Food Standards Agency
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Buidheann Inbhe-Bìdhe

EXECUTIVE NOTE

THE CONTAMINANTS IN FOOD (SCOTLAND) REGULATIONS 2010
S.S.I. 2010/329

1 Description

1.1 The above instrument was made in exercise of the powers conferred by sections 16(1)(a), (e) and (f), 17(2), 26(1)(a) and (3), and 48(1) of the Food Safety Act 1990 and paragraph 1A of Schedule 2 to the European Communities Act 1972. The instrument is subject to negative resolution procedure.

2 Policy Objective

2.1 This instrument provides for the enforcement in Scotland of the provisions of Commission Regulation (EU) No. 165/2010, amending Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins ("the Commission Regulation").

2.2 This instrument provides for offences of contravening certain provisions of Regulation (EC) No. 1881/2006 as most recently amended by the Commission Regulation and for defences in particular circumstances against prosecution for committing an alleged offence and specifies the penalties that the Courts may impose upon conviction for an offence.

2.3 This instrument will also revoke the Contaminants in Food (Scotland) Regulations 2009[1].

3 Matters of special interest to the Subordinate Legislation Committee (SLC)

3.1 None

4 Legislative Context

4.1 European Union (EU) legislation on contaminants in food is made under the contaminants framework Regulation 315/93/EEC ("the framework Regulation). This Regulation lays down the EU procedures for dealing with contaminants in food and it applies general requirements to those contaminants that are not covered by other specific EU legislation. In order to continue reducing the disparities between the existing laws of Member States with regard to maximum limits for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Commission Regulation (EC) No. 1881/2006 was introduced under the framework Regulation to ensure market unity while complying with the principle of proportionality. The provisions and requirements of Commission Regulation 1881/2006 (and its predecessor Regulation (EC) No. 466/2001) have applied across the EU since April 2002.

[1] SSI 2009 No. 215

4.2 The Commission Regulation was published in the Official Journal (OJ) of the EU on 27th February 2010[2], came into force on 8th March and applied as from that date. The Regulation aligns EU limits for total aflatoxins in hazelnuts, almonds and pistachios with those agreed at the Codex Committee on Contaminants in Food (CCCF) in 2008 and the same limit for Brazil nuts, which has now been agreed at CCCF in 2010

5 Territorial Extent and Application

5.1 This instrument applies in relation to Scotland only. Separate but parallel legislation is being made in England, Wales and Northern Ireland.

6 European Convention on Human Rights

6.1 This instrument does not raise any issues regarding The European Convention.

7 Consultation

7.1 The Food Standards Agency has consulted with stakeholders including industry, trade bodies, enforcement bodies and other Government departments throughout the development and negotiations of these measures.

7.2 Two hundred and sixty two stakeholders were consulted by FSA Scotland and one response acknowledges receipt was received.

7.3 However the equivalent consultation in England produced three relevant responses one from the Food and Drink Federation (FDF), one from the East of England Trading Standards Association (EETSA) and one from the Trading Standards Institute (TSI).

7.4 The EETSA agreed with the Agency's assessment that one hour is a sensible estimate for enforcement officers to familiarise themselves with the new requirements. EETSA also agreed with the Agency's assessment that there were no new or additional administrative burdens on businesses or enforcement authorities associated with the new Regulations or the European Regulation.

7.5 The TSI, in response to the specific questions on familiarisation costs, also supported the Agency's assessment that the proposal did not introduce new or additional costs for enforcement bodies, other than familiarisation costs. The TSI further agreed with the Agency's assessment that one hour for familiarisation and a further hour for reading the new Regulations was a reasonable estimate. However, they were unable to comment on familiarisation costs for industry.

7.6 The FDF commented that they circulated the consultation documents on the proposed Regulations to members of the FDF's Residues and Contaminants Committee; however, no comments were received from their members, FDF indicated that the Committee and its members had monitored the development and publication of the underlying EU legislation and were already aware of the issues covered by the consultation.

[2] OJ L50, 27.02.2010 p. 8-12

8 Financial Effects

8.1 Any impact on businesses from these regulatory proposals is likely to be for familiarisation costs associated with the proposed Regulations. These include the reading and dissemination of the Regulations to key staff within the organisation. This view has been supported both by the EETSA and the TSI, who have also indicated that the proposal did not introduce new or additional costs for enforcement bodies. These proposals have no particular impact on, charities or voluntary bodies, rural areas nor on members of the ethnic communities of any particular racial group.

