipment, training, and travel, and the costs of laboratory sampling and analysis.

12. When the Feed Hygiene Regulation came into force in January 2006, flat-rate fees of £451 were set for an establishment both manufacturing and placing certain additive and premixture products on the market and of £226 for an establishment placing such products on the market only. Flat-rate fees were set for ease and simplicity, and to avoid potentially wide disparities in the charges levelled by different local authorities. 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

13. 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 it is not, 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 such as those which occurred in Germany in December 2010-January 2011, because it will help ensure that in future there can be no accidental mixing of feed with non-feed materials.

Testing

14. 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 testing for the presence of dioxins and dioxin-like PCBs. The prescribed volume and frequency of the testing to be undertaken 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

15. 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.

Description of Options Considered

Option 1 -- Do Nothing

16. Doing nothing would mean making no changes to the present requirement for establishments producing or processing certain fats and oils to be registered instead of approved under the Feed Hygiene Regulation. This would mean that no prior official checks would be made to confirm that they have the appropriate equipment and procedures in place to ensure the safe handling of these materials, which would in turn mean that UK producers and processors of these fats and oils were not subject to the same level of scrutiny as those of other Member States. This could have a negative impact on their ability to sell product into the wider EU market since the materials would not have been produced in compliance with EU law.

17. Doing nothing would also mean that establishments producing or processing certain fats and oils would not be required to ensure the separation of materials for feed use from those intended for a non-feed use, to label them accordingly, and to undertake the required sampling and analysis of the fats and oils in question. This too could give rise to doubts in other Member States as to whether UK producers and processors met the appropriate standards, with a negative impact on their ability to sell product elsewhere in the EU. More seriously, it would also not help prevent future contamination incidents of the kind which led to the adoption of Regulation 225/2012 by Member States and the Commission.

18. Doing nothing would also mean failing to respect the provisions of Regulation 225/2012, which applies directly in all Member States. This would be a breach of the UK's obligations as an EU Member State and could attract infraction proceedings from the Commission, which if successful could (in the worst case) result in the imposition of unlimited daily fines on the UK by the European Court of Justice.

Option 2 -- Self-Regulation by the Feed Industry

19. This would also mean making no changes to the present requirement for establishments producing or processing certain fats and oils to be registered instead of approved under the Feed Hygiene Regulation, with the result that no prior checks would be made to confirm they have the appropriate equipment and procedures in place to ensure the safe handling of these materials. (This would not impose a new administrative burden on the feed industry, as registration under the Feed Hygiene Regulation does not attract a fee.) Self-regulation would also mean that the affected businesses were allowed to decide for themselves on the nature and frequency of the sampling and testing to be undertaken, as they do now in line with the principles of HACCP (Hazard Analysis of Critical Control Points) planning to which they are already required to adhere. Businesses are also under an implied general duty of "due diligence" to ensure that they comply with applicable legislation. This would also mean that no new administrative burdens would be imposed.

20. However, allowing self-regulation by the feed industry could also mean that the existing, non-statutory programme of sampling and testing undertaken by the affected businesses, although satisfying both HACCP principles and the "due diligence" duty, fell below the specific requirements to sample and test laid down in Regulation 225/2012. This could mean that the industry took fewer samples than specified and/or did not test the full range of fats and oils specified and/or did not report instances of non-compliance to the competent authorities. Self-regulation may not therefore help prevent future contamination incidents of the kind which led to the adoption of Regulation 225/2012 by Member States and the Commission.

21. As with the doing nothing option, allowing self-regulation by the industry would also mean failure to respect the provisions of Regulation 225/2012, in particular the requirement for the approval of processors and blenders of fats and oils. This would again be a breach of the UK's obligations as an EU Member State, and could again result in infraction proceedings against the UK by the Commission.

