

**EXPLANATORY MEMORANDUM TO**  
**THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2010**

**2010 No. 2228**

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.
2. **Purpose of the instrument**
  - 2.1 This instrument provides for the enforcement in England 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 (England) Regulations 2009<sup>1</sup>.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
  - 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.
  - 4.2 The Commission Regulation was published in the Official Journal (OJ) of the EU on 27<sup>th</sup> February 2010<sup>2</sup>, came into force on 8<sup>th</sup> 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

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<sup>1</sup> SI 2009 No. 1223

<sup>2</sup> OJ L50, 27.02.2010 p. 8-12

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 England only. Separate but parallel legislation is being made in Scotland, Wales and Northern Ireland.

## **6. European Convention on Human Rights**

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## **7. Policy background**

- *What is being done and why*

7.1 The European Food Safety Authority's (EFSA) Scientific Panel on Contaminants in the Food Chain (Contam Panel) adopted an opinion on 25 June 2007 on the potential increase in risk to consumer health by a possible raising of the existing maximum permitted levels for aflatoxins in almonds, hazelnuts and pistachios and derived products. They concluded that a change in the maximum levels, from 4 µg/kg 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). At the same time, the Panel concluded that exposure to aflatoxins from all sources should be as low as reasonably achievable.

7.2 On 16 June 2009 the Panel adopted a statement on the effects on public health of an increase of levels for total aflatoxins from 4µg/kg to 10µg/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 affected if the levels for total aflatoxins were to be raised from 4µg/kg to 10µg/kg for other tree nuts, including Brazil nuts. Given the discussions in the Codex Alimentarius on the maximum levels for aflatoxins in Brazil nuts, it was considered appropriate to align the levels for total aflatoxins in almonds, hazelnuts, pistachios with those agreed at Codex Committee on Contaminants in Food in 2008.

7.3 In the EFSA opinion on aflatoxins it is observed that oilseeds and derived products are an important contributor to the human aflatoxin exposure. 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 has therefore also been agreed to 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 is appropriate to exclude oilseeds, including groundnuts (peanuts), intended for crushing for refined vegetable oils.

- ***Consolidation***

7.4 The policy of maintaining, so far as possible, a unified set of Regulations is being continued. For this reason, rather than implementing the enforcement provisions by amending the 2009 Regulations mentioned in paragraph 2.3, those Regulations will be revoked and re-made, with necessary amendments in a consolidated instrument that includes provisions for enforcement of the 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.

## **8. Consultation outcome**

8.1 The Food Standards Agency fully consulted 800 stakeholders on these proposals and on the draft Regulations to provide for their enforcement. These included sector-specific stakeholders, such as manufacturers of breakfast cereals and cereal-based foods, oils and similar edible fats, as well as importers of commodities such as tree nuts, oil seeds and oil seed oils, rice and apricot kernels. Enforcement bodies, other government departments, consumer organisations, non-government organisations and others with an interest in chemical contaminants in foods were also consulted. The process was carried on consistently during negotiations with the European Commission and other EU Member States on the amendments to Commission Regulation 1881/2006.

8.2 Stakeholders, in particular enforcement bodies, were asked to comment with supporting evidence on the cost of enforcing the new legislation and on the assumptions that it will take 1 hour for enforcement authorities and businesses to read and familiarise themselves with the new Regulations and a further hour to disseminate to key staff within their respective organisations. They were also asked to comment on any other costs associated with the Commission Regulation and or the new Regulations and whether they introduce any additional burden.

8.3 Three responses were received; 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).

8.4 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.

8.5 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.

- 8.6 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, the 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.

## **9. Guidance**

- 9.1 Existing guidance for business will be updated to take into account the new revised limits for aflatoxins in almonds, hazelnuts, pistachios and other commodities. The revised Guidance will be published on the Agency's website at:  
<http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/plasticsguidance>

## **10. Impact**

- 10.1 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 or on members of the ethnic communities of any particular racial group.
- 10.2 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 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 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.
- 10.3 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.
- 10.4 An Impact Assessment is attached to this memorandum.

## **11. Regulating small business**

- 11.1 The contaminants in food legislation will apply to all businesses small and large.
- 11.2 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.

