

**EXPLANATORY MEMORANDUM TO**  
**THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2005**  
**2005 No. 3251**

1. This explanatory memorandum has been prepared by The Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. **Description**

2.1 The Regulations make provision for the execution and enforcement of European Community measures setting maximum levels for certain contaminants in foodstuffs and implement allied European Commission Directives concerning sampling and analysis. The Regulations will revoke and replace The Contaminants in Food (England) Regulations 2004 (SI 2004 No 3062) as amended by The Contaminants in Food (England) (Amendment) Regulations 2005 (SI 2005 No 775).

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None

4. **Legislative Background**

4.1 The Instrument is made under The Food Safety Act 1990, as amended. The new Regulations make provision for the execution and enforcement of Commission Regulation (EC) No. 466/2001, as most recently amended by various new European Community (EC) Regulations which set maximum levels for ochratoxin A, nitrate and polycyclic aromatic hydrocarbons (PAHs) in certain foodstuffs and revise the existing EC maximum levels for heavy metals (lead, cadmium and mercury) in fish. The Regulations will also transpose three allied Commission Directives on detection methods (2005/5/EC [ochratoxin A], 2005/10/EC [PAHs] and 2005/4/EC [heavy metals and 3-MCPD]) into national legislation. A Transposition Note is attached to this memorandum.

4.2 Commission Regulation (EC) No. 466/2001 of 8 March 2001 sets maximum levels for certain contaminants in foodstuffs and has applied since 2002. Commission Regulation 466/2001 is supported by a number of enforcement Commission Directives, which lay down the methods for sampling and analysis for the official control of those contaminants specified in the legislation. In England provision for the enforcement and transposition of these measures is currently under The Contaminants in Food (England) Regulations 2004, as amended.

## **5. Extent**

5.1 This Instrument applies to England only. Corresponding Regulations will apply 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**

7.1 EC legislation on contaminants is made under the framework Regulation for food contaminants, Council Regulation (EEC) No 315/93 of 8 February 1993. The Regulation lays down Community procedures for contaminants in food and applies to those contaminants that are not covered by other specific Community legislation. Article 2 to the Regulation provides that food containing a contaminant in an amount that is unacceptable from the public health viewpoint, and in particular at a toxicological level, shall not be placed on the market. Paragraph 3 to the article requires that maximum levels must be set for specific contaminants and that these levels must be adopted in the form of a non-exhaustive Community list. In view of disparities between the laws of Member States in regard to the maximum levels for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Community measures (Commission Regulation (EC) No 466/2001 of 8 March 2001) were introduced under Council Regulation 315/93/EC.

7.2 The intention of Commission Regulation 466/2001 is to provide consumers with an increased measure of protection by setting maximum levels 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, which has undergone a number of amendments, aims to keep contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain. It also harmonises Member States' existing measures, thus facilitating trade.

7.3 Maximum levels for lead, cadmium, mercury, dioxins and nitrate (environmental chemical contaminants), 3-MCPD (a process contaminant), aflatoxins, ochratoxin A and patulin (mycotoxins) and inorganic tin have already been set under this legislation.

7.4 In view of the requirement to protect public health by keeping contaminants at levels that are toxicologically acceptable, the European Commission, in co-operation with member states, investigates whether limits should be set for additional contaminants and also reviews the maximum limits of those contaminants currently in the legislation. As a result, the following Commission measures, which amend Commission Regulation 466/2001, have been adopted and provision must now be made for their enforcement and implementation:-

(i) Commission Regulation (EC) No 123/2005 of 26 January 2005 setting maximum levels for ochratoxin A in certain foodstuffs. The Regulation is supported by Commission Directive 2005/5/EC. Member States are required to comply with the provisions in this Directive by 18 February 2006 latest.

(ii) Commission Regulation (EC) No 78/2005 of 19 January 2005 revising the current maximum levels for heavy metals in fish.

(iii) Commission Regulation (EC) No 208/2005 of 4 February 2005 setting maximum levels for PAH in certain foodstuffs. The Regulation is supported by Commission Directive 2005/10/EC. Member States must comply with the provisions in this Directive by 8 February 2006 latest.

(iv) Commission Regulation 1822/2005 of 8 November 2005 amending the time periods during summer and winter to which maximum limits apply for nitrate in fresh spinach. It also extends the derogation period for certain Member States including the UK whereby fresh spinach and fresh lettuce are exempt from the limits when produced and placed on the market in the country to which the derogation applies.

(v) Commission Directive 2005/4/EC, which supports Commission Regulation 466/2001 in respect to the methods for sampling and analysis for the official control of lead, cadmium, mercury and 3-MCPD in foodstuffs. The Directive includes updated analytical information and requirements and applies specifically to Public Analysts and those laboratories accredited to carry out official control work. Member States are required to comply with the provisions of this Directive by 8 February 2006 latest.

7.5 Informal and formal consultations have been carried out on the measures and information on the benefits and costs of the legislation to public health and businesses including enforcement authorities is included in the attached Regulatory Impact Assessments. A formal consultation in England of nearly 700 interested parties including consumer groups, industry, enforcement authorities and other government departments, in the 12 weeks from 28 July 2005, produced 15 responses of which only 4 were substantive. Comments raised were mainly from enforcement authorities and industry and indicated the need for simplification of the Regulations. Following these comments the draft Regulations have been revised to simplify certain aspects of the text whilst remaining within the remit of accurately enforcing and implementing the Community measures. Other parties supported the need for making sure food is fit for human consumption or simply acknowledged the consultation.

7.6 Concerns raised during the informal consultations and the outcomes are discussed in detail in the attached RIAs. However, in summary, swordfish, in particular the larger fish were unable to comply with the existing maximum levels for cadmium in fish. Although little quantified information was submitted, importers indicated that this was having a significant detrimental

effect on the industry. Also of concern was the long-term sustainability of this species as in order to comply smaller, younger fish would be taken. The UK successfully negotiated a higher level which went some way to addressing industry's concerns whilst continuing to maintain a high level of consumer protection and choice and helping to promote the sustainability of swordfish.

7.7 Comments from the proposals for PAH varied, with some respondents indicating general support for maximum levels and others indicating opposition to either a specific proposed level and/or a specific food category to be included in the legislation. Although there is little recent data available, industry indicated that the initial proposals for shellfish would have a significant negative impact on the industry with the possible loss of livelihood of those employed in certain regions in England and Wales. The UK successfully negotiated an interim higher level for bivalve molluscs only. This level will be revised when further data become available.

7.8 All stakeholders including industry were kept up-to-date on a regular basis during negotiations on setting new limits for ochratoxin A and were given the opportunity to fully contribute to discussions in respect to setting these limits. As a consequence of industry consultation and discussions at the Commission, limits for soluble coffee were renegotiated and the inclusion of other fruit juices and other alcohol beverages withdrawn from the Regulation. In addition, the setting of certain limits for other commodities such as spices and cocoa has been deferred until more data are available.

## **8. Impact**

8.1 Regulatory Impact Assessments are attached to this memorandum.

8.2 The impact on the public sector is believed to be minimal. However, some costs to the Exchequer may arise from the costs to local authorities and port health authorities in carrying out the sampling and analysis requirements provided for in the Directives.

## **9. Contact**

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## **Annex 1A**

### **FINAL REGULATORY IMPACT ASSESSMENT**

#### **The Contaminants in Food (England) Regulations 2005**

- (i) Revised maximum levels for heavy metals (lead, cadmium and mercury) in fish**
- (ii) Amendment to Annexes I and II to Commission Directive 2001/22/EC: sampling and analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs**
- (iii) New maximum levels for polycyclic aromatic hydrocarbons (benzo(a)pyrene) in foodstuffs**
- (iv) Sampling methods and the methods of analysis for the official control of the levels of benzo(a)pyrene in foodstuffs**

## **1. TITLE OF PROPOSAL**

### **The Contaminants in Food (England) Regulations 2005**

**1.1** Provision for the enforcement of Commission Regulation (EC) No. 78/2005 of 19 January 2005 amending Commission Regulation (EC) 466/2001 as regards heavy metals in foods.

**1.2** Implementation of Commission Directive 2005/4/EC of 19 January 2005 amending Commission Directive 2001/22/EC laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foods.

**1.3** Provision for the enforcement of Commission Regulation (EC) No 208/2005 of 4 February 2005 amending Commission Regulation 466/2001 as regards polycyclic aromatic hydrocarbons in foodstuffs.

**1.4** Implementation of Commission Directive 2005/10/EC of 4 February 2005 laying down the sampling methods and the methods of analysis for the official control of the levels of Benzo(a)pyrene in foodstuffs.

## **2. PURPOSE AND INTENDED EFFECT**

### **2.1 Objective**

**2.1.1** The purpose of this measure is to provide enforcement authorities with the necessary specific legislation to ensure compliance with European Union (EU) measures on contaminants in food. The draft Regulations make provision for the enforcement and execution in England of Commission Regulation 466/2001 as amended by Commission Regulations 78/2005 and 208/2005. The aim of Commission Regulation 466/2001 is to provide an increased level of consumer protection by keeping contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain.

**2.1.2** Commission Regulation 466/2001 as amended is supported by a number of allied enforcement Commission Directives, which lay down the sampling methods and the methods of analysis for the official control of those contaminants specified in the legislation. The aim of the Directives is to ensure a harmonised enforcement approach across the EU. Transposition of Commission Directives 2005/4/EC and 2005/10/EC into national law would fulfil national obligations to implement these measures. The legislation would promote consistent and effective enforcement by reducing uncertainty or dispute in interpreting results against limits. This will benefit industry and consumers through improved confidence in compliance testing.

