

EXPLANATORY MEMORANDUM TO
THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2006

2006 No. 1464

1.

1.1 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 These Regulations make provision for the execution and enforcement of European Community (EC) measures contained in Commission Regulation (EC) 466/2001. This Regulation sets maximum levels for certain contaminants in foodstuffs and implement and prescribes that the methods to be used for sampling and analysis for enforcement purposes are as laid down in specified supporting Commission Directives and a Commission Regulation. The Regulations will revoke and replace The Contaminants in Food (England) Regulations 2005 (SI 2005 No 3251).

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

3.1 None

4. Legislative Background

4.1 The Contaminants in Food (England) Regulations 2006 will provide enforcement authorities with the necessary powers to ensure that food business operators comply with the provisions and statutory limits laid down in Commission Regulation (EC) 466/2001 of 8 March 2001, as amended. The EC measures have applied since April 2002 and are currently enforced in England under the Contaminants in Food (England) Regulations 2005. However, recent amendments to the Commission Regulation have necessitated the development of a new SI.

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

Policy

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 may 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 relating to specific contaminants (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, polycyclic aromatic hydrocarbons (PAHs) and nitrate (environmental chemical contaminants), 3-MCPD (a process contaminant), aflatoxins, ochratoxin A and patulin (mycotoxins) and inorganic tin in certain foodstuffs 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. It also reviews the maximum limits of those contaminants currently in the legislation and the foods that are subject to control. As a result, the following Commission measures, which amend Commission Regulation 466/2001, have been adopted and provision must now be made for their execution and enforcement:

(i) Commission Regulation (EC) No 856/2005 of 6 June 2005, setting maximum levels for Fusarium toxins in certain foodstuffs. The maximum levels will apply from 1 July 2006.

(ii) Commission Regulation (EC) No 199/2006 of 3 February 2006, setting maximum levels for the sum of dioxins and dioxin-like PCBs in a range of foodstuffs. The maximum levels will apply from 4 November 2006.

7.5 Commission Regulation 466/2001 is supported by a number of allied Commission Directives that lay down the methods for sampling and analysis for the official control of those contaminants specified in the legislation. The Regulation sets maximum levels for a variety of mycotoxins and the methods for sampling and analysis for these contaminants is currently carried out under a number of different Directives. Following discussion at Commission level, it was agreed to bring the procedures for all mycotoxins together under a single Commission Regulation in order to make them easier to apply. The following Commission measure was adopted.

(i) Commission Regulation (EC) No 401/2006 of 23 February 2006, laying down the sampling methods and the methods of analysis for the official control of the levels of aflatoxins, ochratoxin A, patulin and Fusarium toxins in foodstuffs. The new Regulation, which will repeal the existing mycotoxin Commission Directives (98/53/EC as amended; 2002/26/EC as amended; 2003/78/EC and 2005/38/EC), will apply from 1 July 2006.

Consultation

7.6 In order to meet the deadline of 1 July 2006 for the application of Commission Regulation 401/2006, a shortened consultation of 6 weeks was carried out on the Contaminants in Food (England) Regulations 2006. However, interested parties were informed of progress during the development of the Commission Regulations and given opportunities to comment throughout the negotiations.

7.7 The formal consultation in England of nearly 700 interested parties including consumer groups, industry, enforcement authorities and other government departments, in the 6 weeks from 10 May 2006, produced five responses of which three were substantive. Comments raised related mainly to Fusarium toxins and the high cost of analysis for dioxins and the limited number of laboratories accredited to carry out this work. As regards Fusarium toxins one respondent, an enforcement authority, supported the setting of maximum limits for Fusarium toxins and welcomed the consolidation of the sampling and analysis for the official control of mycotoxins. However, it commented that some additional costs would be involved in order to ensure compliance (see RIA). Testing would be risk based and the overall risk in the UK, and thus the costs, would be low. Other respondents were concerned that some of the costs set out in the Regulatory Impact Assessment did not take into account various factors including the cost of testing for the toxins. There were no comments relating specifically to the Contaminants in Food (England) Regulations 2006.