## **12. Monitoring & review**

- 12.1 The Agency will aim to review the Regulations in 2011. Local Authorities and Port Health Authorities are responsible for enforcing much of the food safety legislation, including the maximum levels for contaminants in food. Local Government Regulation (formerly LACORS), the Association of Port Health Authorities 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.
- 12.2 Central and local authorities in England 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/science/research/researchinfo/contaminantsresearch/>
- 12.3 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.
- 12.4 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.

## **13. Contact**

- 13.1 Nasreen Shah, Tel: 020 7276 8553, Email: [nasreen.a.shah@foodstandards.gsi.gov.uk](mailto:nasreen.a.shah@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

<b>Title:</b> <b>The Contaminants in Food (England) Regulations 2010</b> <b>Lead department or agency:</b> The Food Standards Agency <b>Other departments or agencies:</b>	<b>Impact Assessment (IA)</b>
	<b>IA No:</b> FOODSA 0012
	<b>Date:</b> 1 <sup>st</sup> August 2010
	<b>Stage:</b> Final
	<b>Source of intervention:</b> European
	<b>Type of measure:</b> Secondary legislation
<b>Contact for enquiries:</b> Nasreen Shah, Telephone: 020 7276 8553	

## Summary: Intervention and Options

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

Contaminants in food can detrimentally affect consumer health. Most consumers are unable to assess the risk of contaminants in their foods and therefore are unable to make fully informed choices about such risk. Government intervention is necessary to address this information asymmetry, minimise the risk to health taking account of the latest scientific evidence and to provide greater clarity in enforcement.

**What are the policy objectives and the intended effects?**

To continue to reduce the long term health risks to consumers in England arising from chemical contaminants in food and to make enforcement provisions that enable authorities to ensure that products placed on the market are safe and thus maintain consumer safety and consumer confidence.

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

1. Do Nothing. This will not prevent the Commission Regulation from being in force in England; it is already legally binding and applicable throughout the European Union (EU) since 8<sup>th</sup> March 2010. However, enforcement authorities would not have the necessary powers to enable them to enforce it.
2. Make appropriate domestic Regulations for the proper enforcement of the Commission Regulation and provide for offences for not complying with the Commission Regulation. This ensures that the enforcement authorities have the necessary powers to fulfil their responsibilities under the Food Safety Act 1990, as amended.

<b>When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?</b>	It will be reviewed 2011
<b>Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?</b>	No

**Ministerial Sign-off** For enactment stage Impact Assessments:

*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 Minister: Anne Milton ..... Date: 6<sup>th</sup> September 2010 .....

# Summary: Analysis and Evidence

# Policy Option 2

## Description:

Impact Assessment of the Contaminants in Food (England) Regulations 2010

Price Base Year 2009	PV Base Year N/A	Time Period Years N/A	Net Benefit (Present Value (PV)) (£)		
			Low:	High:	Best Estimate: 48,011-

COSTS (£)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	N/A	N/A
High	N/A	N/A	N/A
Best Estimate	£48,011	0	£48,011 <sup>1</sup>

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

One-off familiarisation cost to enforcement authorities in England of £16,267 split £14,653 familiarisation cost for Local Authorities and £1,614 familiarisation cost to Port Health Authorities.

One-off familiarisation cost in England for affected businesses of £31,744

Total one-off familiarisation cost of £48,011 in England. Over a 10 year period the total equivalent annual cost is approximately £5,773

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

Non-monetised costs were identified.

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

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

No benefits monetised, see non-monetised benefits below

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

It is anticipated that businesses will benefit financially as a consequence of raised maximum permitted levels for aflatoxins in almonds, hazelnuts, pistachios and Brazil nuts. This will result in fewer products being withdrawn from the market and reducing costs for affected businesses. These actions could benefit the consumer through greater competition which could result in lower prices.

### Key assumptions/sensitivities/risks

Discount rate (%)

3.5

Key risks: the UK has a legal obligation to ensure that the requisite legislative provisions are in place to provide for the enforcement requirements of the European legislation to be met in full. Failure to do so may result in infraction proceedings against the UK government by the Commission, which could result in financial penalties being incurred.