**2.1.3** The draft Contaminants in Food (England) Regulations 2005, which are made under The Food Safety Act 1990 as amended, will -

- (a) revoke and replace The Contaminants in Food (England) Regulations 2004 (SI 2004 No. 3062) as amended by The Contaminants in Food (England) (Amendment) Regulations 2005 (SI 2005 No 775);

- (b) make provision for the enforcement and execution of Commission Regulation 466/2001 as amended, and continue to implement the allied enforcement sampling and analysis Directives;
- (c) make provision for the enforcement and enactment of Commission Regulations 78/2005 and 208/2005; and
- (d) bring into force Commission Directives 2005/4/EC and 2005/10/EC

Similar Regulations will apply in Scotland, Wales and Northern Ireland.

**2.1.4** Commission Regulation 78/2005, amends Commission Regulation 466/2001 in regards to maximum levels for heavy metals (lead, cadmium and mercury) in fish. The Regulation, which has applied since 8 February 2005, makes a number of changes to the fish categories, sets a revised higher limit of 0.3 mg/kg for cadmium in swordfish and a revised lower limit for lead in tuna of 0.2 mg/kg. The Regulation modifies Section 3 of Annex I to Regulation 466/2001 as amended by Commission Regulation 221/2002, which has applied since 5 April 2002.

**2.1.5** Commission Directive 2005/4/EC amends Directive 2001/22/EC, which supports Commission Regulation 466/2001 in respect to the methods for sampling and analysis for the official control of lead, cadmium, mercury and 3-MCPD in foodstuffs. The Directive, which applies to enforcement authorities and specifically only to Public Analysts and those laboratories accredited to carry out official control work, includes updated standard information for contaminants in food and in particular takes into account the measurement uncertainty for analysis. Member states are required to comply with the provisions of the Directive by 8 February 2006 latest.

**2.1.6** Commission Regulation 208/2005 amends Commission Regulation 466/2001 in regards to maximum levels for polycyclic aromatic hydrocarbons (PAHs) in certain foodstuffs. The Regulation, which has applied since 1 April 2005 sets maximum limits specifically for benzo(a)pyrene (BaP) in oils and fats for human consumption; foods for babies, infants and young children; smoked meats and meat products; muscle meat of smoked fish and fishery products; unsmoked muscle meat of fish and unsmoked shellfish. **Article 2 to the Regulation provides that the maximum levels do not apply to products placed on the market before 1 April 2005.**

**2.1.7** Commission Regulation 208/2005 is supported by Commission Directive 2005/10/EC, which applies to enforcement authorities only. The intention of the Directive is to ensure effective and consistent enforcement sampling and analysis procedures for BaP. Member states are required to comply with the provisions in the Directive by 8 February 2006 latest.

**2.1.8** This Regulatory Impact Assessment (RIA) is concerned only with the provisions for the enforcement of Commission Regulations 78/2005 and 208/2005 and the transposition of Commission Directives 2005/4/EC and 2005/10/EC. A separate RIA for Commission Regulation 123/2005, setting maximum levels for ochratoxin A in wines, grape juices and coffee, and its allied enforcement sampling and analysis Directive is included as part of this consultation package as Annex 1. Commission Regulation 466/2001, as amended, and the allied Commission Directives referred to at point (b) above have already been dealt with in previous RIAs<sup>1</sup>.

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<sup>1</sup> Consultations on this Regulation and the Directives were carried out under:  
(i) The Contaminants in Food (England) Regulations 2002 in July 2001 (aflatoxins in spices), December 2001 (ochratoxin A) and March 2002 (lead, cadmium, mercury, dioxins, 3-MCPD and nitrates);  
(ii) The Contaminants in Food (England) Regulations 2003 in February 2003 (dioxins sampling and analysis Directive); and

## **2.2 Background**

**2.2.1** European Community (EC) legislation on contaminants in food is made under the contaminants in food framework Regulation, Council Regulation 315/93/EEC. The Regulation lays down Community procedures for contaminants in food and applies to those contaminants that are not covered by other specific Community legislation. In view of the disparities between the existing laws of member states in regard to the maximum levels for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Community measures (Commission Regulation 466/2001) were introduced under Council Regulation 315/93/EEC. The provisions and requirements of Commission Regulation 466/2001 have applied across the EU since April 2002.

**2.2.2** The intention of Commission Regulation 466/2001 is to provide consumers with an increased measure of protection by setting EC maximum levels 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 keep contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain. They also harmonise member states' existing measures, facilitating trade. Maximum levels for lead, cadmium, mercury, dioxins, nitrates, 3-MCPD, aflatoxins, ochratoxin A, patulin and inorganic tin have already been set under this legislation.

**2.2.3** In view of the requirement to protect public health by keeping contaminants at levels that are toxicologically acceptable, 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. An overview of the background to the development of the heavy metals and PAHs legislation and the health effects of these contaminants is given at paragraphs 2.2.4 to 2.2.12.

### **Heavy Metals**

**2.2.4** Commission Regulation 466/2001 committed the Commission to reviewing the maximum levels for lead, cadmium and mercury for the first time by 5 April 2003, with further reviews to take place every five years. The overall objective of the review, which commenced in June 2003, is to continue to ensure a high level of consumer protection. In October 2003 the Commission proposed that new or revised maximum limits for these contaminants should be introduced for certain food groups. The proposals included a review of the lists of fish specified in the legislation with the view to replacing the current list with a positive list of the most commonly traded species, and a review of the maximum limits for these metals in fish.

**2.2.5** In January 2004, it was agreed to revise the existing limit for lead in tuna from 0.4 mg/kg to the lower general limit of 0.2 mg/kg as available data indicated that this fish would be able to meet the lower limit. In addition, following concerns that swordfish, in particular the larger fish, exceeded the general maximum limit for cadmium in fish of 0.05 mg/kg, it was proposed, subject to a dietary intake assessment, to set a higher limit of 0.1 mg/kg. In October 2004, following further discussion, it was agreed to have a separate category for swordfish with a maximum

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(iii) The Contaminants in Food (England) Regulations 2004 in June 2004 (Tin, patulin, dioxins and aflatoxins).



limit of 0.3 mg/kg. Member states agreed that consumer protection would still be maintained at this higher level and the proposal was adopted. Intake estimates of cadmium in swordfish at 0.3 mg/kg and sources of cadmium from the rest of the diet would contribute 32% of the provisional tolerable weekly intake<sup>2</sup> (PTWI) as set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The proposal to replace the current lists of fish was agreed in March 2004 and the list of fish has been modified to include a list of the main traded species in the EU.

**2.2.6** Discussions on the review of maximum limits for heavy metals in other foodstuffs are still at an early stage and maximum limits have not yet been agreed.

### **Health Effects**

**2.2.7** An overview of the potential health effects of lead, cadmium and mercury is attached as sub-annex 1a(i) at the end of this document. However, in summary, lead, cadmium and mercury are metals that are present in the environment naturally and also as a result of human activities (e.g. industrial emissions, leaded petrol). They are present at low concentrations in most foods, with environmental sources being the main routes of contamination. Lead, cadmium and mercury have no known beneficial biological effects and long-term (chronic) exposure can be harmful. Food is a major contributor to consumers' overall exposure to metals, although other routes such as inhalation or occupational exposure may also be significant<sup>3</sup>. Sporadic contamination of food with unacceptable levels of these contaminants continues to occur and potential risks to consumers from such contaminants need to be effectively controlled.

### **Amendment to Commission Directive 2001/22/EC**

**2.2.8** Commission Directive 2001/22/EC lays down the methods for sampling and analysis for the official control of lead, cadmium, mercury and 3-MCPD in those foodstuffs specified in Annex I, Sections 3 and 4, of Commission Regulation 466/2001. A draft Directive, which proposed amendments to Directive 2001/22/EC, was circulated for discussion at the Commission Working Group meetings in June 2004. Following comments and recommendations from the UK the draft was revised and agreed as Commission Directive 2005/4/EC. The Directive applies to the official control laboratories only and amends Annexes I and II to Directive 2001/22/EC. It reinforces and expands on point 5 in Annex I in respect of compliance and lays out new performance criteria in Annex II, point 3.3.3 in relation to the uncertainty to assess the suitability of the method. Text in point 3.4 in Annex II is replaced to include the requirement to report the results as +/- the measurement uncertainty.

### **Polycyclic Aromatic Hydrocarbons (PAHs)**

**2.2.9** In November 2002, the Commission signalled its intention to set harmonised maximum limits for PAHs in foods as soon as possible.

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<sup>2</sup> Definition of PTWI – the exposure limit is presented in micrograms of contaminants per week and per 1 kg of body weight. Weekly intake is used to stress the importance of limiting period of time to a certain contaminant

<sup>3</sup> 2000 Total Diet Study of Twelve Elements, FSIS No 48/04 March 2004

**2.2.10** In its opinion of 4 December 2002<sup>4</sup>, the European Scientific Committee on Food (SCF) concluded that a number of PAHs, in particular benzo(a)pyrene (BaP), were genotoxic carcinogens. In view of the non-threshold effects of genotoxic substances (i.e. the toxicant has no safe threshold and there is some risk at any level of exposure) it was agreed that the levels of PAHs in foods should be reduced to as low as is reasonably achievable. The SCF concluded that BaP could be used as a marker for the occurrence and effect of carcinogenic PAHs in food. Further analyses of the relative proportions of these PAHs in foods to inform a future review of the sustainability of maintaining BaP as a marker will be carried out.