Option 3 -- Approval of Establishments Producing or Processing Fats and Oils and 100% Sampling and Analysis of all Fats and Oils, plus the Introduction of Fees for Approval of these Businesses at Increased Levels

22. Approval of establishments producing or processing certain fats and oils would require the physical inspection of them by the competent authorities, as required by Regulation 183/2005 on feed hygiene. These inspections would ensure that these establishments have the appropriate equipment and procedures in place and meet the required standards. Inspections could 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 and other costs (for example, to the reputation of the business). Approval would also help ensure the physical separation of fats and oils for feed use from those intended for a non-feed use (where a business deals in both); ensure that they are labelled accordingly and that materials intended for a non-feed use cannot subsequently be relabelled; and require the payment of a fee to the competent authority for the inspection work undertaken.

23. 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. This would mean that increases in costs over time should be reflected in increased fees payable by the operator. Local authority representatives have advised that increases in their costs over the past seven years suggest 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); and that for an establishment placing products on the market only, the flat-rate fee would be (as at present) half of this, at between £325 and £350.

24. These increased fees would be payable by both (a) the producers and processors of certain fats and oils to which Regulation 225/2012 applies and (b) any new businesses in the existing categories of establishments to which the requirement for approval applies. It is estimated that the number of establishments in the first group is no more than a dozen; and that the number in the second is even smaller -- probably five or less per year.

25. With respect to sampling and analysis, however, 100% sampling and analysis of all fats and oils of vegetable and marine origin would be disproportionate, as it would not reflect whether they were intended for a feed or a non-feed use and (if the latter) represent a misallocation of time, effort and other resources. In addition, 100% sampling and analysis would not be based on the actual risks posed by the type and source of each fat and oil, because certain types of these fats and oils have a higher probability of containing significant levels of dioxins and dioxin-like PCBs (for example, coconut oil is considered to be high risk due to the use of open fires to dry the material before the oil is obtained). 100% sampling and analysis would also be administratively and financially very burdensome for the affected businesses; and it would impose additional workloads on the feed industry and the laboratories contracted to undertake the testing of fats and oils for dioxins and dioxin-like PCBs. Laboratories may benefit financially from the additional revenue thus generated, but there is also the possibility that the additional workload could so stretch their resources that it could lead to a delay in the uncovering and reporting of non-compliant results, with potentially adverse effects throughout the feed supply chain and on the health of animals and the human consumers of animal products. 100% sampling and analysis might therefore have the paradoxical effect of hindering work to exclude contaminated material from the feed chain.

Option 4 -- Approval of Establishments Producing or Processing Fats and Oils and 100% Sampling and Analysis of all Fats and Oils, plus the Introduction of Fees for Approval of these Businesses at their Existing Levels

26. The same arguments in respect of 100% sampling and analysis, as set out in paragraph 25 above, apply here.

27. Although 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, this 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.

28. In any case, the charging of a flat-rate fee for approvals could also 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. It is therefore considered that the current flat-rate fees are perhaps just as good an estimate of the costs as any updating of them might be.

Option 5 -- Approval of Establishments Producing or Processing Fats and Oils and Risk-Based Sampling and Analysis of Certain Fats and Oils, plus Introduction of Fees for Approval of these Businesses at Increased Levels

29. As for options 3 and 4, approval of establishments producing or processing certain fats and oils would require their physical inspection by the competent authorities; it would ensure that the affected businesses have the appropriate equipment and procedures in place and meet the required standards; it would provide the competent authority with the opportunity to offer advice which may help prevent inadvertent breaches of feed law; would also help ensure the physical separation of fats and oils for feed use from those intended for a non-feed use (where a business deals in both); and ensure that they were labelled accordingly and that materials intended for a non-feed use could not subsequently be relabelled. It would also require the payment of a fee to the competent authority for the inspection work.

30. Risk-based sampling and analysis of fats and oils of vegetable and marine origin would also be in line with the requirements to sample and test 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 material it has received has been subject to analysis and declared as compliant at an earlier stage of its production and use, thus permitting a more efficacious allocation of time, effort and other resources.