7.8 Regular informal consultations on the potential impact of the Commission's proposals for mycotoxins and dioxins and dioxin-like PCBs were carried out throughout the negotiations. On each occasion interested parties including consumer groups, industry and enforcement authorities were contacted via information letters both to provide information on progress and to seek comments and data to help inform the UK's negotiating position. Concerns raised and the outcomes are discussed in detail in the attached RIAs.

7.9 However, in summary, interested parties have been aware since 2001 that in order to maintain a high level of consumer health protection specific maximum levels for dioxin-like PCBs would be included in the dioxins legislation once more data on these contaminants was available. Discussions on this issue began in January 2004 and continued throughout 2004 and 2005 with final agreement and adoption of Commission Regulation 199/2006 in November 2005. The main focus of the negotiations and comments received, related to the technical detail on how PCBs might be brought into the legislation and the various options regarding setting limits for dioxin-like PCBs. Information letters, including an initial RIA in February 2005, were sent to nearly 400 interested parties. Eight responses (1 individual, 1 consumer group and 6 from Trade Associations) were received during this period. Responses indicated the preference to set a limit for the sum of dioxins and dioxin-like PCBs with a transitional period where the existing limits would continue to apply in addition to the new levels. Commission Regulation 199/2006 will be reviewed by the end of 2008 with the view to establishing maximum levels for other foodstuffs including specific lower limits for infant and baby food and dispensing with the separate maximum levels for dioxins.

7.10 Fusarium toxins belong to a group of chemicals called mycotoxins, produced by Fusarium moulds, which are commonly found on cereals grown in the temperate regions of America, Europe and Asia. Fumonisin toxins are acutely toxic to humans causing sickness and diarrhoea and in some very extreme cases death. They have also been shown to cause increased susceptibility to infections, growth retardation and reproductive effects in laboratory animals.

7.11 Discussions on the possibility of setting maximum limits for Fusarium toxins began in January 2003. The results of a Scientific Co-operation task on the assessment of dietary intake of Fusarium toxins by the population of EU Member States finalised in September 2003 indicated that certain high risk groups such as infants and young children might be at risk to exposure to Fusarium toxins. It was, therefore, considered that, for the protection of public health, that maximum limits should be set for these toxins to avoid highly contaminated products entering the food chain. In November 2003 a Commission consultation document was circulated to over 300 interested parties, including consumer groups, industry and enforcement authorities. Discussions continued throughout 2003, 2004 and 2005 with final agreement and adoption of Commission Regulation 856/2005 in April 2005. Eighteen information letters were sent out to interested parties during this period to which 26 responses (1 individual, 9 from industry, 13 from trade associations and 3 from central government) were received. Most responses indicated a preference for setting maximum limits for the unprocessed grain or when the grain is marketed for first processing. However, if limits were to be set for processed products these should be consistent with the limits set for the raw material and take into account the effect of processing. In order to assess the costs to business in implementing the new legislation over 25 businesses, large, intermediate and small, were contacted to obtain an estimate of these costs. However, only a minimal number of responses were received.

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. 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 Commission Regulations (see RIA). However, such testing would be risk based and the overall risk in the UK is low.

9. Contact

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FINAL REGULATORY IMPACT ASSESSMENT

THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2006

Maximum limits for fusarium toxins in certain foodstuffs

1. TITLE OF PROPOSAL

The Contaminants in Food (England) Regulations 2006

1.1. Provision for the enforcement of Commission Regulation (EC) No. 856/2005 of 6 June 2005 amending Commission Regulation (EC) No. 466/2001 as regards fusarium toxins in certain foodstuffs.

1.2. Implementation, (via Regulation 466/2001), of Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the sampling methods and the methods of analysis for the official control of the levels of mycotoxins in foodstuffs.

2. PURPOSE AND INTENDED EFFECT OF MEASURE

2.1. The Objective

2.1.1. The first objective of these Regulations is to make provision for the enforcement, in England, of Commission Regulation 856/2005, which amends Commission Regulation 466/2001 and sets maximum limits for fusarium toxins in various foodstuffs. The Regulation will apply from 1 July 2006 and will only apply to products, which were placed on the market on or after 1 July 2006.