<sup>1</sup> This is the combined total cost to Local Authorities and Industry in England

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

## Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			20/10/2010		
Which organisation(s) will enforce the policy?			LAs and PHAs		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)			<b>Traded:</b> N/A	<b>Non-traded:</b> N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			<b>Costs:</b>		<b>Benefits:</b>
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	<b>Micro</b> N/A	<b>&lt; 20</b> N/A	<b>Small</b> N/A	<b>Medium</b> N/A	<b>Large</b> N/A
Are any of these organisations exempt?	No	No	No	No	No

## Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on...?	Impact	Page ref within IA
<b>Statutory equality duties<sup>2</sup></b> <a href="#">Statutory Equality Duties Impact Test guidance</a>	No	
<b>Economic impacts</b>		
Competition <a href="#">Competition Assessment Impact Test guidance</a>	No	10
Small firms <a href="#">Small Firms Impact Test guidance</a>	No	11
<b>Environmental impacts</b>		
Greenhouse gas assessment <a href="#">Greenhouse Gas Assessment Impact Test guidance</a>	No	
Wider environmental issues <a href="#">Wider Environmental Issues Impact Test guidance</a>	No	
<b>Social impacts</b>		
Health and well-being <a href="#">Health and Well-being Impact Test guidance</a>	No	8
Human rights <a href="#">Human Rights Impact Test guidance</a>	No	
Justice system <a href="#">Justice Impact Test guidance</a>	No	
Rural proofing <a href="#">Rural Proofing Impact Test guidance</a>	No	
<b>Sustainable development</b> <a href="#">Sustainable Development Impact Test guidance</a>	No	11

<sup>2</sup> Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.



## Evidence Base (for summary sheets) – Notes

### References

No.	Legislation or publication
1	2008 Consultation <a href="http://www.food.gov.uk/consultations/consulteng/2008/?completed=Yes">http://www.food.gov.uk/consultations/consulteng/2008/?completed=Yes</a>
2	EU Legislation <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:050:0008:0012:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:050:0008:0012:EN:PDF</a>
3	Interested Party Letters <a href="http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/contaminants">http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/contaminants</a>
4	2010 Consultation on draft Statutory Instrument <a href="http://www.food.gov.uk/multimedia/pdfs/consultation/contamregseng.pdf">http://www.food.gov.uk/multimedia/pdfs/consultation/contamregseng.pdf</a>

+ Add another row

### Evidence Base

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

	Y <sub>0</sub>	Y <sub>1</sub>	Y <sub>2</sub>	Y <sub>3</sub>	Y <sub>4</sub>	Y <sub>5</sub>	Y <sub>6</sub>	Y <sub>7</sub>	Y <sub>8</sub>	Y <sub>9</sub>
<b>Transition costs</b>	5,773	5,773	5,774	5,773	5,773	5,773	5,773	5,773	5,773	5,773
<b>Annual recurring cost</b>	0	0	0	0	0	0	0	0	0	0
<b>Total annual costs</b>	5,773	5,773	5,773	5,773	5,773	5,773	5,773	5,773	5,773	5,773
<b>Transition benefits</b>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<b>Annual recurring benefits</b>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<b>Total annual benefits</b>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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

# Evidence Base (for summary sheets)

## Policy objective

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

1. The UK's aim is to reduce the long term health risks to consumers in England 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 which 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.

## Rationale for Intervention

2. 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.

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

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

4. The Food Standards Agency ("the Agency") believes that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework that removes trade barriers and enhances 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.

5. The risk of contaminated products i.e. oil seeds 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 in pistachios and Brazil nuts will avoid confusion for enforcement authorities and avoid any potential barrier to trade that may occur, whilst maintaining protection of consumer health.

**To make enforcement provisions to ensure that products placed on the market are safe and thus increase consumer confidence.**

6. 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 England 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 Scotland, Wales and Northern Ireland.

7. The proposal for a Statutory Instrument (SI) entitled The Contaminants in Food (England) Regulations 2010 will provide for the enforcement of Regulation (EC) No. 1881/2006 as most recently

amended by Regulation (EU) No. 165/2010 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins in England (“the Commission Regulation”). The proposed Regulations will revoke the Contaminants in Food (England) Regulations 2009 (SI 2009 No. 1223) and remake them with necessary amendments, taking into account the requirements of the Commission Regulation 165/2010.