8.2 Whilst the Regulations are not specifically aimed at any one type of food business, the proposed Regulations apply to any food business operator involved in placing on the market products covered by the European Regulation, i.e. almonds, hazelnuts and pistachios and other commodities. Thus, importers, distributors, wholesalers, supermarkets etc are all responsible and it would be the responsibility of individual businesses to ensure compliance with the Regulations at the relevant point within the supply chain. However, the primary business sectors likely to be affected by these proposals will be those that manufacture breakfast cereals and cereal-based foods, oils and fats and margarine and similar products, as well as importers of commodities such as tree nuts, oil seeds and oil seed oils, rice and apricot kernels. For these sectors, there will be a small one-off cost for reading and familiarising themselves with the new Regulations.

8.3 The impact on the public sector is believed to be minimal. However, there may be an impact on the Food Standards Agency as and when it carries out surveys on foods. This impact may involve having to carry out more research into the official controls on chemical contaminants, including work to establish methodologies for determining such migration and to ensure compliance with the legislation.

8.4 A Business and Regulatory Impact Assessment is attached to this memorandum.

9 Regulating small business

9.1 The contaminants in food legislation will apply to all businesses small and large.

9.2 The impact on small and medium sized businesses is unlikely to be significant. This view has been supported by industry following earlier consultations, when they indicated that the proposals would not disproportionately affect them, nor would they hinder competitiveness. Such businesses are also encouraged to respond to issues which they feel may have an impact on their ability to compete in the wider market. To date no comments have been received from small businesses.

10 Monitoring & review

10.1 The Agency will aim to review the Regulations in 2011. Local Authorities are responsible for enforcing much of the food safety legislation, including the maximum levels for contaminants in food. Convention of Scottish Local Authorities (COSLA) and the Association of Public Analysts are consulted specifically through established liaison mechanisms and provide feedback to the Agency about the effectiveness of these instruments. Businesses operators act similarly through their representative bodies and directly in response to consultation mechanisms.

10.2 Local authorities in Scotland routinely monitor foodstuffs on sale to the public to ensure compliance with the Regulations. The results of this work carried out by the Agency are published and are openly available on the Agency's website at:

http://www.food.gov.uk/enforcement/monitoring/

10.3 The European Commission investigates whether limits should be set for additional contaminants and also reviews the maximum limits for those contaminants currently in the legislation and the foods that are subject to control. Such limits may be moved upwards or downwards in the light of ongoing monitoring and of advances in scientific knowledge within the EU as a whole.

10.4 The Agency will also work with enforcement authorities where problems or suspected infringements of the Regulations arise. The effectiveness of the Regulations will be also be monitored via feedback from stakeholders as part of the ongoing policy process.

Food Standards Agency in Scotland
13 Sept 2010

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BUSINESS AND REGULATORY IMPACT ASSESSMENT

Title of Proposal

1. The Contaminants in Food (Scotland) Regulations 2010.

Policy Objective

To continue to reduce the long term health risks to consumers in Scotland arising from chemical contaminants in food.

2. The aim is to reduce the long term health risks to consumers in Scotland arising from ingesting foods that may be contaminated by chemical contaminants, such as aflatoxins; by providing harmonised rules within which business can compete and to provide for the proper enforcement of EU harmonised Regulations that provide businesses with clear provisions that lead to safe products and increase consumer confidence. In view of the requirement to protect consumers' health by keeping contaminants at levels that are toxicologically acceptable, the European Commission investigates whether limits should be set for additional contaminants and reviews the maximum limits for those contaminants currently in the legislation and the foods that are subject to control. Scientific data has shown that reduction of total dietary exposure to aflatoxins could be achieved by reducing the number of highly contaminated foods reaching the market through more effective enforcement and reducing exposure from food sources other than almonds, hazelnuts and pistachios.

Background

3. The European Food Safety Authority's (EFSA) Scientific Panel on Contaminants in the Food Chain (Contam Panel) adopted an opinion on 25th January 2007 on the potential increase in risk to consumer health by a possible risk of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products. They concluded that a change in the maximum levels for total aflatoxins 4 to 8 or 10 µg/kg in almonds, hazelnuts and pistachios, would have minor effects on the estimates of dietary exposure, cancer risk and the calculated margins of exposure (MOEs). Furthermore, the Panel concluded that exposure to aflatoxins from all sources should be as low as reasonably achievable.