31. Approval of establishments producing or processing certain fats and oils and risk-based testing of fats and oils of vegetable or marine origin in line with Regulation 225/2012 would also be commensurate with the UK's obligations as an EU Member State. It would also mean that UK establishments producing or processing certain fats and oils, and all businesses using fats and oils of vegetable and marine origin, would be subject to the same controls as those in other Member States, and therefore that trade between them would be unaffected.

32. The case for increases in the levels of the fees for approvals to take account of the increased costs to competent authorities for this inspection work is the same as those set out in paragraphs 23-24 above.

Option 6 -- Approval of Establishments Producing or Processing Fats and Oils and Risk-Based Sampling and Analysis of Certain Fats and Oils, plus the Introduction of Fees for Approval of these Businesses at their Existing Levels

33. The arguments in respect of risk-based sampling and analysis are the same as those set out in paragraphs 30-31 above.

34. The arguments in respect of retaining the levels of fees for approvals at their existing levels are the same as those set out in paragraphs 27-28 above.

Sectors and Groups Affected

Industry

35. The Interdepartmental Business Register (IDBR) 2012 contains a list of all UK VAT-registered businesses in the UK. SIC¹ Code 1091 contains all businesses involved in the

¹Standard 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>

manufacture of prepared feeds for farm animals. Last year there were 245 feed manufacturing companies operating within the UK; of these, 185 operate in England, with a further 10 in Wales, 15 in Scotland, and a further 35 businesses in Northern Ireland.

36. However, not all of these businesses are likely to be affected by the legislation -- from discussions with industry, it is estimated that no more than a dozen processors of fats and oils will be affected; see paragraph 24 above.

37. The legislation also requires laboratories to report any breach of permitted dioxin levels as soon as they are discovered. However, it is anticipated that this cost will be minimal.

Enforcement Authorities

38. Local authorities may incur familiarisation costs associated with these changes to existing feed hygiene legislation. In this case, however, the only change as far as local authorities are concerned is the addition of a new category of feed business operators to the list of those which require to have their operations approved instead of registered; as local authorities are already very familiar with the inspection work necessary to approve an establishment, it is thought that the familiarisation costs to them will be minimal.

Consumers

39. 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.

Monetised and Non-Monetised Costs and Benefits of Each Option

Option 1 -- Do Nothing

Benefits

40. There are no benefits associated with this option, as there would be no change to the existing position. However, there could be severe costs associated with doing nothing, because it could leave open the potential for future incidents of the kind which occurred in Germany in December 2010-January 2011, as discussed in paragraphs 1-3 above, or that which occurred in Ireland in December 2008. Both had serious cost impacts on the feed and food chains, and associated sectors.

Costs

41. 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)² 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" (*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, available online at

² Euro-Sterling conversion rate sourced from www.xe.com/ucc, at 14:24 on 10/05/2013; where €1.000 = £0.834

42. 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)³. 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.

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

Option 2 -- Self-Regulation by the Feed Industry

Benefits

44. As with doing nothing, there are no benefits associated with this option because it does not require industry to undertake any more or less sampling and analysing than it does already as part of its normal "due diligence" procedures to warrant that its materials and products are fit for their intended purpose.

Costs

45. This could have 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 in any case gives rise to a risk that the testing may not meet the specific requirements laid down in Regulation 225/2012, and therefore that potentially contaminated consignments of fats and oils may not be detected prior to their entry into the feed chain, with consequences similar to those outlined in paragraphs 41-42 above.