**2.2.11** Although some member states had existing national maximum levels for PAHs in certain foods, others including the UK did not. In view of the disparities between member states and the consequent risk of distortion of competition, Community measures were considered necessary in order to ensure market unity whilst abiding by the principle of proportionality. In the UK prior to the adoption of the EU wide maximum limits, it was recommended that foods, including shellfish, affected by pollution incidents were not consumed if levels of any one of the three most toxic PAHs (BaP, BaA (benzo(a)anthracene) and DBahA (dibenzo(a,h)pyrene)) exceeded 15 µg/kg wet weight. This recommendation was an interim pragmatic guideline, which applied only in emergency situations.

**2.2.12** At a Working Group meeting in June 2003, member states agreed to initially set limits only for BaP, with limits for other PAHs to be included in the legislation after more information became available. Discussions on the limits to be set and on the food categories to be included in the legislation and the methods for sampling and analysis for enforcement purposes continued throughout 2003. During the negotiations, significant changes were made to the draft proposals. Final drafts of the Regulation and Directive were agreed in October 2004, and adopted as Commission Regulation 208/2005 and Commission Directive 2005/10/EC. In addition to the statutory limits for BaP, a draft Commission Recommendation on the further investigation into the levels of PAHs in certain foodstuffs was adopted as Commission Recommendation 108/2005. The results of these investigations, which should be submitted to the Commission by 31 October 2006, will be used to inform the review of the maximum levels and the suitability of maintaining BaP as a marker, by 1 April 2007.

### **Health Effects**

**2.2.13** PAHs are a group of lipophilic chemicals (i.e. chemicals that build up in the fatty parts of, for example fish, livestock and humans) that are present widely in the environment as pollutants. Some PAHs, in particular BaP, have been shown to be genotoxic carcinogens (i.e. interact directly with the genetic material in the cell). Humans are exposed to a mixture of PAHs from air, food and drinking water, as well as from tobacco smoke. The principal sources of PAHs in the atmosphere are combusted fossil fuels, burnt refuse, coke ovens and vehicle emissions. PAHs can also be formed directly in foods by smoking or when freshly harvested wet seed, from which vegetable oils are produced, is direct dried e.g. by smoking processes. Smoked and grilled food may contribute significantly to the intake of PAHs if such foods are part of the usual diet.

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<sup>4</sup> SCF. (2002). Opinion of the Scientific Committee on Food on the risks to human health of Polycyclic Aromatic Hydrocarbons in food, available at [http://europa.eu.int/comm/food/fs/sc/scf/out153\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scf/out153_en.pdf)

## **2.3 Rationale for Government Intervention**

**2.3.1** Commission Regulations have general application and the direct force of law in all member states. The UK has a legal obligation to ensure that provisions are in place for their enforcement. Commission Directives are binding on member states as to the result to be achieved but the method of implementation is left to national governments. Therefore they must be transposed into national legislation. Consequently the UK also has a legal obligation to implement Commission Directives.

**2.3.2** In England, the provisions for the enactment, enforcement and implementation of Commission Regulation 466/2001 as amended and its allied enforcement Directives, is currently under The Contaminants in Food (England) Regulations 2004 (Statutory Instrument 2004 No 3062) as amended. Similar Regulations apply in Northern Ireland, Scotland and Wales. A new Statutory Instrument is now necessary to make provision for the enforcement of Commission Regulations 78/2005 and 208/2005 and transpose Commission Directives 2005/4/EC and 2005/10/EC into national legislation. The draft Contaminants in Food (England) Regulations 2005 have been developed for this purpose in England. Similar Regulations have been developed in Scotland, Wales and Northern Ireland.

**2.3.3** Failure to make these provisions will leave enforcement authorities without the necessary specific statutory legislation to ensure compliance with the Commission measures. As stated above, the UK is under a legal obligation to implement Commission Directives and, following the informal consultations, supported the procedures laid down in the Directives. Failure to implement the Directives would result in infraction proceedings against the UK and may also lead to an adverse report from the Commission Food and Veterinary Office. In addition, the lack of national recognition of the effectiveness of a harmonised enforcement approach across the EU is also likely to have an impact on trade and consumer protection.

## **3. CONSULTATION**

### **3.1 Formal consultation on the draft Regulations**

**3.1.1** As a result of comments received from previous consultations on earlier versions of the Contaminants in Food Regulations, during this consultation, the Agency requested comments and suggestions from stakeholders, in particular enforcement authorities, on ways of making the Regulations as user friendly as possible. Four substantive comments were received (summarised at Annex 4) and the draft SI has been revised. The Agency is also developing guidance on the legislation.

### **3.2 Informal consultations during the negotiations with the European Commission**

**3.2.1** During the course of the negotiations, the Agency carried out regular informal consultations with stakeholders. On each occasion, nearly 400 stakeholders including consumer groups, industry, research institutes, enforcement authorities and other

interested parties were contacted via information letters. The following paragraphs summarise the main concerns raised during the negotiations and the outcomes.

### **Within Government**

**3.2.2** Other government departments including the Department for Environment Food and Rural Affairs, the Department of Health, the Department of Trade and Industry and the Cabinet Office were included in the informal consultations. No comments were received.

### **Public Consultation**

#### Draft sampling and analysis Directive

**3.2.3** Informal consultations on the draft Directive were carried out in July and August 2004. No comments on the potential implications of implementing this legislation were received from enforcement organisations. A further letter addressed specifically to Public Analysts and other control laboratories dated 3 May 2005 did not generate any comments.

#### Heavy Metals

**3.2.4** Five information letters in particular, dated 10 October 2003, and 27 January, 17 March, 27 April, and 08 July 2004 requested views, comments and data on the Commission's proposals.

**3.2.5** Comments received during this period generally related to swordfish, in particular the larger fish, which could not comply with the existing general maximum limit of 0.05 mg/kg for cadmium in fish. This was having a considerable negative impact on the industry, particularly those importing swordfish from outside the EU, although the Agency did not receive any quantified information on this issue. Also of concern was the potential negative impact on the long-term sustainability of this species if it remained under the general limit, as in order to comply, smaller, younger fish would be taken. These concerns were presented to and discussed with the Commission and other member states and it was proposed that swordfish should be added to the fish species under the higher limit of 0.1 mg/kg. However, data submitted by UK enforcement authorities from a survey carried out in 2001 showed that levels of cadmium in swordfish fell into two groups, those containing less than 0.13 mg/kg and those containing more than 0.2 mg/kg. The UK raised this issue with the Commission and an alternative level of 0.3 mg/kg was put forward for consideration.

**3.2.6** Member states accepted this higher level as it was considered that it would go some way to addressing industry's concerns whilst continuing to maintain a high level of consumer protection and consumer choice and help to promote the sustainability of swordfish.

#### PAHs

**3.2.7** In particular, information letters dated 11 November 2002, 25 June, 21 July, 10 October and 02 December 2003 and 27 January, 17 March, 27 April, 08 July and 22 October 2004 requested views, comments and data on the Commission's proposals.

**3.2.8** Comments from the early informal consultations varied, with some respondents indicating general support for the proposals to set maximum limits for PAHs and others indicating opposition to either a specific proposed limit and/or a specific food category to be included in the legislation. Concerns included proposals to include limits for food supplements and cocoa butter. Although some member states already have national limits for food supplements, it was agreed that further investigation was needed to clarify the levels that are reasonably achievable in foods such as food supplements, and dried fruits. It was agreed that in the interim, the maximum levels for BaP in the relevant ingredients such as in oils and fats would apply. Following concerns raised by the industry, Cocoa butter is currently excluded from the legislation by a derogation, which applies until 1 April 2007 when the PAHs legislation will be reviewed, during which time industry will develop a management plan to reduce BaP levels.

**3.2.9** Initially there had been a great deal of concern regarding the proposals for smoked fish. The opinion of the fishing industry and smokehouses was that the proposed levels were likely to decimate the smoked food industry. An interim report submitted by The Sea Fish Industry Authority in October 2003 indicated that the total value of smoked fish was over £100 million per annum and involved a diverse range of products and processes. The industry includes those companies with a production of up to £18 million per annum as well as many small-scale producers supplying niche markets. However, data submitted by Sea Fish in January 2004 on the analysis of a representative range of 33 products showed that BaP levels were well below the proposed level of 5 µg/kg, suggesting that smoked fish in the UK would be able to meet this limit.

**3.2.10** In addition to the potential negative impact on the smoked food industry concerns were also expressed about the cost of testing for PAHs which at that time was around £250 per sample.

**3.2.11** Industry also remained concerned about the inclusion of shellfish in the proposed general limit of 2 µg/kg for unsmoked fishery products. Of particular concern were bivalve molluscs that inhabit inshore, often estuarine, areas. Although the proposed limit of 2 µg/kg, may have benefited shellfish consumers by reducing their dietary exposure to carcinogenic BaP, for the majority of the UK population, shellfish are not the main route of exposure of PAHs. As a result, the UK proposed that there should be a separate limit for shellfish. Data submitted to the Commission showed that more than 22% of cockles and mussels and more than 35% of native oysters sampled between February 1995 and May 1996 from several parts of the coast around England and Wales would be above the proposed limit.

**3.2.12** A revised draft Regulation (SANCO/70/2003 revision 5) which included a revised limit for shellfish of 5 µg/kg was circulated to stakeholders under cover of an information letter dated 27 April 2004. One response received from an individual, disagreed with the proposal to revise the limit and noted that "the proposed maximum level of 2 µg/kg was considered to be protective of health". This respondent also commented on the impact of the organo-chemical production and automotive

industries on the environment and proposed shellfish farms as a possible way to reduce high levels of pollution.