4. On 16 June 2009 the Panel adopted a statement on the effects on public health of an increase of levels for aflatoxin total from 4µg/kg to10µg/kg for tree nuts other than almonds, hazelnuts and pistachios. Based on the information that was available in 2007, the Panel concluded that public health would not be adversely affecting if the levels for total aflatoxins from 4µg/kg to 10µg/kg for other tree nuts, including Brazil nuts. Given the current discussions in Codex Alimentarius on the maximum levels for aflatoxins in Brazil nuts, it was considered appropriate to align the level for total aflatoxins in almonds, hazelnuts, pistachios with those agree at Codex Committee on Contaminants in Food in 2008. Separate limits for aflatoxin B1 are to be retained in the interim.

5. Aflatoxins are mycotoxins produced primarily by two species of *Aspergillus,* a fungus which is especially found in areas with hot and humid climates. Aflatoxins are known to be genotoxic and carcinogenic in some animal species and exposure through food should be kept as low as possible. Aflatoxins can occur in foods such as groundnuts, tree nuts, maize, rice, figs and other dried foods, spices, crude vegetable oils, and cocoa beans. They arise as a result of fungal contamination before and after the harvest.

6. Several types of aflatoxins are produced by nature. Aflatoxin B1 is the most common in food and amongst the most potent genotoxic carcinogenic aflatoxins. It is produced both by *Aspergillus flavus* and *Aspergillus parasiticus.* Aflatoxin M1 is a major metabolite of aflatoxin B1 in humans and animals, which may be present in milk from animals fed with feed contaminated by aflatoxin B1.

7. Codex Alimentarius established a level of 15 µg/kg aflatoxin total in almonds, hazelnuts and pistachios intended for further processing and a level of 10µg/kg aflatoxin total for almonds, hazelnuts and pistachios 'ready-to-eat'.

8. In the EFSA opinion on aflatoxins it is observed that oilseeds and derived products are an important contributor to the human aflatoxin exposure. EFSA concluded that exposure to aflatoxins from all sources should be as low as reasonably achievable. Furthermore, notifications in the Rapid Alert System for Food and Feed (RASFF) indicate high levels of aflatoxins in oilseeds such as sunflower seeds, melon seeds etc. It is therefore proposed to also set a maximum level for oilseeds other than groundnuts (peanuts), in line with the existing levels for groundnuts (peanuts). However, as aflatoxins are nearly completely removed by the process of producing refined vegetable oils, it appropriate to exclude oilseeds, including groundnuts (peanuts), intended for crushing for refined vegetable.

9. European Union (EU) legislation on contaminants in food is made under the contaminants framework Regulation, Council Regulation 315/93/EEC ("the framework Regulation"). This Regulation lays down the EU procedures for dealing with contaminants in food and it applies general requirements to those contaminants that are not covered by other specific EU legislation. In order to continue reducing the disparities between the existing laws of Member States in regard to maximum limits for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Commission Regulation (EC) No. 1881/2006 was introduced under the framework Regulation to ensure market unity while complying with the principle of proportionality. The provisions and requirements of Commission Regulation 1881/2006 (and its predecessor Regulation (EC) No. 466/2001) have applied across the EU since April 2002.

10. The intention of Commission Regulation 1881/2006 is to provide consumers with an increased measure of protection by setting maximum EU limits for mycotoxins and undesirable process and environmental contaminants in those foodstuffs that are significant contributors to the total dietary exposure of consumers to those contaminants. The Regulation aims to exclude seriously contaminated food from entering the food chain and harmonise Member States' existing measures, thus facilitating trade. Maximum levels for lead, cadmium, mercury, dioxins, polycyclic aromatic hydrocarbons (PHAs), nitrate, 3-MCPD, aflatoxins, ochratoxin A, patulin and inorganic tin have already been set under this legislation.

Rationale for Government Intervention

11. Contaminants in food can have an adverse effect on human health. Consumers are unable to assess the risks involved when consuming a product because they cannot observe the level of contaminants. In most cases it is difficult for Food Business Operators (FBOs) to credibly inform consumers of the degree to which this risk has been minimised. Therefore, consumers are unable to make informed choices about such risk. This information asymmetry implies a benefit from government intervention to minimise the risk posed to human health and provide greater clarity in enforcement.