46. It might nevertheless be worth noting that, in response to previous high-profile instances of contamination, UK feed compounders have recently established their own monitoring scheme for dioxins and dioxin-like PCBs under the auspices of the Universal Feed Assurance Scheme (UFAS) operated by the Agricultural Industries Confederation (AIC), the main trade association which groups together merchants, millers, feed compounders, firms which transport animal feed, and associated sectors. The aim under this voluntary programme is to take 108 samples per year over the two years commencing from July 2012 from all compound feed mills subscribing to UFAS, for which AIC has negotiated a bulk rate with the participating laboratory of £425 per sample. The total cost will therefore be £45,900 per year, over and above the costs associated with testing under HACCP. However, this voluntary testing programme will apply only to the feed materials used, and the finished feeds produced, by compound feed mills, which are at the end of the supply chain for fats and oils for use in feed, so will not address all the requirements for the testing of certain fats and oils set out in Regulation 225/2012.

³ *ibid*

47. For these reasons, the Self-Regulation option is not supported.

Option 3 -- Approval of Establishments Producing or Processing Fats and Oils and 100% Sampling and Analysis of all Fats and Oils, plus the Introduction of Fees for Approval of these Businesses at Increased Levels

Benefits

48. The benefits associated with this option would accrue largely to local authorities, who would be reimbursed for the full costs of the inspection work necessary before an establishment can be approved to undertake its activities; and also to the human consumers of animal products (meat, milk and eggs), who would be assured 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. However, few if any benefits would be derived by the feed industry, which would have to bear the costs of monitoring for dioxins and dioxin-like PCBs at every stage of the use of certain fats and oils.

Costs

49. The costs associated with this option would fall 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.

50. 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, 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 explained in paragraph 7 above, 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.

51. 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 may 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.

52. The UK compound feed industry made some calculations of the possible costs to feed compounders 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 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 potential cost to the UK compound feed industry of this testing was therefore estimated as around £3 million a year.

53. For reference purposes, 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 256,000 tonnes (split between crude oils (mainly soya oil) of 150,000 tonnes and processed oils of 106,000 tonnes).

Direct sales of feed materials to livestock farmers 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 say what quantities may be involved (although it is thought that they are likely 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.

54. However, the cost calculations set out in paragraphs 51-52 would not be proportionate to the actual risks -- firstly because 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 because 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 because 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 represent an efficient allocation of resources.

55. 100% testing would therefore have amounted to "gold-plating", imposing (as indicated at paragraph 25 above) excessive administrative and financial burdens on the affected businesses, tasking the laboratories contracted to undertake the testing with additional work for which they had not or could not develop the capacity, and leading to delays in uncovering and reporting non-compliant results. In such cases, the delay could be such that contaminated product may have already entered the feed supply chain, with potential consequences similar to those outlined in paragraphs 36-37 above.

56. As explained in paragraphs 23-24 above, 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 would also mean 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 suggest 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.

57. This would mean 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 £7,800 and £8,400. This increase would be 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 However, increasing the fee payable for approvals would be inconsistent with the government's policy of minimising or reducing the administrative burdens on business, and may also be particularly unhelpful in the current economic conditions which business in general currently faces.

58. For these reasons, the option of 100% Sampling and Analysis plus the Introduction of Fees for Approval of these Businesses at Increased Levels is not supported.

Option 4 -- Approval of Establishments Producing or Processing Fats and Oils and 100% Sampling and Analysis of all Fats and Oils, plus the Introduction of Fees for Approval of these Businesses at their Existing Levels

Benefits

59. Most of the benefits from this option would accrue to the human consumers of animal products (meat, milk and eggs), who would be assured 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 is also the possibility, raised in paragraph 55 above, that 100% testing could lead to delays in uncovering and reporting non-compliant results, with the possible consequence that contaminated product may have already entered the feed supply chain. In any case, few if any benefits would be derived by the feed industry, which would have to bear the costs of monitoring for dioxins and dioxin-like PCBs at every stage of the use of certain fats and oils.

Costs

60. The costs to feed business operators of 100% sampling and analysis would be the same as those set out in paragraphs 51-52 above.