8. If the relevant changes to the Contaminants in Food (England) Regulations 2009 were not made, this might lead to the impacts set out in paragraph 14 and might also create a barrier to trade within the UK and with other countries of the EU. It would run counter to the important role the UK plays in agreeing EU harmonised measures and leave regulation of contaminants in England 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 revised requirements laid down in the new Commission Regulation and thus increase consumers’ exposure to risk.

## Background

9. The European Food Safety Authority’s (EFSA) Scientific Panel on Contaminants in the Food Chain (Contam Panel) adopted an opinion on 25<sup>th</sup> January 2007 on the potential increase in risk to consumer health by a possible risk from 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 from 4 µg/kg 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). At the same time, the Panel concluded that exposure to aflatoxins from all sources should be as low as reasonably achievable.

10. 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 to 10µg/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 affected if the levels for total aflatoxins were raised from 4µg/kg to 10µg/kg for other tree nuts, including Brazil nuts. Given the discussions in Codex Alimentarius on the maximum levels for aflatoxins in Brazil nuts, it was considered appropriate to also change the level for total aflatoxins in Brazil nuts to that for almonds, hazelnuts, and pistachios as agreed at Codex Committee on Contaminants in Food in 2008. Separate limits for aflatoxin B1 are to be retained in the interim.

11. 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.

12. 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.

13. At the Codex Committee on Contaminants in Food 2008, 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’ were established.

14. 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 was 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 is appropriate to exclude oilseeds, including groundnuts (peanuts), intended for crushing for refined vegetable.

15. 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 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.

16. 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.

## **Options**

### **Option 1 – Do Nothing – Do not provide for the enforcement of the new European Regulation in England**

17. Doing nothing will not prevent the Commission Regulation from applying in England; 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 Commission Regulation will 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.**

18. 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 Commission Regulation. Also, local authorities and port health authorities will benefit from the greater clarity provided by the Commission Regulation.

## **Sectors and groups affected**

**Local authorities, port health 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**

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

#### **Option 2**

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

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

22. 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

23. This option is the baseline for comparison

### Option 2

#### Costs to Enforcement Authorities

24. 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. In some cases this is divided between the Environmental Health Departments of the local, district/borough etc. councils and the Trading Standards Departments of the county councils. Where appropriate these two departments of the different levels in local government liaise closely and deal with issues in common to make it easier for consumers and businesses.

25. Each food authority in its area and each port health authority in its district 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 Agency believes that the incremental costs to enforcement authorities are unlikely to have a significant cost impact and are likely to be minimal, if any. Local authority enforcement bodies have always had responsibility for the enforcement of chemical contaminants legislation. The new Regulations for England merely provide the means by which this role can take account of the requirements of the Commission Regulation.

26. There are a total of 354<sup>3</sup> Local Authorities (LA's) and 39 Port Health Authorities (PHAs) in England that will be affected by the Regulations. It is expected that one Environmental Health Officer (EHO) from each LA and one official from each PHA will read the Regulations and disseminate the information to key staff. We estimate that each officer will invest one hour reading and familiarising themselves with the Regulations and a further one hour disseminating to key staff in the organisation; meaning a total of two hours for familiarising. Earlier consultation responses have also indicated the Trading Standards Officers (TSO's) would need to read and understand these Regulations. We assume that the time taken would be the same as for EHOs. We have calculated the familiarisation cost to all LA's by applying an EHO wage rate and not a TSO rate for consistency.

27. A wage rate of £20.70<sup>4</sup> has been applied to EHOs and port health officials which equates to a one-off familiarisation cost £14,653 for LA's and £1,614 to PHA's in England, which gives a total one-off familiarisation cost of £16,267. Table 1 displays the one-off familiarisation cost for Enforcement Authorities for the UK. While this legislation applies only to England, we assume similar incremental familiarisation costs will also be faced by the devolved administrations.

*Table 1 – Familiarisation costs for Enforcement Authorities*

Region	Number of Local Authorities	Local Authorities
England <sup>5</sup>	393	£16,267
Wales <sup>6</sup>	23	£952

<sup>3</sup> The number of English Local Authorities has been updated to reflect boundary changes and the creation of nine new Unitary Authorities.