**3.2.13** Comments from the industry indicated that it did not have data to show the current levels of contamination but it remained concerned about the potential negative impact the proposed legislation would have on the shellfish industry. Of particular concern was the possible loss of livelihood of those employed in the industry in the affected regions in England and Wales.

**3.2.14** During a Working Group meeting in October 2004, the UK submitted data that highlighted the significant seasonal affect on the levels of contamination – the seasons when bivalves are at their best and can be harvested commercially are believed to correspond to seasonally high levels of contamination. In addition, new data submitted by other member states also indicated that 5 µg/kg could have a significant impact on the industry. As a result, the Commission proposed that the limit for bivalve molluscs only, should be raised to 10 µg/kg with the intention that this limit would be reviewed when further data became available. The proposal was discussed and adopted at the October Standing Committee. Industry indicated that it was content with this revised higher limit as it went some way to addressing the potential negative impact on this sector.

## **4. OPTIONS**

**4.1** The Options are those discussed below

**Option 1** Do nothing

**Option 2** Make provision for the enforcement of Commission Regulations 78/2005 and 208/2005, and implement Commission Directives 2005/4/EC and 2005/10/EC in full as The Contaminants in Food (England) Regulations 2005. Similar Regulations would be introduced in Scotland, Wales and Northern Ireland.

## **5. COSTS AND BENEFITS**

### **5.1 Sectors and Groups Affected**

**5.1.1** The draft Contaminants in Food (England) Regulations 2005 apply to enforcement authorities and all businesses involved in the food sector. As stated earlier in this RIA, the draft Regulations will revoke and replace earlier versions of The Contaminants in Food (England) Regulations.

**5.1.2** In summary, the draft Regulations

- i) set out the offences and penalties for non-compliance with Commission Regulation 466/2001, as amended;
- ii) modify section 29 of the Food Safety Act 1990, as amended; and
- iii) make consequential amendments to the Food Safety (Sampling and Qualifications) Regulations 1990 in so far as they apply in relation to England.

**5.1.3** The draft Regulations will not have any race equality or sustainability impacts. There are no specific costs to industry arising from these Regulations. The potential impact on the public sector is discussed in paragraph 5.2 below.

## **5.2 Analysis of Costs and Benefits**

### **Option 1: Costs and Benefits**

**5.2.1** This is not a viable option. Commission Regulations are directly applicable in Member States from the date that they take effect and the UK agreed to the measures after consultation during the negotiating stages. The UK has a legal obligation to ensure that provisions are in place providing for their enforcement. The draft Contaminants in Food (England) Regulations 2005 have been developed for this purpose and will provide enforcement authorities with the necessary domestic legislation to enable them to enforce the revised heavy metals limits and the new maximum limits for BaP.

**5.2.2** The UK also has a legal obligation to implement Commission Directives 2005/4/EC and 2005/10/EC. To do nothing would:

- result in infraction proceedings against the UK government;
- perpetrate inconsistent sampling and analysis procedures in the control laboratories,
- possibly lead to an adverse report from the Food and Veterinary Office

**5.2.3** There are no quantifiable health risks or benefits by not implementing the Directives as enforcement authorities would continue to use existing sampling and analysis legislation. However, the lack of implementing the agreed method may reduce enforcement, which could adversely affect consumer safety.

### **Option 2: Costs and Benefits**

#### **Benefits**

**5.2.4** As highlighted in paragraph 2 above, The draft Contaminants in Food (England) Regulations 2005 will make the necessary provisions for the enforcement and enactment of Commission Regulation 466/2001 as amended. Consumers will benefit from the new Regulations, as enforcement of the limits and implementation of the sampling and analysis methods will ensure that enhanced and more consistent measures are in place.

**5.2.5** Benefits to industry and the impact on the environment arise mainly from the Commission Regulations - the revised higher limit for cadmium in swordfish and the revised higher limit for BaP in bivalve molluscs. Food operating businesses will also benefit from the new Regulations in that they will ensure that measures, which are applicable to all member states, are in place, thereby facilitating trade and ensuring a level 'playing field'.

**5.2.6** Transposition of Commission Directives 2005/4/EC and 2005/10/EC into national law would fulfil national obligations to implement these measures. The legislation would promote consistent and effective enforcement by reducing

uncertainty or dispute in interpreting results against limits. This will benefit industry and consumers through improved confidence in compliance testing.

## Costs

**5.2.7** Although industry and enforcement authorities should be carrying out checks to ensure compliance with the Commission measures, neither Commission Regulation 466/2001, as amended, nor the sampling and analysis Directives prescribe the number of checks that should be carried out by these organisations. In addition those working in the production, processing, storage, distribution and sale of food have general responsibilities and should be taking all reasonable precautions including carrying out checks to ensure compliance with The Food Safety Act 1990, as amended.

**5.2.8** As discussed earlier, maximum limits for heavy metals in fish have applied since 2002 and industry and enforcement authorities should already be carrying out checks to ensure compliance with the existing heavy metals legislation. Information provided by these businesses did not indicate that additional costs would arise from checking compliance with the maximum limits set in Commission Regulation 78/2005.

**5.2.9** Commission Directive 2005/4/EC amends Commission Directive 2001/22/EC in particular in respect to the measurement uncertainty for analysis and as such applies to the Public Analysts and other control laboratories. Enforcement authorities were kept informed throughout the development of the draft Directive and were included in two informal consultations on the possible implications of the amendments. The Agency did not receive any substantive comments from these organisations during the negotiations and the draft document was adopted.

**5.2.10** During the formal consultation, comments received by the Agency's office in Scotland from the Association of Public Analysts indicated that there would be additional costs associated in validating methods and in the purchase of suitable certified reference material. However, as these comments have not been quantified, it is difficult to estimate the potential costs to Public Analysts and control laboratories. The amendments to the existing enforcement Directive are in line with analytical laboratories ongoing requirements to keep pace with advances in technology and increasing analytical sophistication.

**5.2.11** Commission Regulation 208/2005 introduces new statutory limits for BaP in certain foodstuffs and industry and enforcement authorities should check compliance with the legislation. The cost of analysis for PAHs in foodstuffs is currently around £200 to £300 per sample, with analysis for BaP at around £200 per sample. During the informal consultations, the Agency received little quantified information on the potential cost to industry and enforcement authorities arising from this legislation.

**5.2.12** The limits have been set at levels which take account of the possible degree of non-compliance but which are considered proportionate to the risk from consuming contaminated products. Although the higher limit for BaP in bivalve molluscs will go some way to lessen the loss of a large proportion of shellfish beds, it is possible that a number of beds, particularly those in populous or industrialised regions, may still be lost. However, the Agency believes that the industry as a whole should be able to provide products from clean waters that will meet the regulatory limits.



**5.2.13** A copy of the draft proposals for the sampling and analysis for BaP for enforcement purposes was circulated to stakeholders for comment on 17 March 2004. No information on the potential impact of implementing Directive 2005/10/EC has been received from enforcement authorities.

## **6. SMALL FIRMS IMPACT TEST**

**6.1** Stakeholders including the Small Business Service, the Federation of Small Businesses and the British Chamber of Commerce were consulted throughout the negotiations on the EU measures. No comments on the Commission's proposals were received from these organisations. No comments specifically from small businesses were received in respect to heavy metals. Small businesses involved in the fishing and shellfish industries were included in the Agency's informal consultations and the industry's internal consultation on the proposals for PAHs. Comments received have been included in paragraph 3.3.

## **7. COMPETITION ASSESSMENT**

**7.1** Commission Regulations 78/2005 and 208/2005 apply to all businesses involved in the food industry and enforcement authorities. Commission Directives 2005/4/EC and 2005/10/EC apply to Public Analysts and other control laboratories only.

**7.2** A competition filter has been completed. Although some costs to businesses from the implementation of the EC Directives and the enforcement of the EC Regulations have been identified there are no anticipated effects on competition. From the information received from the informal consultations, it would appear that the Commission Regulations have had a positive impact on competition in particular for importers of swordfish and the shellfish industry. Consistent and effective enforcement of the maximum limits set in Commission Regulation 466/2001 as amended, across the EU encourages competition in these industries.

## **8. ENFORCEMENT, SANCTIONS AND MONITORING**

### **8.1 Enforcement**

Local Authorities and Port Health Authorities are responsible for enforcing Food Safety Regulations.

### **8.2 Sanctions**

Local Authorities and Port Health Authorities will be responsible for enforcing The Contaminants in Food (England) Regulations 2005. A fine not exceeding level 5 on the standard scale will apply in the case of breaches of the main offence of placing on the market (regulation 3).

## **9. IMPLEMENTATION AND DELIVERY PLAN**

**9.1** The Contaminants in Food (England) Regulations 2005 revoke and replace earlier Statutory Instruments. They make provision for the enforcement of EU measures setting maximum levels for certain contaminants in food and the transposition of the allied enforcement Commission Directives. As highlighted in paragraph 8 above, Local Authorities and Port Health Authorities are responsible for enforcing Food Safety Regulations, including the maximum levels for contaminants in food. The Local Authorities Co-ordinators of Regulatory Services (LACORS), the Association of Port Health Authorities and the Association of Public Analysts (APA) are consulted specifically through established Agency liaison mechanisms such as Interested Parties letters during the development of the EU proposals and the formal consultations during the implementation process. In addition, the Agency is currently developing guidance on the Regulations in consultation with stakeholders.

## **10. POST-IMPLEMENTATION REVIEW**

**10.1** The Agency will continue to consult with enforcement, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation. As part of this process, the Agency meets regularly with representatives from enforcement organisations (Enforcement Liaison Group) and Public Analysts (the APA Liaison meetings) to help inform this review.