61. 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 is both manufacturing and placing products on the market or placing products on the market only.) On the assumption that there are a dozen establishments operating in this sector of the feed industry, the total saving to industry would be between £2388 (assuming that all the establishments are placing products on the market only) and £2988 (assuming that all establishments are both manufacturing placing products on the market). This would represent 0.8% to 0.9% 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. The costs of 100% sampling and analysis would thus vastly exceed any saving from retaining the fees for approvals at their existing levels.

62. There could also be a cost to local authorities, which might not recover the full costs of the inspection work necessary before an establishment can 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 plus the Introduction of Fees for Approval of these Businesses at their Existing Levels is not supported.

Option 5 -- Approval of Establishments Producing or Processing Fats and Oils and Risk-Based Sampling and Analysis of Certain Fats and Oils, plus the Introduction of Fees for Approval of these Businesses at Increased Levels

Benefits

63. The benefits associated with this option would accrue to local authorities, who would be reimbursed for the full costs of the inspection work necessary before an establishment can be approved to undertake its activities; to the human consumers of animal products (meat, milk and eggs), who would be assured 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 benefit from the fact that the costs of monitoring for dioxins and dioxin-like PCBs would fall mainly on their producers and processors rather than themselves.

Costs

64. The proposal 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 will be lower. Under this option, the costs would fall 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.

65. The costs to the producers and processors of certain fats and oils of testing these materials -- because sampling will be necessary only for incoming consignments -- will be around half of the figures set out in paragraph 51.

66. 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 46 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 would therefore be around £58,000 a year.

67. In any case, the additional costs to all sectors of 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 costs to the feed and livestock industries, national and local government authorities, and public health.

68. However, the arguments against introducing fees for the approval of the affected businesses at the increased levels are the same as those set out in paragraph 57 above. For this reason, the option of Risk-Based Sampling and Analysis plus the Introduction of Fees for Approval of these Businesses at Increased Levels is not supported.

Option 6 -- Approval of Establishments Producing or Processing Fats and Oils and Risk-Based Sampling and Analysis of Certain Fats and Oils, plus the Introduction of Fees for Approval of these Businesses at their Existing Levels

69. The arguments in respect of risk-based sampling and analysis are the same as those set out in paragraphs 64- 66 above, while the arguments in respect of introducing fees for approval at their existing levels are the same as those set out in paragraphs 27-28 above. For these reasons, the option of Risk-Based Sampling and Analysis plus the Introduction of Fees for Approval of these Businesses at their Existing Levels is the one supported.

Risks and Assumptions

Risks

70. Approval of an establishment following an inspection, and (if necessary) any capital and other investment by a feed business operator in new equipment and procedures if an inspection shows that such is necessary to achieve the required standards, cannot in itself safeguard against fraud or other deliberate criminal activity, such as the mixing of feed grade with

technical oils which is thought to have been the cause of the German incident. However, this is true of all legislative measures, and is not therefore specific to this particular case.

71. A lesser risk is that feed business operators who -- following an inspection which has identified gaps and oversights in the supply and production chains -- cannot or will not meet the costs of investment in new equipment and procedures may have to switch to other activities, with consequent adaptation costs, or even cease trading altogether. It could be argued, however, that this will help protect the integrity of the feed supply and production chains because it would remove potential sources of risk which, if they were the cause of a subsequent contamination incident, would result in higher costs for all feed business operators, including end-users of the fats and oils (e.g. feed compounders and livestock farmers), and for the human consumers of animal products (milk, meat and eggs).

72. An additional risk is that there may be inconsistencies in understanding of the new requirements for the monitoring of fats and oils for dioxins and dioxin-like PCBs amongst the feed industry, laboratories and enforcement authorities, with consequent inconsistencies in the reporting of results and action taken in the event of suspected breaches. Consideration of these requirements has already shown that there are a number of questions outstanding, for example over levels of quantification, reporting arrangements for laboratories, the destination of material which may have a dual use, whether distillation at source (in particular by a third country exporter to the EU) qualifies as processing, and whether mixtures of fats of various sources should be regarded as compound feeds. Draft guidance for the use of all parties on these and allied issues has therefore been developed and forms part of the public consultation on the implementation of the measure. Consultees will be invited to suggest any additional queries about the application of these monitoring requirements which might be included in the finalised version of the guidance.