2.1.2. The second objective is to ensure that enforcement authorities act in accordance with a recently adopted Commission Regulation laying down the sampling methods and the methods of analysis for the official control of the levels of mycotoxins in foodstuffs. This will replace the existing Commission Directives on sampling methods and the methods of analysis for the official control of the levels of aflatoxins (98/53/EC, as amended), ochratoxin A (2002/26/EC, as amended), patulin (2003/78/EC) and fusarium toxins (2005/38/EC), all of which will be revoked.

2.1.3. The purpose of setting maximum levels for fusarium toxins in food is to provide consumers with an increased measure of protection against undesirable contaminants i.e. deoxynivalenol, zearalenone and fumonisins in those foods that contribute significantly to the total dietary exposure of consumers to those contaminants. The purpose of the sampling and analysis Regulation (401/2006) is to provide a consistent and harmonised approach for the enforcement of the maximum limits throughout the European Union.

2.1.4. Currently the maximum limits set in Commission Regulation 466/2001 are enforced in England under The Contaminants in Food (England) Regulations 2005 [SI 2005 No. 3251]. The associated Commission Directives on sampling and analysis for official control purposes are also currently implemented in these Regulations. Similar Regulations apply in Scotland, Wales and Northern Ireland. These and preceding Regulations have previously been consulted on¹.

¹ 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

2.1.5. New Regulations have now been drafted and will revoke and replace The Contaminants in Food (England) Regulations 2005. These Regulations will be The Contaminants in Food (England) Regulations 2006 and will extend to England only.

2.1.6. A review of the maximum limits for fusarium toxins is due to be carried out by 1 July 2008, including deoxynivalenol, zearalenone and fumonisins and with a view to including a maximum limit for T-2 and HT-2 toxins in cereals and cereal products.

2.1.7. This Regulatory Impact Assessment (RIA) is concerned only with the enforcement of Commission Regulation (EC) No. 856/2005 and the implementation of Commission Regulation 401/2006. As part of this consultation, a separate RIA (annex B) addresses the enforcement of Commission Regulation (EC) 199/2006 amending Commission Regulation 466/2001 as regards dioxins and dioxin-like PCBs.

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 limits for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Community measures controlling specific contaminants (Commission Regulation 466/2001) were introduced under Council Regulation 315/93/EEC to ensure market unity while complying with the principle of proportionality. 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, polycyclic aromatic hydrocarbons (PAHs), nitrate, 3-MCPD, aflatoxins, ochratoxin A, patulin and inorganic tin have already been set under this legislation.

canned foodstuffs), The Contaminants in Food (England) (Amendment) Regulations 2005 (nitrate, aflatoxins & ochratoxin A in foods for infant and young children) and under The Contaminants in Food (England) Regulations 2005 (ochratoxin A in certain foods, PAHs in certain foods, revised limits for lead & cadmium & revised fish species and updated Directive on sampling & analysis for lead, cadmium, mercury & 3-MCPD).

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.

2.2.4. *Fusarium* toxins belong to a group of chemicals called mycotoxins, produced by moulds. There are a variety of *Fusarium* fungi, which produce a number of different mycotoxins of the class of trichothecenes such as deoxynivalenol (DON), T-2 toxin and HT-2 toxin as well as other toxins such as zearalenone and fumonisins. The *Fusarium* fungi are commonly found on cereals grown in the temperate regions of America, Europe and Asia. Several of the toxin-producing *Fusarium* fungi are capable of producing to a variable degree two or more of these toxins. *Fusarium* species infect the grain pre-harvest although toxin production may also take place during storage of improperly dried grain. In connection with *Fusarium* infection and mycotoxin formation several risk factors have been identified. Climatic conditions during the growth, in particular at flowering, have a major influence on the mycotoxin content.

2.2.5. It is important for the protection of public health that maximum limits are set on unprocessed cereals in order to prevent highly contaminated cereals entering the food chain and to encourage and ensure that all measures are taken during the field, harvest and storage stage of the production chain. The Commission has produced a draft Recommendation, which should be published in the near future, on the “Principles for the prevention and reduction of fusarium toxin contamination in cereals, zearalenone, fumonisins and trichothecenes, including deoxynivalenol” for general use by Member States, which it anticipates should provide a means of reducing the risk of contamination of cereals. Maximum levels are set at a level taking into account the current human exposure in relation to the tolerable intake of the toxin in question and which can be reasonably achieved by following good practices at all stages of production and distribution. Such an approach ensures that food business operators apply all possible measures to prevent or reduce the contamination as far as possible in order to protect public health. Accordingly, businesses involved in the cereal production and supply chain should be encouraged to adopt good practices to prevent and reduce fusarium toxin contamination.