12. These proposals fulfil the UK Government's policies of meeting its European Union (EU) obligations to bring into effect in law harmonised rules that:

    - reduce the chronic and acute health risks to consumers arising from chemical contaminants in the food they eat; and

- meet the intergovernmental Lisbon Agenda aimed at improving the competitiveness of businesses in Europe by providing harmonised rules that are not overly burdensome within which businesses can compete on an equal footing.

13. The Food Standards Agency (FSA) believes that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework that removes trade barriers and enhance consumer protection in an area of food control where inadequate controls could have serious long-term implications or are suspected of carrying an unacceptable risk to consumer health, particularly among vulnerable people.

14. The risk of contaminated products entering the market will be reduced by the new maximum levels set out in European Regulation (EU) No. 165/2010, amending (EC) Regulation No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins. Enforcement of these maximum levels will increase consumer protection. Having correct enforcement provisions for the revised limits on aflatoxins in almonds, in hazelnuts and pistachios will avoid confusion for enforcement authorities and avoid any potential barrier to trade that may occur, whilst maintaining protection of consumer health.

15. The requirements of Commission Regulation (EC) No. 1881/2006 and its amendments are directly applicable in all EU Member States from the date that they take effect. The UK therefore has a legal obligation to ensure that provisions are in place to provide for the enforcement requirements of the European legislation so as to give enforcement authorities in Scotland the appropriate powers with which to ensure compliance of food business operators with Commission Regulation (EC) No. 1881/2006 as amended. Similar, parallel legislation will be made in England, Wales and Northern Ireland.

16. The proposal for a Scottish Statutory Instrument (SSI) entitled The Contaminants in Food (Scotland) Regulations 2010 will provide for the enforcement of Regulation (EC) No. 1881/2006 as recently amended by Regulation (EU) No. 165/2010 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins in Scotland. The proposed Regulations will revoke the Contaminants in Food (Scotland) Regulations 2009 (SSI 2009 No. 215) and remake them with necessary amendments, taking into account the requirements of the EU Regulation 165/2010.

17. If the relevant changes to the Contaminants in Food (Scotland) Regulations 2009 were not made, this may lead to the impacts set out in paragraph 3.6 and may also create a barrier to trade across the EU. It would run counter to the important role the UK plays in agreeing EU harmonised measures and leave regulation of contaminants deficient in comparison with other EU Member States. It would also leave enforcement bodies without adequate statutory powers to prevent the placing on the market of those commodities which fail to meet the maximum limits laid down in the new Commission Regulation and thus increase consumers' exposure to risk.

Consultation

18. During the course of negotiations with the European Commission, officials of the FSA have kept other government departments and the devolved administrations informed of its progress including the Scottish Government. The UK fully supported the Commission's intention to relax the levels for aflatoxins almonds, hazelnuts and pistachios and other commodities. The final proposal was subsequently adopted by the Standing Committee on the Food Chain and Animal Health. To date no adverse comments have been received.

Public Consultation

19. The FSA has consulted with all of its stakeholders including industry, trade bodies, enforcement bodies and other government departments consistently during negotiations with the European Commission and other EU Member States on the amendments to Commission Regulation (EC) No. 1881/2006. For example, it has released several Interested Parties Letters, notifying stakeholders and these can be found at:

    www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/

20. Any comments received to date from stakeholders have been taken into consideration. Earlier consultation responses from businesses have encouraged the FSA to persist with its programme of formal and informal consultations on European contaminant legislation as it is being discussed and drafted.

Options

Option 1 – Do Nothing – Do not provide for the enforcement of the new Commission Regulation in Scotland

21. Doing nothing will not prevent the new Commission Regulation from applying in Scotland; it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enable them to enforce it. Therefore the obligation to put in place provisions for its enforcement, for offences to be prosecuted and for penalties for those found to be in breach of the new Commission Regulation would not be fulfilled. This would lead the UK Government being cited in infraction proceedings by the Commission and these could result in financial penalties being incurred.

Option 2 – Fully implement the necessary requirements and make appropriate domestic Regulations for the execution and enforcement that will support the European Regulation and provide for its enforcement.