Assumptions

73. It is considered highly unlikely that any of the producers and processors of certain fats and oils to whom Regulation 225/2012 applies will be unable to meet the standards required for approval of their activities. This assumption is based on the informal consultation with the feed industry which took place both during the negotiations on the measure and subsequently. The affected businesses have also confirmed that the requirements for approval are very similar to those currently laid down by the Feed Materials Assurance Scheme (FEMAS), one of the key industry assurance schemes operated by the Agricultural Industries Confederation (AIC, the main trade association). This provides further assurance that the affected businesses will be able to -- and already do -- meet the required standards.

74. Two further assumptions follow from this. Firstly, that the requirements for approval will not be so onerous as to cause any of the affected businesses to cease trading and exit the sector; and, secondly, there will be no new obligations (such as investment in new equipment, training of personnel in new procedures, or revision of existing HACCP plans) laid on the affected businesses as a consequence of the introduction of the approval of their activities.

75. It is also assumed that the draft guidance referred to at paragraph 70 above, which has been developed in co-operation with both feed industry and enforcement interests, will be sufficient to resolve the existing queries about the operation of the new monitoring requirements and capable of being revised from time to time to address any new issues which may arise.

76. 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.

77. It is further assumed that the requirement for laboratories to report non-complying results will not incur significant costs to them, and that any minor costs which may arise will be more than offset by the income generated from the additional analyses they will be requested to undertake.

One In, Two Out Policy

78. Regulation 225/2012 is not within the scope of One In Two Out policy, and identification of savings equivalent to twice the burden of the estimated costs to business is not therefore required.

Wider Impacts

Economic and Financial

79. Flat fees for approvals, as explained in paragraph 12 above, would clearly fall more heavily on small and medium-sized than on larger businesses. However, it is thought that in this case none of the affected businesses, although individually not particularly large, would fall to be defined as small and medium-sized enterprises. The actual costs to each of the affected businesses of sampling and testing certain fats and oils of vegetable and marine origin will depend on the volumes and types of these fats and oils they handle; however, these costs are not expected to fall disproportionately on one or more firms than on any others, and in consequence the likely impact on competition, and thus on the number of firms producing and processing these fats and oils, will be insignificant. There will be no impact on other sectors of the economy. There are no financial or resource implications for national government, although there may be some implications for local government given that the retention at their existing levels of the fees for approvals could mean trading standards departments do not recover the full costs of the inspection work they undertake.

Social

80. There will no impacts on existing health, wellbeing or other social inequalities, on human rights, on levels of crime or crime prevention, or on skills and education. There will be no differential impact on rural or urban areas vis-a-vis the other, nor will there be any specifically local or regional effects.

Environmental

81. It is possible that there could be some environmental side-effects from the introduction of the requirement to test certain fats and oils of vegetable and marine origin for dioxins and dioxin-like PCBs, because consignments of these materials found to be in breach of the permitted maxima will need to be disposed of outside the feed chain -- either by incineration for biofuel purposes, by disposal to landfill, or by redespach to the country of origin. The exact environmental impacts -- for example, increased emissions of greenhouse gases from transport vehicles, or adverse impacts on air quality or water tables -- will depend on the number of breaches found and the route chosen for the disposal of the contaminated material. However, it might be expected that the number of breaches -- and thus their environmental impacts -- will fall over time as testing identifies the most prevalent geographical sources of contaminated fats and oils, resulting in their exclusion from the feed chain.

Enforcement

82. 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) (England) 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 (i.e., in a magistrate's court), or a fine and/or imprisonment for up to two years for conviction on indictment (i.e., in a higher court).