2.2.6. Both industry and Defra were consulted on the draft Commission Recommendation. Based on the principles in this Recommendation the UK is producing a Code of Practice, which will be specifically relevant to the UK. Additionally, The Codex Alimentarius Commission adopted in 2003 a “Code of Practice for the prevention and reduction of mycotoxins contamination in cereals, including annexes on ochratoxin A, zearalenone, fumonisins and trichothecenes.

2.2.7. Trichothecenes are acutely toxic to humans causing sickness and diarrhoea and in some very extreme cases death. Acute exposure to deoxynivalenol causes gastrointestinal effects (particularly vomiting) in humans. This mycotoxin has also been shown to cause increased susceptibility to infections, growth retardation and reproductive effects in laboratory animals. Acute exposure to T-2 toxin is a suspected cause of alimentary toxic aleukia (ATA) in humans. Symptoms include gastrointestinal effects and leukopenia. Furthermore, this mycotoxin has been shown to effect the growth, reproduction and immune systems of laboratory animals.

2.2.8. The EU’s Scientific Committee on Food (SCF) concluded in 2002 that the available data did not support the establishing of a group Tolerable Daily Intake (TDI) for the trichothecenes evaluated, and established a TDI of 1 µg/kg body weight/day for

deoxynivalenol (DON)² and a combined temporary TDI of 0.06 µg/kg body weight/day for T-2 and HT-2 toxin³. The TDI is an estimate of the amount of contaminant expressed on a bodyweight basis that can be ingested daily over a lifetime without appreciable risk to human health.

2.2.9. Fumonisin are observed primarily on maize and in maize-based products and have been shown to cause kidney and liver damage in laboratory animals. High levels of exposure to fumonisins, which include fumonisin B₁, B₂ and B₃, have been observed to cause liver and kidney damage in animals if consumed over long periods. It is possible that they could have the same effect on humans given similar levels of exposure. The SCF has designated a TDI of 2-µg/kg body weight/day for both fumonisin B₁⁴ and in combination with fumonisin B₂ and B₃⁵.

2.2.10. Zearalenone has been shown to have oestrogenic effects on laboratory animals, as well as having carcinogenic effects at higher doses. Apart from a possible incidence of precocious puberty associated with zearalenone in Hungary, there have been no recent reports of human mycotoxicoses in Member States of the European Union. The SCF has established a temporary TDI of 0.2 µg/kg body weight/day⁶.

2.2.11. In the framework of Council Directive 93/5/EEC of 25 February 1993 on assistance to the Commission and cooperation by Member States in the scientific examination of questions relating to food, a scientific cooperation (SCOOP) task 3.2.10 'Collection of occurrence data on fusarium toxins in food and assessment of dietary intake by the population of EU Member States'⁷ was performed and finalised in September 2003.

2.2.12. The results of that task demonstrate that fusarium mycotoxins are widely distributed in the food chain in the Community. The major sources of dietary intake of fusarium toxins are products made from cereals, in particular wheat and maize. The report also demonstrated that the dietary intakes of fusarium toxins for risk groups like infants and young children are close to or exceed the TDI for the respective toxin.

2.2.13. The UK has carried out some work on the occurrence of fusarium toxins in the food chain previously. A survey of trichothecenes and zearalenone was reported in 2003⁸. In the vast majority of the 377 samples analysed, the levels of the mycotoxins were low. The highest levels of both trichothecenes and zearalenone were found in breakfast cereals from the first part of the survey where samples were traced to the 1999 UK cereal crop, where there was a high incidence of *Fusarium* ear-blight, which also highlighted the dependency of formation of *Fusarium* species on climatic conditions.

² European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Part 1. Deoxynivalenol, 2 December 1999.