<sup>4</sup> Wage rate obtained from The Annual Survey of Household Earnings (2009) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage for 'Environmental health officers' is used (£20.70 including 30% overheads).

<sup>5</sup> England Local Authorities (LA's) figure is a combination of English LA's (354) and Port Health Authorities (39)

Scotland	32	£1,325
N. Ireland	26	£1,076
<b>UK</b>	<b>474</b>	<b>£19,620</b>
<b>Rounded*</b>		<b>£20,000</b>

\*Totals may not sum due up to rounding

### **Equivalent Annual Costs (EAC)**

28. In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula<sup>7</sup>. Under Standard HMT Green book guidance<sup>8</sup> a discount rate of 3.5% is used.

29. Total one-off costs to enforcement authorities in England have been estimated as £16,267 (includes familiarisation costs of £14,653 for Local Authorities and £1,614 for Port Health Authorities). This yields an EAC for industry in England of approximately £1,956 over 10 years and for the UK as a whole approximately £2,539<sup>9</sup> over 10 years.

### **Costs to Industry**

30. 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.

31. 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 Commission Regulation, e.g. nuts, oilseeds 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 appropriate point within the supply chain.

32. 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, edible fats, 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.

*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
<b>UK*</b>	<b>515</b>	<b>80</b>	<b>120</b>	<b>45</b>	<b>35</b>	<b>795</b>

\*Totals may not sum up due to rounding

Notes:

1. 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.

2. 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.

33 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.

<sup>6</sup> Wales Local Authorities (LA's) figure is a combination of Welsh LA's (22) and Port Health Authorities (1)

<sup>7</sup> The equivalent annual cost formula is as follows:  $EAC = PVS/A$ , where  $A = [1 - 1/(1+r)^t]/r$ , where PVS is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

<sup>8</sup> [http://www.hm-treasury.gov.uk/data\\_greenbook\\_index.htm](http://www.hm-treasury.gov.uk/data_greenbook_index.htm)

<sup>9</sup> Please note these figures have been rounded to the nearest £1.

34. To calculate the familiarisation cost for businesses a wage rate of £25,19<sup>10</sup> 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 England of £31,800. Table 3 displays the one-off familiarisation cost to industry broken down by region.

Table 3 – Familiarisation costs to industry in the UK

Region	Number of affected businesses	Industry
England	630	£31,744
Wales	40	£2,016
Scotland	80	£4,031
N. Ireland	45	£2,267
<b>UK</b>	<b>795</b>	<b>£40,058</b>
<b>Rounded*</b>		<b>£40,000</b>

\*Totals may not sum up due to rounding

35. As for enforcement authorities (see above), the one-off costs to industry must also be expressed as equivalent annual costs. The EAC industry in England is therefore approximately £3817 and for the UK as a whole is approximately £4817<sup>11</sup>

### Impact on other Government bodies

36. Government departments, such as the Agency 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 Agency 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.

*No comments were received from OGD's on these proposals.*

### Administrative Burden Costs

37. The cross-Government Admin Burdens Measuring Exercise (ABME) in 2005 measured the administrative burdens for Regulations on businesses in England using the Standard Cost Model. The Agency 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 Commission Regulation, 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 Agency's website. This is acknowledged by the Food and Drink Federation. Copies of the draft documents have been made available for comments and views. The latest update of the letter was published on 16<sup>th</sup> March and can be accessed at the following link:

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

### Policy costs

38. The Agency believes that there are no new or additional policy and administration costs associated with the proposed statutory instrument that is the specific subject of this impact assessment and that will provide for the enforcement provisions. The benefits of complying with the levels in the EU

<sup>10</sup> 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)

<sup>11</sup> Please note these figures have been rounded to the nearest £1.

measure do not represent any new compulsory action. This view is also supported by the Trading Standards Institute.

#### **Consultation questions:**

(1). It is our assumption that there is a familiarisation cost for enforcement authorities associated with the new 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 new Regulations. Is this an accurate assessment for both enforcement authorities and businesses? If you disagree, please provide evidence to support you views.

*Comments received from stakeholders on these proposals are outlined in paragraphs 39-42 below.*

## **Consultation**

### **Within Government**

39. During the course of negotiations with the European Commission, officials of the Agency have kept other government departments informed of its progress. These included; the Department of Health, the Department for Business Innovation and Skills, the Foreign and Commonwealth Office, the Cabinet Office, DEFRA and the Office of Fair Trading. The UK fully supported the Commission's proposal. 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 from any department.