**10.2** As stated earlier in this RIA, 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. The Agency will consult stakeholders for information to inform these investigations, including data available from enforcement or industry testing, and any data from surveillance the Agency may undertake on these contaminants in food.

## **11. SUMMARY AND RECOMMENDATION**

**11.1** European Community measures (Commission Regulation 466/2001) setting maximum levels for certain contaminants in foodstuffs have applied since 2002. The aim of Commission Regulation 466/2001 is to provide an increased level of consumer protection by keeping contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain. It also harmonises member states' existing measures facilitating trade. The European Commission, in co-operation with member states, investigates whether limits should be set for additional contaminants and also reviews the maximum levels for those contaminants currently in the legislation. Consequently Commission Regulation 466/2001, which has applied since April 2002, has undergone a number of amendments. The Regulation is supported by various allied Commission Directives, which lay down the procedures for the methods of sampling and analysis for the official control of those contaminants specified in the Regulation.

**11.2** In 2002, the Commission signalled its intention to set maximum levels for polycyclic aromatic hydrocarbons (PAHs). In addition, a review of the maximum levels for heavy metals (lead, cadmium and mercury) in fish commenced in 2003.

Stakeholders including consumer groups, industry and enforcement authorities were consulted throughout the negotiations on the Commission's proposals. Concerns raised and the outcomes are discussed in detail at paragraphs 3.2.2 to 3.2.14 above. Following consultation Commission Regulation 466/2001 was amended in regards to PAHs (Commission Regulation (EC) 208/2005) and heavy metals (Commission Regulation 78/2005). In addition, two Commission Directives (2005/4/EC (amending Directive 2002/22/EC in respect to heavy metals and 3-MCPD) and 2005/10/EC (PAHs)) have been adopted. Member states must comply with the provisions in the Directives by 8 February 2006.

**11.3** The UK has a legal obligation to make provision for the enforcement of Commission Regulations and to transpose Commission Directives into national legislation. Comments received from the formal consultation on the draft SI were mainly in respect to the wording of the draft. In view of these comments, the Agency has restructured the text and introduced sub-headings in regulation 5 to the draft SI to make this section more understandable. The Agency is also developing Guidance Notes on the legislation. Details of the comments are at Annex 4. The Agency did not receive any quantified information from stakeholders on the costs or benefits of implementing these measures. The table below provides a qualitative summary of the options for the UK.

**Summary Costs and Benefits Table**

<b>OPTION</b>	<b>Total benefit per annum: economic, environmental, social</b>	<b>Total cost per annum: • economic, environmental, social • policy &amp; administrative</b>
<b>1 – Do Nothing</b>	None	<ul style="list-style-type: none"> <li>• Infraction proceedings against the UK government</li> <li>• Possible adverse report from the Commission's Food &amp; Veterinary Office</li> <li>• Possible financial costs to industry arising from lack of consumer confidence in the safety of the UK food supply</li> </ul>
<b>2 – Implement the EC measures as The Contaminants in Food (England) Regulations 2005</b>	<ul style="list-style-type: none"> <li>• Fulfils the UK's legal obligations to make provision for the enforcement of EC Regulations and to implement the Directives</li> <li>• Continued high level of public health safety &amp; improved consumer confidence in compliance testing</li> <li>• The new Regulations will ensure that measures, which are applicable to all member states, are in place, thereby facilitating trade and ensuring a level 'playing field'.</li> <li>• Environmental and social benefits were addressed during the negotiations of the Commission Regulations</li> </ul>	<ul style="list-style-type: none"> <li>• No quantified information received from stakeholders in respect to costs arising from the EC legislation. There are likely to be some costs arising from the costs of analysis but these are expected to be minimal. The EC legislation does not specify the number of checks to be carried out to ensure compliance with the limits.</li> <li>• The Directives apply to enforcement authorities only. Little quantified information from these organisations was received during the consultations</li> <li>• The UK successfully addressed the economic, social and environmental concerns raised during the negotiations on the Commission's proposals for maximum limits.</li> </ul>

It is recommended that **Option 2 is supported**.

The Contaminants in Food (England) Regulations 2005 will provide enforcement authorities with the necessary provisions to effectively enforce the limits set in Commission Regulation 466/2001, as amended. They also fulfil the UK's legal obligation to transpose Directives 2005/4/EC and 2005/10/EC, which lay down harmonised statutory official controls, into national legislation. The Regulations will revoke and replace The Contaminants in Food (England) Regulations 2004 (SI 2004 No 3062) as amended.

## 12. DECLARATION AND PUBLICATION

### **Declaration**

*I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.*

**Signed by the responsible Minister: Caroline Flint**

**Date: 23<sup>rd</sup> November 2005**

**Parliamentary Under Secretary of State, Department of Health.**

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## **Health effects of Lead, Cadmium and Mercury**

### **Lead**

Lead absorption may constitute a serious risk to public health. It is a cumulative poison, which may induce reduced cognitive development and intellectual performance in children and increased blood pressure and cardiovascular diseases in adults. Food is one of the major sources of lead exposure in the UK. However, due to the commitment by the UK and the Commission to reduce lead exposure (e.g. the phase-out of leaded petrol, controls on industrial emissions) there has been a steady decrease in the population dietary exposure to lead since 1980. Lead levels in food now largely reflect background environmental levels.

### **Cadmium**

Cadmium is a cumulative contaminant, which can affect kidney function. It may also induce skeletal damage and reproductive deficiencies. It cannot be excluded that cadmium acts as a human carcinogen. Cadmium is present at low concentrations in most foods, with those that are consumed in larger quantities making the greatest contribution to the dietary exposure. There has been little change in the dietary exposure of the general UK population to cadmium over the last 20 years.

### **Mercury**

Mercury compounds are neurotoxins, which may induce alterations in the normal development of the brain in infants and at higher levels may induce neurological changes in adults. The main sources of exposure to mercury are from the diet and dental amalgam. Mercury is present in most foods naturally. It can exist in inorganic and organic forms in food, with the organic forms, such as methylmercury, being more toxic following ingestion.

**FINAL REGULATORY IMPACT ASSESSMENT**

**THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2005**

**Maximum limits for ochratoxin A in certain foodstuffs**

## **1. TITLE OF PROPOSAL**

### **The Contaminants in Food (England) Regulations 2005**

1.1. Provision for the enforcement of Commission Regulation (EC) No. 123/2005 of 26 January 2005 amending Commission Regulation (EC) No. 466/2001 as regards ochratoxin A in certain foodstuffs.

1.2. Implementation of Commission Directive 2005/5/EC of 26 January 2005 amending Commission Directive 2002/26/EC as regards sampling methods and methods of analysis for the official control of the levels of ochratoxin A in certain foodstuffs.

## **2. Purpose and intended effect of measure**

### **2.1. The Objective**

2.1.1. The first objective of these Regulations in relation to this RIA is to make provision for the enforcement, in England, of Commission Regulation 123/2005, which amends Commission Regulation 466/2001 and sets maximum limits for ochratoxin A in coffee, wine and grape juice and grape must. These limits have applied across the European Union to all such products placed on the market on or after 1 April 2005.

2.1.2. The second objective is to transpose the associated Commission Directive 2005/5/EC, amending Directive 2002/26/EC, on sampling methods and methods of analysis for the official control of the levels of ochratoxin A into national law.

2.1.3. The purpose of both these measures is to provide consumers with an increased measure of protection against undesirable contaminants i.e. ochratoxin A in those foods that contribute significantly to the total dietary exposure of consumers to those contaminants.

2.1.4. Currently the maximum limits set in Commission Regulation 466/2001, as amended are enforced in England under The Contaminants in Food (England) Regulations 2004 [SI 2004 No. 3062] as amended by The Contaminants in Food (England) (Amendment) Regulations 2005 [SI 2005 No 775]. The associated Commission Directives on sampling and analysis for official control purposes are also implemented in these Regulations. Similar Regulations apply in Scotland, Wales and Northern Ireland. These and preceding Regulations have previously been consulted on<sup>5</sup>.

2.1.5. New Regulations have now been drafted and will revoke and replace The Contaminants in Food (England) Regulations 2004, as amended. These Regulations

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<sup>5</sup> Consultations on Commission Regulation 466/2001 and the Directives were carried out under The Contaminants in Food (England) Regulations 2002 in July 2001 (aflatoxins in spices), December 2001 (ochratoxin A) and March 2002 (lead, cadmium, mercury, dioxins, 3-MCPD and nitrates), The Contaminants in Food (England) Regulations 2003 in February 2003 (dioxins sampling and analysis Directive), The Contaminants in Food (England) Regulations 2004 (patulin, aflatoxins in maize, dioxins and inorganic tin in canned foodstuffs) and under The Contaminants in Food (England) (Amendment) Regulations 2005 (nitrate, aflatoxins & ochratoxin A in foods for infant and young children)

will be The Contaminants in Food (England) Regulations 2005 and will extend to England only.

2.1.6. A review of the maximum limits for ochratoxin A in the annex of Commission Regulation 123/2005 is due to be carried out at the latest by 30 June 2006, based on an up to date risk assessment on ochratoxin A to be performed by the European Food Safety Authority. The review will concern in particular the maximum limits for ochratoxin A in dried vine fruit and grape juice and the consideration of setting maximum limits for ochratoxin A in some other products including spices and cocoa.