22. Option 2 meets the Government's commitment to fulfil its EU obligations and contributes significantly to providing for the means of protecting consumers from ingesting harmful chemical contaminants in food. European Regulations are binding in their entirety and directly applicable in Member States from the date they take effect. The UK has a legal obligation to ensure that provisions are in place to provide for their enforcement in full. Failure to do so may result in infraction proceedings against the UK government. This option would also provide enforcement authorities with the necessary powers to enforce the new Commission Regulation. Also, local authorities will benefit from the greater clarity provided by the new Commission Regulation and from the power of enforcement devolved to them from these proposed Regulations.

Sectors and groups affected

23. Local authorities and industry will need to read and familiarise themselves with the new Regulations and take appropriate actions to achieve compliance.

Costs and benefits options

Benefits

Option 1 – Do Nothing

24. There are no identifiable incremental benefits for this option.

Option 2

25. This option would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of the new Commission Regulation in Scotland, which is binding in its entirety and directly applicable to all EU Member States.

26. Option 2 would also consolidate the important role that the UK plays in negotiating and agreeing standards for contaminants in food within the EU.

27. This option would also harmonise standards across the Member States and prevent any barrier to trade occurring as a result of there being different regulations in different Member States. This could encourage additional trade and introduce greater market competition with benefits for the wider UK economy. It is also anticipated that businesses will benefit financially as a consequence of maximum levels for aflatoxins in almonds, hazelnuts and pistachios being relaxed. This would reduce food wastage as fewer commodities are rejected and removed from the supply chain, reducing the marginal costs of Food Business Operators (FBOs). In a competitive market this would be reflected through lower consumer prices and an increase in consumer benefit. However, these benefits are unquantifiable as it depends on the size and type of business including the volume of and profit from production.

Costs

Option 1

28. This option is the baseline for comparison

Option 2

Costs to Enforcement Authorities

29. There will be a small one-off cost to businesses and enforcement authorities for reading and familiarising themselves with the new Regulations. The enforcement of food law is devolved to the enforcement authorities.

30. Each Local Authority (LA) in its area is responsible for enforcing the legislation with respect to food safety and food hygiene. They have responsibility for enforcing the contaminants in food legislation and will, as outlined above, be affected by these proposals. The FSA believes that the incremental costs to enforcement authorities are unlikely to have a significant cost impact and is likely to be minimal, if any. Local Authority enforcement bodies have always had responsibility for the enforcement of chemical contaminants legislation. The proposed Regulations for Scotland merely provide the means by which this role can be extended to cover the new Commission Regulation.

31. There are a total of 32 (LAs) in Scotland that will be affected by the Regulations. It is expected that one Environmental Health Officer (EHO) from each LA will read the Regulations and disseminate the information to key staff. We estimate that each EHO will invest one hour reading and familiarising themselves with the Regulations and a further hour disseminating to key staff in the organisation; meaning a total of two hours for familiarising.

32. A wage rate of £20.70[1] has been applied to EHOs which equates to a one-off familiarisation cost £1324.80 for LAs in Scotland. Table 1 displays the one-off familiarisation cost for Enforcement Authorities for the UK. While this legislation applies only to Scotland, similar incremental familiarisation costs are assumed for the other UK countries.

[1] Wage rate obtained from The Annual Survey of Household Earnings (2009) (http://ww.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage for 'Environmental health officers' is used (£20.70 including 30% overheads).

Table 1 – Familiarisation costs for Enforcement Authorities

Region	Local Authorities
England	£17,716
Wales	£911
Scotland	£1,325
N. Ireland	£1,076
UK	£21,027
Rounded*	**£21,000**

*Totals may not sum due up to rounding

Costs to Industry

33. The affected industries themselves will determine the extent and regularity with which they check compliance with the new maximum levels, as they currently do with the existing maximum levels.

34. Whilst the Regulations are not specifically aimed at any one type of food business, however, the proposed Regulations apply to any food business operator involved in placing on the market products covered by the Commission Regulation, i.e. almonds, hazelnuts and pistachios and other commodities. Thus, importers, distributors, wholesalers, supermarkets etc are all responsible and it would be the responsibility of individual businesses to ensure compliance with the Regulations, within the supply chain.

35. The primary businesses sectors likely to be affected by these proposals will be those that manufacture breakfast cereals and cereal-based foods; oils and fats; margarine and similar edible fats; importers of commodities such as, treenuts, oil seeds and oil seed oils, rice and apricot kernels. For these sectors, there will be a small one-off cost for reading and familiarising themselves with the new Regulations.