### **Public Consultation**

40. The Food Standards Agency 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/](http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/)

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

### **Results of the Consultation**

42. In total 800 stakeholders were consulted on these proposals. These ranged from sector specific, such as manufacturers of breakfast cereals and cereal-based foods, oils and fats, and similar edible fats, as well as importers of commodities, such as tree nuts, oil seeds and oil seed oils, rice and apricot kernels. Enforcement bodies, consumer organisations, non-government organisations and others with an interest in chemical contaminants in foods were also consulted.

43. Stakeholders, enforcement bodies in particular, were asked to comment with supporting evidence on the cost of enforcing the new legislation and to comment on the assumptions that it will take 1 hour for enforcement authorities and businesses to read and familiarise themselves with the new Regulations and a further hour to disseminate to key staff within their respective organisations. They were also asked to comment on any others costs associated with the Commission Regulation and or the new Regulations and whether they introduce any additional burden.



## **Consultation comments**

44. Three responses were received; 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).

45. 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 and agreed that they were already familiar with the remainder of the domestic Regulations. 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 Commission Regulation.

46. The TSI welcomed the opportunity to comment on the new Regulations. In relation to the specific questions on familiarisation costs, they 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.

47. The FDF commented that they circulated the consultation documents on the proposed Regulations to members of the FDF Residues and Contaminants Committee; however, no comments were received from their members, which they commented was an indication 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.

48. All respondents were thanked for taking part in the consultation.

## **Enforcement**

49. The purpose of The Contaminants in Food (England) Regulations 2010 is to provide enforcement authorities e.g. Environmental Health Officers, Trading Standards Officers and Port Health Officers 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 new Regulations on which we consulted will provide the means by which this role can be extended taking into account the new requirements for enforcement of the Commission Regulation.

## **Sanctions**

50. The criminal sanctions in the current Contaminants in Food (England) 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 (£5,000).

## **Simplification**

51. The policy of maintaining a simplified set of Regulations is being continued. For this reason, rather than implementing the enforcement provisions of the new Regulation by amending the 2009 Regulations mentioned above, those Regulations will be revoked and re-made in a consolidated instrument that includes enforcement of the measures introduced by the 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.

## **Competition Assessment**

52. We fully considered the questions posed in the Office of Fair Trading competition assessment test ([http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft876.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf)) and have concluded that the new Regulations that implement the enforcement provisions of the 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.

53. There is no current requirement for industry to carry out sampling and analysis within Commission Regulation 1881/2006, as amended. However, a business 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.

## **Small Firms Impact Test**

54. 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. We continue to welcome input from small businesses on how the new Regulations affect their business in practice 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.

## **Sustainable development**

55. Impacts under the three pillars (environmental, economic and social) of sustainable development have been and continue to be considered in the preparation of this Impact Assessment. The Agency'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 England. 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**

56. The Agency 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.

## Annex 1: Post Implementation Review (PIR) Plan

<p><b>Basis of the review:</b> To review progress on how the new levels on aflatoxins are being complied with by FBO's.</p>
<p><b>Review objective:</b> To ensure new maximum levels continue to provide an appropriate level of protection for consumers and that they are reasonably achievable by industry.</p>
<p><b>Review approach and rationale:</b> We will continue to communicate so that any unforeseen difficulties that may arise can be dealt with promptly and hopefully to the satisfaction of all parties.</p>
<p><b>Baseline:</b> Number of non-compliances reported compared with previously. Levels of aflatoxins found compared with previously to estimate consumer exposure; none reported to date, hence, it's not possible to make a comparison.</p>
<p><b>Success criteria:</b> The new levels for aflatoxins in various foods will be far more sustainable and easier for businesses to comply with. This in turn will mean fewer commodities will be rejected and removed from the supply chain, leading to a reduction in food wastage.</p>
<p><b>Monitoring information arrangements:</b> Routinely survey commodities on the market to ensure compliance with the Regulations. The Agency will work with enforcement authorities where problems 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.</p>
<p><b>Reasons for not planning a PIR:</b> N/A</p>