2.1.7. This Regulatory Impact Assessment (RIA) is concerned only with the enforcement of Commission Regulation (EC) No. 123/2005 and the implementation of Commission Directive 2005/5/EC. As part of this consultation, a separate RIA (annex 1A) addresses the enforcement of Commission Regulations 78/2005 in respect to heavy metals in fish and 208/2005 in respect to polycyclic aromatic hydrocarbons (PAHs) in certain foodstuffs. The latter RIA also addresses the issue of implementation of Directives in respect to the sampling and analysis of lead, cadmium, mercury and 3-MCPD in foodstuffs (2005/4/EC) and of benzo-a-pyrene (BaP) in foodstuffs (2005/10/EC).

## **2.2. The Background**

2.2.1 European Community (EC) legislation on contaminants in food is made under the contaminants in food framework Regulation, Council Regulation 315/93/EEC. The Regulation lays down Community procedures for contaminants in food and applies to those contaminants that are not covered by other specific Community legislation. In view of the disparities between the existing laws of Member States in regard to the maximum levels for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Community measures (Commission Regulation 466/2001) were introduced under Council Regulation 315/93/EEC. The provisions and requirements of Commission Regulation 466/2001 have applied across the EU since April 2002.

2.2.2 The intention of Commission Regulation 466/2001 is to provide consumers with an increased measure of protection by setting EC maximum levels 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 grossly contaminated food from entering the food chain and harmonises Member States' existing measures, thus facilitating trade. Maximum levels for lead, cadmium, mercury, dioxins, nitrates, 3-MCPD, aflatoxins, ochratoxin A, patulin and inorganic tin have already been set under this legislation.

2.2.3 In view of the requirement to protect public health by keeping contaminants at levels that are toxicologically acceptable, the European Commission investigates whether limits should be set for additional contaminants and/ or foods and also reviews the maximum limits for those contaminants currently in the legislation. There is currently harmonised EC legislation on ochratoxin A in certain foodstuffs. In England, this legislation is implemented by The Contaminants in Food (England) Regulations 2004 [SI 2004 No. 3062], as amended and enforces limits for ochratoxin



A in foods including cereals, products derived from cereals, dried vine fruits and foods for infants and young children.

2.2.4. Ochratoxin A belongs to a group of chemicals called mycotoxins and is produced by *Aspergillus ochraceus*, a mould species that grows in warm humid conditions. The toxin is also produced by *Penicillium verrucosum*, which generally favours climates with lower temperatures and humidity. Ochratoxin A is found as a contaminant in a wide range of commodities and surveys have indicated that cereals, cereal products and dried vine fruit are the biggest contributors to ochratoxin A intake in the UK diet. However, other commodities can also be affected including coffee and coffee products, wine, grape juice, beer, cocoa and cocoa products and spices. It has also been detected in food products from non-ruminant animals exposed to ochratoxin A from animal feed.

2.2.5. Ochratoxin A has been implicated as a cause of kidney damage in humans and in addition has been shown to cause renal toxicity, nephropathy and immunosuppression in several animal species. It is considered by the UK Committees on Carcinogenicity (COC) and Mutagenicity (COM) of Chemicals in Food, Consumer Products and the Environment to be a potential genotoxic carcinogen, although the mechanism is still unclear. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) has recommended that ochratoxin A concentrations in food should be reduced to the lowest technologically achievable.

2.2.6. In addition, ochratoxin A was considered by the European Union's Scientific Committee on Food (SCF) in 1998. It concluded that it would be prudent to reduce exposure of ochratoxin A as much as possible, ensuring that exposures are towards the lower end of the range of Tolerable Daily Intakes (TDI) of 1.2 – 14 nanograms/kg bodyweight per day, which have been estimated by other bodies e.g. less than 5 nanograms/kg bodyweight per day.

2.2.7. International organisations such as the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) are actively involved in providing information on various aspects of prevention and control of ochratoxin A. The Codex Alimentarius Commission (Codex) is a joint FAO/WHO committee that offers such advice to countries world-wide and has produced documents on the prevention and reduction of ochratoxin A in cereals.

2.2.8. The FAO Food Quality and Standards Service has recently launched a new web-site, 'Reducing ochratoxin A in coffee', supporting an international project being implemented by the Service: 'Enhancement of coffee quality through the prevention of mould formation'. The web-site provides information on the background and context of this issue and outlines activities being carried out as part of the project. An electronic training resource will also be made available in due course.

2.2.9. The UK has carried out work on the occurrence of ochratoxin A in coffee previously. A survey for ochratoxin A in retail coffee products was completed in 1995<sup>6</sup>, where the toxin was detected in 64 of the 80 soluble product samples and in 17 of the 20 roast and ground products. Levels detected ranged from 0.1 to 8 µg/kg. A survey was also carried out the following year on the occurrence of ochratoxin A in

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<sup>6</sup> MAFF (1995) Surveillance for Ochratoxin A in retail coffee products. *Food Surveillance Information Sheet No. 73*, September 1995

green (unroasted) coffee beans<sup>7</sup>. A total of 181 (62 percent) of samples did not contain measurable amounts of ochratoxin A. The maximum level found was 27.3 µg/kg.

2.2.10. In addition, a UK survey was completed in 1998<sup>8</sup> to determine the levels of ochratoxin A contamination in a total of 501 retail products including red wine and grape juice. Ochratoxin A was detected in 385 (77%) of the food samples analysed. The highest levels of contamination however occurred in dried vine fruit whereas only low levels of ochratoxin A were detected in red wine (0.1 – 0.08 µg/l) and grape juice (0.03 – 2.05 µg/l).

2.2.11. Current data shows that coffee is an extremely popular drink, with approximately 70 million cups of coffee per day drunk in the UK alone<sup>9</sup>. Indeed, approximately four-fifths of a group of Britons surveyed recently indicated that they drunk either instant or fresh ground coffee<sup>10</sup>. In addition, instant coffee is drunk by twice as many people as fresh ground, although consumption of the former appears to be dropping at present in favour of the latter.

2.2.12. The annual consumption of wine in the UK rose sharply during the 1990's and beyond from 12.6 litres per person in 1992 to 19.6 litres per person in 2002<sup>11</sup>. In addition, wines are also consumed in greater proportion to other alcoholic beverages with 41% of a population of adults questioned declaring that they drink white wine compared with 37% who drink lager and 35% who drink red wine<sup>12</sup>. Other alcoholic beverages were drunk by 20% (ale/bitter) or less.

2.2.13. The volume of grape juice used in the UK is a very small percentage of the total amount of fruit juice used, even compared to grapefruit or tomato and there are few statistics on consumption. The majority of grape juice consumed in the UK is combined with other fruit juice concentrates such as mango or guava. Products containing grape juice however, would be covered by the legislation.

### **2.3. Rationale for Government Intervention**

2.3.1. Enforcing the new limits laid down in Commission Regulation 123/2005 for ochratoxin A in coffee, wines and grape juice will provide consumers with an increased measure of protection by ensuring that enforcement authorities have sufficient means by which to prevent contaminated products from entering the market. To do nothing would 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 Commission Regulation 466/2001, as amended, which are directly applicable to all Member States.

2.3.2. The purpose of Directive 2005/5/EC is to amend Commission Directive 2002/26/EC and continue to provide a harmonised enforcement approach throughout

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<sup>7</sup> MAFF (1996) Surveillance for Ochratoxin A in green (unroasted) coffee beans. *Food Surveillance Information Sheet No. 80 (revised)*, March 1996

<sup>8</sup> MAFF (1999) Survey of retail products for ochratoxin A. *Food Surveillance Information Sheet No. 185*, August 1999

<sup>9</sup> British Coffee Association web-site, [www.britishcoffeeassociation.org](http://www.britishcoffeeassociation.org)

<sup>10</sup> Mintel report on Coffee in UK, January 2004

<sup>11</sup> British Beer and Pub Association 2003 web-site, [www.beerandpub.com](http://www.beerandpub.com)

<sup>12</sup> Mintel report on Wines in UK, January 2003

Member States for the sampling methods and methods of analysis for official control purposes. The introduction of these harmonised statutory controls would reduce uncertainty or dispute in interpreting results against limits and would reduce inconsistency or dispute of sampling and analytical procedures. This would provide benefits to industry and consumers in improved confidence in compliance testing. Failure to adopt harmonised sampling and analytical controls would undermine enforcement bodies' ability to enforce the legislation effectively and efficiently.

### **3. CONSULTATION**

#### **3.1. Within Government**

3.1.1 Other government departments including the Department for Environment, Food and Rural Affairs, the Department of Health, the Department of Trade and Industry, the Foreign & Commonwealth Office and the Cabinet Office were made aware of negotiations relating to the Regulation and Directive through Commission Working Group and Standing Committee meeting reports and Interested Parties letters. No comments have been received from these departments.

#### **3.2. Public Consultation**

3.2.1 During the course of the negotiations with the Commission, the Food Standards Agency has frequently conveyed information to interested organisations including industry, research institutes, consumer groups, enforcement authorities and other interested parties. Discussions on possible limits for ochratoxin A in foodstuffs began at the Commission Working Group of Agricultural Contaminants meeting in September 1999. However, limits for products other than cereals, cereal products and dried vine fruits were then removed from the draft Regulations.

3.2.2. Further discussions on limits for coffee, wine and grape juice recommenced in June 2003. All stakeholders were kept informed, via interested parties letters, on a regular basis throughout negotiations on these limits. Stakeholders including industry were given the opportunity to fully contribute to discussions in respect to setting further limits. Ochratoxin A forums and workshops were held at the European Commission to take views into consideration and representations from the coffee, wine and grape juice industries were made at these meetings, who presented data on ochratoxin A contamination.