83. 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) (England) Regulations 2005, as the existing enforcement provisions are considered to be sufficient to encompass the requirements of Regulation 225/2012.

Summary and Preferred Option with Description of Implementation Plan

Summary

84. Regulation 225/2012 has been introduced to require the approval of producers and processors of certain fats and oils; to ensure the segregation of fats and oils intended for feed use from those for a non-feed use; to set down risk-based criteria for the sampling of certain consignments of these fats and oils for dioxins and dioxin-like PCBs; and to require that laboratories report non-compliant analyses to competent authorities as well as the owner of the sample sent for analysis. The intention is to help prevent feed contamination incidents such as that which occurred in Germany in December 2010-January 2011, when fatty acids of vegetable origin for use in pig and poultry feed were mixed (fraudulently or negligently) with fats derived from an industrial use containing high levels of dioxins, and which 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.

Preferred Option

85. Five options have been considered alongside the Do Nothing option (option 1). These are Self-Regulation by the industry (option 2); 100% Sampling and Analysis plus the Introduction of Increased Fees for Approvals (option 3); 100% Sampling and Analysis plus the Introduction of Fees at their Existing Levels (option 4); Risk-Based Sampling and Analysis plus the Introduction of Increased fees for Approvals (option 5); and Risk-Based Sampling and Analysis plus the Introduction of Fees at their Existing Levels (option 6). As explained at paragraphs 16-32 above, all bar option 6 have drawbacks:

- option 1 would not help prevent future instances of contamination of the kind discussed in paragraphs 1-4 above;
- option 2 would not ensure either that producers and processors of certain fats and oils of vegetable and marine origin had the necessary equipment and procedures in place or undertook relevant risk-based testing of these materials;
- option 3 would require certain establishments to be approved for their activities under the Feed Hygiene Regulation and to segregate material intended for feed use from that intended for a non-feed use, but (a) the sampling and analysis regime would be administratively and financially burdensome for both feed business operators and the laboratories carrying out the testing work, and (b) the increased fees would not be

consistent with the government's policy of minimising or reducing the administrative burdens on business;

- option 4 would impose the same requirement to be approved and the same 100% sampling and analysis regime, but the saving from retaining the fees for approvals at their existing levels would be a minor fraction of a percentage of the costs of testing; and
- option 5 would be in line with the risk-based sampling and analysis requirements of Regulation 225/2012 but an increase in fees would again be inconsistent with the drive to reduce administrative burdens.

Option 6 would therefore be in line with the requirements of Regulation 225/2012, ensuring a more focused programme of sampling and analysis of the most high-risk fats and oils and, by introducing fees for the approval of the affected businesses at their existing levels, would help constrain the administrative burdens on business.

Implementation Plan

86. The requirements of Regulation 225/2012 will be implemented by means of an amendment to the Feed (Hygiene and Enforcement) (England) Regulations 2005. However, it is considered that good policy-making requires that government departments check whether the policy objectives have been achieved and whether the low-cost criteria have been met; a proportionate post-implementation review will therefore be undertaken not less than two years after the amending regulations have come into force.

87. Regulation 225/2012 requires the Commission to undertake a review of the effectiveness of the dioxin-monitoring provisions two years after its adoption (i.e. by March 2014).

SPECIFIC IMPACT TESTS

Note: the Health and Wellbeing specific impact test is not in the list, because the whole of an FSA IA focuses on food safety in the health context.

| Type of test and link to guidance (Double click on each of the headings to follow link) | Click on a box for EACH row to show if the test is relevant or not: | |
|---|---|-------------------------------------|
| | Relevant | Not relevant |
| Competition assessment | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Small firms impact test | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Sustainability: Economic impact Social impact Environmental impact | <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> | |
| Carbon impact | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Equality impact | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Justice impact | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Rural proofing | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Human rights | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Privacy impact | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Creation of new criminal offence * | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Impact on powers of entry | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

* Consideration of this will be included in the final, post-consultation impact assessment.