Table 2 – Number of UK Businesses Affected by the Regulations

Summary of firms by size	Micro	< 20	Small	Medium	Large	Total
England	408	63	95	36	28	630
Wales	26	4	6	2	2	40
Scotland	52	8	12	5	4	80
N. Ireland	29	5	7	3	2	45
UK*	**515**	**80**	**120**	**45**	**35**	**795**

*Totals may not sum up due to rounding

Notes:

- Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees; <20 – 10-20 employees; Small 20-49 employees; Medium – 50-249 employees; Large – more than 250 employees.
- Distribution of premises by employees' size is available only at UK level, for individual regions of the UK distribution of premises by size is applied by the total number of premises in each region.

- We have estimated that such businesses will typically invest one hour reading and familiarising themselves with the new single set of Regulations. In addition, we have estimated that each person uses a further hour for dissemination to key staff within the organisation, meaning a total of two hours.
- To calculate the familiarisation cost for businesses a wage rate of £25.19[2] has been applied to the employee who reads and familiarises themselves with the Regulations. The wage rate is multiplied by the number of businesses affected by the Regulations, which is then multiplied by the reading and dissemination time. This equates to a one-off familiarisation cost to industry in Scotland of £4030.40. Table 3 displays the one-off familiarisation cost to industry broken down by region.

Table 3 – Familiarisation costs to industry in the UK

Region	Industry
England	£31,744
Wales	£2,016
Scotland	£4,031
N. Ireland	£2,267
UK	£40,058
Rounded*	£40,000

*Totals may not sum up due to rounding

Impact on other Government bodies

36. Government departments, such as the FSA may also be affected as and when they carry out any surveys on foods. This impact may involve having to carry out more research on chemical contaminants in food, including work to establish methodologies for determining such contamination and to ensure compliance with the legislation. These are carried out to inform consumers, monitor trends and assess dietary exposure to harmful contaminants in food.

Consultation question

Whilst the FSA believes that OGD's are unlikely to be affected by these proposals, we would welcome comments if you feel that the proposals affect any research programmes in the area of chemical contaminants. Please provide evidence to support your views.

Administrative Burden Costs

37. The cross-Government ABME in 2005 measured the administrative burdens for Regulations on businesses using the Standard Cost Model. The FSA believes that these proposals place no new administration burdens on businesses. Interested parties will already be aware of the maximum levels for aflatoxins introduced by the new Commission Regulations, as they have been consulted via interested parties letters on the possible implication of the EU measures under the 'rapidly developing policy' section on the FSA's website. Copies of the draft documents have been made available for comments and views. The latest update of the letter was published on 16th March and can be accessed at the following link:

    http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/contaminants

[2] Wage rate obtained from The Annual Survey of Household Earnings (2009 (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Production Manager' is used (£25,19 including 30% overheads)

Policy costs

38. The FSA believes that there are no new or additional policy and administration costs associated with the proposed Scottish Statutory Instrument that is the specific subject of this business and regulatory impact assessment and that will provide for the enforcement provisions. The benefits of complying with the levels in the EU measure do not represent any new compulsory action.

> **Consultation questions:**
>
> **(1).** It is our assumption that there is a familiarisation cost for enforcement authorities associated with the proposed Regulations. We invite enforcement authorities to comment on our estimated of as one hour for familiarisation and a further hour for reading the new Regulations. If you disagree with this assessment, please provide evidence to support your views.
>
> **(2).** It is our assumption that there is a familiarisation cost for industry associated with the proposed Regulations. We invite businesses to comment on our estimated of one hour for familiarisation and a further hour for reading the new Regulations. If you disagree with this assessment, please provide evidence to support your views.
>
> **(3).** Is our assumption that there are no new or additional administrative burdens associated with the proposed Regulations. Is this an accurate assessment for both enforcement authorities and businesses? If you disagree, please provide evidence to support you views.

Small Firms Impact Test

39. Stakeholders, including the Enterprise Directorate in BIS, the Federation of Small Businesses and small businesses themselves, including those that are members of trade associations, have been consulted throughout the negotiations on the legislation via interested parties' letters. Small businesses will continue to have the opportunity to put forward their views throughout the consultation procedure and we very much welcome representation from them and their representative organisations. Any potential additional costs arising from checking compliance with the maximum levels will be proportionate to small businesses. It is the responsibility of individual business operators to show how they satisfy compliance with the food law, which may include having systems in place to try and ensure their supplier is providing them with products that are compliant. For example, this may require that businesses specify requirements to be met by their supplier prior to receiving the product to ensure that their products are not contaminated above the permitted limits and would therefore not impact disproportionately on SMEs.