3.2.3. As a consequence of industry consultation and discussions at the Commission, limits for soluble coffee were renegotiated and the inclusion of other fruit juices and alcohol beverages withdrawn from the Regulation. In addition, the setting of limits for other commodities such as spices and cocoa has been deferred until more data are available. Draft Commission Regulations setting limits for ochratoxin A in coffee, wine and grape juice were finally agreed at the Standing Committee meeting in October 2004. In addition, trade organisations of the relevant businesses have been contacted directly to request information on compliance and financial implications. Responses have been received in relation to coffee and grape juices, which has helped to formulate this RIA.

3.2.4. In total, 15 responses were received during the formal 12-week consultation period (July – October 2005). The majority of these simply acknowledged the consultation or provided comments on the structure of the Statutory Instrument. Only one comment related to the introduction of limits for ochratoxin A in those products concerned, which supported the need for making sure food is fit for human consumption at the point of sale. A summary table of all responses can be found in the Food Standards Agency's Library and Information Service.

## **4. Options**

**Option 1:** Do nothing.

**Option 2:** Make provision for the enforcement of Commission Regulation (EC) No. 123/2005 and transpose Commission Directive 2005/5/EC under The Contaminants in Food (England) Regulations 2005. Corresponding legislation would be introduced separately in Scotland, Wales and Northern Ireland.

## **5. COST AND BENEFITS**

### **5.1. Sectors and groups affected**

5.1.1. Typical businesses that will be affected by enforcing the maximum limits are manufacturers, importers, traders, processors, wholesalers and retailers of coffee, wine and grape juices, who will need to ensure that they comply with the maximum limits. It is not anticipated that the new measures will have any impact on the level of competition within the affected sectors. Food operating businesses will gain from the Regulations in that they will ensure that measures, which are applicable to all Member States, are in place, thereby facilitating trade and ensuring a level 'playing field'.

5.1.2. In all cases, local authorities and port health authorities are responsible for enforcing Regulations with respect to food safety and will therefore be affected. Other government departments such as the Food Standards Agency may also be affected as they currently carry out surveys on foods to protect and inform consumers, monitor trends and assess dietary exposure and to ensure that the legislation is effective in protecting consumers from exposure to harmful contaminants.

5.1.3. Consumers of coffee, wines and grape juices would gain from the new Regulations, as enforcement of the limits and implementation of the sampling and analysis Directive would ensure that enhanced and more consistent measures are in place to protect them against harmful chemicals, specifically ochratoxin A. The Regulations will not have any impact on race equality and there are no other anticipated social or environmental impacts of the Regulations.

### **5.2. Benefits**

#### **Option 1**

5.2.1. This is not a viable option and there are no foreseeable benefits with this option. Commission Regulations are binding in their entirety and directly applicable

in Member States from the date that they take effect. The UK has a legal obligation to ensure that provisions are in place to provide for their enforcement in full. The UK also has a legal obligation to implement Commission Directive 2005/5/EC by 18 February 2006. This option would therefore result in infraction proceedings against the UK government.

5.2.2. To do nothing may endanger human health and would leave the UK enforcement authorities without any domestic legislation for the enforcement and execution of Commission Regulation 123/2005. It would also leave the UK enforcement authorities without appropriate statutory sampling and analysis procedures in respect to ochratoxin A in coffee, wines and grape juices. This would leave any results of sampling and analysis for enforcement purposes open to interpretation. This option may therefore compromise consumer health.

## **Option 2**

5.2.3. This option would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of Commission Regulation 123/2005. It would also provide UK enforcement authorities with statutory sampling and analysis procedures to ensure adherence with the limits.

5.2.4. This option would harmonise standards across Member States and prevent any barrier to trade occurring as a result of existing or future legislation in place in individual Member States.

5.2.5. The potential benefits to health are difficult to quantify but are likely to be significant including improving health protection for a large section of the population, including those who consume the foods covered by Commission Regulation 123/2005, particularly coffee and wines. Ochratoxin A has been implicated as a cause of kidney damage in humans and is considered by the COC and COM to be a potential genotoxic carcinogen and may cause cancer in humans. This option may therefore potentially avoid an additional burden on the health service through prevention of long-term illness.

5.2.6. Therefore, **option 2 is the preferred option.**

## **5.3. Costs**

### **Business Costs**

5.3.1. Industry has been made aware of the potential for a limit to be set since 2003 and the maximum limits introduced by Commission Regulation 123/2005 have applied across the EU since 1 April 2005. Industry should already be taking steps to assure themselves that their products comply.

5.3.2. Industry must currently carry out checks to satisfy compliance with the “due diligence” requirement under section 21 of the Food Safety Act 1990. However, there are no specific requirements to test products under Commission Regulation 466/2001, as amended and it is the responsibility of individual food operating businesses to determine how they satisfy this requirement.

5.3.3. Coffee trade organisations have indicated that approximately 75 – 80% of businesses are already complying with the requirements. The British Soft Drinks industry has also indicated that the responsibility to show compliance falls upon the grower/ producer of grape juices, who are in the vast majority of cases, non UK-based and the impact on UK businesses would therefore be negligible.

5.3.4. The Agency would expect any changes in costs to industry to be minimal. The Agency has not received any additional comments from industry on these issues during the formal consultation period.

### **Government costs**

5.3.5. The Regulations are being enforced by local authorities and in relation to imported products, by port health authorities. The distribution of costs incurred across England may vary depending on location. It is difficult to estimate these costs without details of the precise regime that will operate; for example, what proportion of an authority’s budget would be allocated for checking compliance with the Regulations. There may be some extra costs to these authorities due to the additional sampling and associated staff time that may be required to check compliance with the new limits. This point has been raised by enforcement groups. The decision to undertake sampling and analysis however is made by each enforcement authority on a risk assessment basis and is not dictated by the Food Standards Agency.

5.3.6. The Association of Public Analysts (APA) in Scotland has indicated during the Scottish consultation that there will be additional costs to public analysts. However, it is expected that these costs will be minimal as there have been limits for ochratoxin A in other foods since 2002 and it is possible to adapt existing methodology, where appropriate reference materials should already be in place. No other comments have been received from enforcement bodies in relation to the introduction of new limits for ochratoxin A.

5.3.7. As previously stated in this RIA, ochratoxin A has been implicated as a cause of kidney damage in humans and is considered by the COC and COM to be a potential genotoxic carcinogen and may cause cancer in humans. Any prevention of long-term illness through introduction of the Regulations (option 2) may therefore potentially avoid an additional burden on the health services and lost productivity from lost working days. It is not anticipated that option 2 would have any other environmental or social impact related costs.

### **Summary of costs and benefits**

	<b>Costs</b>	<b>Benefits</b>	<b>Groups affected</b>
<b>Option 1</b>	None	None	None
<b>Option 2</b>	Minimal	Provide enforcement of Regulation 123/2005 & implement Directive 2005/5/EC, improving consumer protection & potentially minimising burden on health service	Enforcement authorities & industry

## **6. the small firms' impact test**

6.1. Stakeholders including the Small Business Service, the Federation of Small Businesses and small businesses themselves, including those that are members of trade associations have been consulted throughout 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 if not already contacted as part of the consultation process.

6.2 Coffee trade associations have indicated that there may be a disadvantage to small businesses in comparison to larger businesses due to disproportionate costs caused by additional testing. However, as previously stated in section 5.3, it is the responsibility of individual food operating businesses to show how they satisfy compliance with the "due diligence" requirement under section 21 of the Food Safety Act 1990. This may require for example, that businesses specify requirements to be met by their supplier prior to receiving the product to ensure that the products are not contaminated above the permitted limits. This is currently the case in other sectors as demonstrated by comments made by the grape juice industry. It therefore maybe the case that there are few or no cost implications for businesses, including in particular small businesses. No further comments have been received on this issue during the 12-week consultation.

## **7. Competition assessment**

7.1. The coffee, wine and grape juice markets will all be affected. This will include manufacturers, importers, traders, processors, wholesalers and retailers of these products.

### **7.2. Market characteristics**

#### **Coffee**

7.2.1. Approximately 4000 people are employed in the UK coffee industry, which is worth an estimated £738 million<sup>10</sup>. The approximate value of imports into the UK is £52 million, based on members of the British Coffee Association, who represent the majority of the industry.

7.2.2. The market for coffee divides into two primary sectors: instant roast and ground. Instant coffee remains the dominant sector in the market and one of the most prominent grocery markets in the UK. Retail sales of instant coffee in the UK stood at £651 million in 2002. Regular instant coffee accounts for almost half the market share with premium freeze dried making up another quarter. Two suppliers dominate the market for instant coffee in the UK, with Nestlé accounting for 57% and Kraft (Kenco) in second place with 25% of the instant sector. The Douwe Egberts brand

(Sara Lee), accounts for a little over 3% with the rest made up by own-label and a series of specialised niche producers which tend to focus on the more diverse sub-sectors of the coffee market<sup>10</sup>.

7.2.3. UK retail sales of ground coffee/ coffee beans represent a small proportion of the total coffee consumed in the UK, although the balance against instant coffee is slowly changing due in part to the growing presence of dedicated coffee shops on the high street. The value of this particular part of the market was £100 million in 2002<sup>10</sup>. While two major players are dominant in the instant market, the ground sector is far more open with a number of suppliers holding a reasonable share. The market for fresh ground coffee has grown over years 1999 – 2003 by just under 10%, with Douwe Egberts as the number one brand (15% market share) with a multitude of other brands and own-label coffee making up the rest in roughly equal proportions of just over 40% each<sup>10</sup>.