³ European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Part 5. T-2 and HT-2 toxins, 30 May 2001

⁴ European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Part 3. Fumonisin B₁, 17 October 2000.

⁵ European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Total Fumonisin, 4 April 2003.

⁶ European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Part 2. Zearalenone, 22 June 2000.

⁷ Report available on the web-site of the European Commission, DG Health and Consumer Protection (<http://europa.eu.int/comm/food/fs/scoop/task3210.pdf>)

⁸ Food Standards Agency, Food Survey Information Sheet 35/03, March 2003.

2.2.14. In 2005, a survey of maize-based retail products for various mycotoxins was completed and reported⁹. Although levels were low in the majority of samples analysed, concentrations of fumonisins in two of the maize meal products were high and these were withdrawn from sale. A short, follow-up survey also identified several more of these types of products that were contaminated with high levels of fumonisins. The results of this survey, together with details of the action taken by the Agency are available at:

<http://www.food.gov.uk/news/newsarchive/2003/sep/moremaize>.

2.2.15. In addition, 2 out of the 292 samples from the main survey were found to contain DON above the limits (then under discussion) of 500 µg/kg for bread, pastries, biscuits, snacks and breakfast cereals and 750 µg/kg for cereal flour, including maize flour, semolina, maize grits and maize semolina, including polenta. The results of the survey underlined the importance of introducing regulatory limits for these toxins and the establishment of codes of practice to help the reduction and prevention of them from the food chain.

2.3. Rationale for Government Intervention

2.3.1. Enforcing the new limits laid down in Commission Regulation 856/2005 for fusarium toxins in cereal and cereal products 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 Commission Regulation (EC) No 401/2006 of 23 February 2006 is to consolidate the existing Commission Directives on sampling methods and the methods of analysis for the official control of the levels of aflatoxins, ochratoxin A, patulin and fusarium toxins. Sampling plays a crucial part in the precision of the determination of mycotoxins in food. Thus, it is appropriate to apply whenever possible the same sampling procedure to the same product for the control of mycotoxins and to provide for the sampling provisions and performance criteria for the methods of analysis to be used for the official control of all mycotoxins into one legal text to simplify and improve the applicability.

2.3.3. The introduction of these harmonised statutory controls would reduce uncertainty or dispute in interpreting results against limits directly applicable to all Member States and would also 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 legislation effectively and efficiently.

3. CONSULTATION

3.1. Within Government

⁹ Food Standards Agency, Food Survey Information Sheet 72/05, January 2005.

3.1.1. Other government departments including the Department for Environment, Food and Rural Affairs (Defra), 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 through Commission Working Group and Standing Committee meeting reports and Interested Parties letters. In particular, the Agency has been in close contact with Defra on this matter and has held several discussions with them. No comments have been received from any other departments.

3.2. Public Consultation

3.2.1. Discussions on possible limits for fusarium toxins in foodstuffs began at the Commission Working Group of Agricultural Contaminants meeting on 13 & 14 January 2003, when the Commission tabled their initial position on limits for deoxynivalenol, nivalenol, T-2 toxin, HT-2 toxin, zearalenone and fumonisins in various cereals and cereal products. During the course of the negotiations with the Commission, the Food Standards Agency has regularly conveyed information to interested organisations including industry, enforcement authorities, research institutes, consumer groups and other interested parties. In addition, the Commission has held several stakeholder meetings during negotiations to consult, exchange views and formulate discussion with interested parties including industry.

4. OPTIONS

Option 1: Do nothing.

Option 2: Make provision for the enforcement of Commission Regulation (EC) No. 856/2005 and introduce measures to include the use of Commission Regulation (EC) No 401/2006 of 23 February 2006 under The Contaminants in Food (England) Regulations 2006. Corresponding legislation would be introduced separately in Scotland, Wales and Northern Ireland.

COST AND BENEFITS

5.1 Sectors and Groups Affected

5.1.1. Typical businesses that will be affected by the enforcement of the maximum limits are growers and producers of cereals and manufacturers, importers, traders, processors, wholesalers and retailers of flour, bread, pastries, biscuits, cereal snacks, breakfast cereals, pasta and foods for infants and young children who will need to ensure that they comply with the maximum limits. 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 non-discriminatory competitive environment.