Competition Assessment

40. We fully considered the questions posed in the Office of Fair Trading competition assessment test (http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft876.pdf) and have concluded that the proposed Regulations that implement the enforcement provisions of the new Commission Regulation are unlikely to hinder the number or range of businesses or the ability of operators to compete. As such, the proposals are unlikely to significantly affect competition. The proposals do not contain a strong competition element or any significant new or additional burden. This is not expected to result in any reduction or change in businesses operating in this area, nor in their competitiveness or incentive to compete.

41. There is no current requirement for industry to carry out sampling and analysis within Commission Regulation 1881/2006, as amended. However, it may wish to do so (and may already be doing so) when carrying out its existing programme of checks for contamination in excess of legal limits to gain the protection of 'due diligence' defence under section 21 of the Food Safety Act 1990. This is applicable to all food businesses operating in the import, production, processing, storage, distribution and sale of food and in this respect is not likely to have a disproportionate effect on any business or group of businesses.

Environmental Impact

42. The FSA's remit is to protect the interest of consumers in relation to food safety, both now and in the future. In doing so, the FSA will take sustainable development into account in all of its activities and policy decisions.

Enforcement

43. The purpose of The Contaminants in Food (Scotland) Regulations 2010 is to provide enforcement authorities with the necessary powers to prevent contaminated products from entering the market. They have done so with respect to the maximum levels for contaminants since 2002. Thus the proposed Regulations on which we are consulting will provide the means by which this role can be extended taking into account the new requirements for enforcement of the new Commission Regulation.

Sanctions

44. The criminal sanctions in the current Contaminants in Food (Scotland) Regulations 2009, as amended, would apply in the case of prosecution against those in breach of the new Regulations. This is currently a fine not exceeding level 5 on the standard scale.

Simplification

45. The policy of maintaining a simplified set of Regulations is being continued. For this reason, rather than implementing the enforcement provisions of the European Regulation by amending the 2009 Regulations mentioned above, those Regulations will be revoked and re-made in a consolidated instrument that includes the measures introduced by the new Commission Regulation. This will ensure that we continue to keep to a minimum the number of instruments to which stakeholders such as business operators and enforcement authorities need to refer.

Sustainable development

46. Impacts under the three pillars (environmental, economic and social) of sustainable development have been and continue to be considered in the preparation of this Business and Regulatory Impact Assessment. The FSA's remit of consumer protection in relation to food safety continues to be paramount both now and in the future. Option 2 is relatively more sustainable, as businesses will benefit financially as a consequence of the maximum levels for aflatoxins in almonds, hazelnuts and pistachios being relaxed. This could result in fewer commodities being removed from the supply chain; this in turn would lead to a reduction in food wastage. The proposal will have a positive impact for businesses economically, whilst maintaining a high level of consumer safety. The impact in terms of financial costs will be a one-off cost, in familiarising and reading the new Regulations for Scotland. The proposal

would have little if any impact on the delivery of the Government's five principles of sustainable development, on the environment or in relation to public health.

Race/Gender/Disability issues

47. The FSA believes that the proposal will have no impact on race, gender or disability equality issues. Charities and voluntary organisations are also unlikely to be affected by these proposals.

Review of implementation

48. FSA will continue to regularly communicate with industry through interested parties letters to ensure that no unforeseen difficulties arise from the proposed Regulations.

49. To ensure new maximum levels continue to provide an appropriate level of protection for consumers and are achievable by industry, the FSA will review progress on how the new levels on aflatoxins are being complied with by FBOs

50. Commodities on the market will be surveyed to ensure compliance with the Regulations. The FSA will work with enforcement authorities where problems arise or suspected infringements of the Regulations arise. The effectiveness of the proposed Regulations will also be monitored via feedback from stakeholders as part of the ongoing policy process.

Declaration and publication

51. I have read the business and regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed ……..

Date …….

SHONA ROBISON

MINISTER FOR PUBLIC HEALTH & SPORT,

HEALTH AND WELLBEING DIRECTORATE