## **Wines**

7.2.4. Volume sales of still wine in the UK showed 33% growth over the period 1997 to 2002, to stand at an estimated 985 million litres in the latter year. In the UK, big brands have acquired an ever-increasing share of what is still an expanding market. Up-to-date figures show that wine, including sparkling wine taken out of bond and released for home consumption in the UK for December 2004 was over 115,000 litres, a rise of 22% and 35% for still and sparkling wines respectively for the same period in 2003<sup>13</sup>.

7.2.5. UK retail wine sales registered 55% growth at current prices between 1997 – 2002, and were worth an estimated £7.63 billion in 2002<sup>12</sup>. Growth in the UK market has come primarily from the wines of the New World - predominantly Australia and the US - and is a result of generally improved product quality, increased media exposure and more aggressive marketing. UK retail sales of sparkling wines (including champagne) stood at an estimated £1.14 billion in 2002<sup>14</sup>, taking the total market value to just under £8.8 billion.

7.2.6. Still wines can be split into two main sectors, red/rosé and white, with the former accounting for just over 55% of UK retail sales. Most wine is imported from overseas with well over 1,000 million litres being imported in 2001<sup>12</sup>. The English wine industry is still very small in comparison, but is steadily improving and sales have doubled since 1997 according to the UK Vineyards Association. There are now some 350 vineyards in the UK, producing around 2 million bottles.

7.2.7. As with many other categories within the drinks market, the wine category is steadily dividing up with a relatively small number of major, comparatively well-known brands and then several hundreds of others (including own-labels). Indeed, the UK wine market remains extremely diverse, whereby even the largest brands have a relatively small share of total sales. Mintel's 2003 report identified E&J Galla (4.2%), Jacob's Creek (4.0%) and Stowells of Chelsea (4.0%) as the UK leading wine brands, by volume in 2001<sup>12</sup>. By comparison, over half (56%) of wine sold (by volume) were own brand-labels.

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<sup>13</sup> Wine and Spirits Trade Association web-site, [www.wsa.org](http://www.wsa.org)

<sup>14</sup> Mintel report on Sparkling Wines, April 2002



7.2.8. The UK market for sparkling wines, other than champagne, has been appreciating steadily for over a decade. Imports of sparkling wines into the UK in 2001 were estimated at 17.4 million litres and a value of £42 million. As with still wines, most sparkling wine is imported from overseas with over three-quarters of volume imports originating from the EU. Like many categories within the alcoholic beverages market, own-label is a dominant force within the UK sparkling wine market, accounting for over half the market's volume and almost one third of value. The main brands in 2001 by volume sales were Freixenet (9.3%) and Asti Martini (8.3%).

## **Grape Juices**

7.2.9. Information on grape juice sales and consumption is not readily available. The British Soft Drinks Association (BSDA) have no reported statistics. As previously stated, the volume of grape juice used in the UK is a very small percentage of the total, compared to grapefruit or tomato for example. Most grape juice is imported as concentrate for use as a low cost 'filler' for combination with other more expensive juices such as mango or guava etc.

## **7.3. Effect on competition**

7.3.1 The Competition Filter Test has been completed and it is not anticipated that the structure of the existing sector would be significantly affected by enforcing Commission Regulation 123/2005.

7.3.2 There is no current requirement for industry to carry out sampling and analysis within Commission Regulation 466/2001, as amended. However, it may wish to do so (and may already be doing so) when carrying out its existing programmes of checks for contamination in excess of legal limits to gain the protection of the 'due diligence' defence under section 21 of the Food Safety Act 1990. This is applicable to all food operating businesses in the import, production, processing, storage, distribution and sale of food and in this respect is not disproportionate on any one business or group of businesses.

## **8. Enforcement, Sanctions AND MONITORING**

### **8.1. Enforcement**

8.1.1. Local authorities and port health authorities are responsible for enforcing Regulations with respect to food safety.

### **8.2. Sanctions**

8.2.1. Local authorities and port health authorities will be responsible for enforcing the new limits introduced by The Contaminants in Food (England) Regulations 2005. The criminal sanctions in the current Contaminants in Food (England) Regulations 2004 as amended, would apply in the case of prosecution against those in breach of the limits. This is currently a fine not exceeding level 5 on the standard scale.

### **8.3. Monitoring**

8.3.1. The Food Standards Agency will continue to consult with enforcement authorities, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation.

## **9. implementation and delivery plan**

9.1. The Contaminants in Food (England) Regulations 2005 will revoke and replace earlier Statutory Instruments. They will make provision for the enforcement of EU measures setting maximum levels for certain contaminants in food and the transposition of the allied enforcement Commission Directives on sampling and analysis for official control purposes.

9.2. As stated in section 8, local authorities and port health authorities are responsible for enforcing food safety Regulations, including those laying down the maximum levels for contaminants in food. The Local Authorities Co-ordinators of Regulatory Services (LACORS), the Association of Port Health Authorities (APHA) and the Association of Public Analysts (APA) are consulted specifically through established Agency liaison mechanisms such as Interested Parties letters during the development of the EU proposals and the formal consultations during the implementation process. In addition, the Agency is currently developing guidance on the Regulations in consultation with stakeholders.

## **10. post-implementation review**

10.1 The Agency will continue to consult with enforcement, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation. As part of this process, the Agency meets regularly with representatives from enforcement organisations (Enforcement Liaison Group) and Public Analysts (the APA Liaison meetings) to help inform this review.

10.2 As stated earlier in this RIA, the European Commission investigates whether limits should be set for additional contaminants and/ or foods and also reviews the maximum limits for those contaminants currently in the legislation. The Agency will consult stakeholders for information to inform these investigations, including data available from enforcement or industry testing, and any data from surveillance the Agency may undertake on these contaminants in food.

## **11. summary and recommendation**

11.1. As discussed previously in this RIA, the intention of Commission Regulation (EC) No. 466/2001 is to protect public health by providing a single set of harmonised maximum levels for chemical contaminants targeted at those foods that make a significant contribution to consumer exposure. Maximum levels have already been set under this legislation and implemented in English law. The Regulation is also supported by a number of Commission Directives on sampling and analysis for official control purposes.

11.2. Ochratoxin A belongs to a group of chemicals called mycotoxins and is found as a contaminant in a wide range of commodities including cereals, dried vine fruit, coffee and wine. It has been implicated as a cause of kidney damage in humans and is considered by the COC and COM to be a potential genotoxic carcinogen and may cause cancer in humans.

11.3. Discussions to set limits for ochratoxin A in coffee, wine and grape juice commenced in 2003. During the course of negotiations, the Food Standards Agency has consulted extensively with interested organisations including industry, research institutes, consumer groups, enforcement authorities and other interested parties. In addition, some responses have been received during the formal 12-week consultation period and have been addressed accordingly.

11.3. Comments received from the formal consultation on the draft SI were mainly in respect to the wording of the draft. In view of these comments, the Agency has restructured the text and introduced sub-headings in regulation 5 to the SI to make this section more understandable. The Agency is also in the process of developing Guidance Notes on the legislation. The Agency did not receive any quantified information from stakeholders on the costs or benefits of implementing these measures. The table over-leaf provides a qualitative summary of the options for the UK.

#### Summary Costs and Benefits Table

<b>Option</b>	<b>Total benefit per annum inc. economic, environmental, social factors</b>	<b>Total cost per annum inc. economic, environmental, social factors</b>
<b>1 – Do Nothing</b>	None	<ul style="list-style-type: none"> <li>• Infraction proceedings against the UK government</li> <li>• Possible adverse report from the Commission’s Food &amp; Veterinary Office</li> <li>• Possible financial costs to industry arising from lack of consumer confidence in the safety of the UK food supply</li> </ul>
<b>2 – Implement the EC measures in The Contaminants in Food (England) Regulations 2005</b>	<ul style="list-style-type: none"> <li>• Fulfils the UK’s legal obligations to make provision for the enforcement of EC Regulations and to implement the Directives</li> <li>• Continued high level of public health safety &amp; improved consumer confidence in compliance testing</li> <li>• The new Regulations will ensure that measures, which are applicable to all member</li> </ul>	<ul style="list-style-type: none"> <li>• No quantified information received from stakeholders in respect to costs arising from the EC legislation. There are likely to be some costs arising from the costs of analysis but these are expected to be minimal. The EC legislation does not specify the number of checks to be carried out to ensure compliance with the limits.</li> <li>• The Directives apply to enforcement authorities only.</li> </ul>

	<p>states, are in place, thereby facilitating trade and ensuring a level ‘playing field’.</p> <ul style="list-style-type: none"> <li>• Environmental and social benefits were addressed during the negotiations of the Commission Regulations</li> </ul>	<p>Little quantified information from these organisations was received during the consultations</p> <ul style="list-style-type: none"> <li>• The UK successfully addressed the economic, social and environmental concerns raised during the negotiations on the Commission’s proposals for maximum limits.</li> </ul>
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11.4. The UK has a legal obligation to make provision for the enforcement of Commission Regulations and to transpose Commission Directives into national law. The Contaminants in Food (England) Regulations 2005 will make provision for enforcement of Commission Regulation 466/2001, as amended. They will also transpose Commission Directive 2005/5/EC, which lays down harmonised statutory official control, into national legislation. The Regulations will revoke and replace The Contaminants in Food (England) Regulations 2004 (SI 2004 No 3062), as amended.

11.5. It is therefore recommended that **Option 2 is supported.**

**12. declaration and publication**

**I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.**

**Signed by the responsible Minister: Caroline Flint**

**Date: 23<sup>rd</sup> November 2005**

**Parliamentary Under Secretary of State, Department of Health.**

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