5.1.2. Local authorities and port health authorities are responsible for enforcing Regulations with respect to food safety and will therefore also be affected. In particular they will need to comply when procuring formal samples, with the sampling methods laid down in Commission Regulation 401/2006 and in relation to this RIA the sampling methods for controls on fusarium toxins. Additionally, public analysts will also need to comply with the requirements for the methods of analysis.

5.1.3. Other government departments such as the Food Standards Agency may also be affected as they currently carry out surveys on foods to inform consumers, monitor trends and assess dietary exposure and to ensure that the legislation is effective in protecting consumers from exposure to harmful contaminants.

5.1.4. Consumers of the commodities and food products specified in Commission Regulation 856/2005 would gain from the new Regulations. Enforcement of the limits would ensure that enhanced and more consistent measures were in place to protect the consumer against the potential damaging effects caused by fusarium toxins.

5.1.5. Impact on Race Equality

As stated earlier in the RIA, the purpose of the draft Contaminants in Food (England) Regulations 2006 is to provide enforcement authorities with the appropriate powers to carry out their official control responsibilities. The draft Regulations make provision for the enforcement and enactment of EC measures which aim to provide a high level of consumer protection by setting maximum levels for certain contaminants in a wide range of foodstuffs. Consequently the draft Regulations are not considered to have any race equality impacts.

5.1.6. Impact on Sustainability

The draft Regulations will not have a specific impact on sustainability. However, the maximum levels set under the Commission Regulation 856/2005 may result in some UK grain being rejected for food use. It is envisaged that grain exceeding the limits could be re-directed to animal feed, depending on the extent of contamination. Separate guidance limits for fusarium toxins in feed have also been agreed.

5.1.7. No pertinent comments on the specific costs to industry arising from these Regulations were received by the Agency. The potential impact on the public sector is discussed below.

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 therefore has a legal obligation to ensure that provisions are in place to provide for their enforcement in full. Failure to do so may result in infraction proceedings against the UK government.

5.2.2 To do nothing may maintain an unacceptable risk to human health and would leave the UK enforcement authorities without any domestic legislation for the enforcement and execution of Commission Regulation 856/2005. It would also leave the UK enforcement authorities without appropriate statutory sampling and analysis procedures in respect to mycotoxins in foodstuffs specified in Commission Regulation 466/2001, as amended. 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 856/2005. 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, indeed it may even facilitate beneficial trade creation.

5.2.5. The potential benefits to health are difficult to quantify but are likely to include reducing the risk of illness through exposure to fusarium toxins. Fusarium toxins have been associated with various adverse effects on human health, including the potential to cause cancer. This option may therefore reduce such burden on the health service through prevention of serious chronic illness.

5.3 Costs

Business Costs

5.3.1. Industry has been made aware of the maximum limits set by Commission Regulation 856/2005 since 2003. The Food Standards Agency is working with industry to produce a Code of Practice which will help minimise the formation of fusarium toxins. Preliminary advice has been issued and industry may therefore already be taking steps to assure themselves that their products comply with the maximum limits.

5.3.2. There are no specific requirements to test products under Commission Regulation 466/2001, as amended; however, it is the responsibility of individual food operating businesses to determine how they satisfy these requirements. For example, checks on food commodities are likely to involve sampling and analysis, to ensure that contamination is not in excess of legal limits or alternatively reliance on checks carried out by the supplier of the food commodity in order to satisfy compliance with the “due diligence” requirement under section 21 of the Food Safety Act 1990. The Agency’s research has shown that the occurrence of fusarium toxins in the UK is low. Therefore, firms already operating such risk based systems as standard are not expected to incur significant extra operating costs. Also, the costs related to product withdrawal will be minimised since there is no requirement for products already on sale before 1 July 2006 to comply.

5.3.3. A comprehensive list of trade associations representing bakers, millers, farmers, food and cereal ingredients manufacturers, grain and animal feed traders were contacted to ascertain the costs of the Regulations to the affected businesses. No comments or indication from industry suggested anything other than minimal changes in costs were expected. However, during the consultation some respondents raised concerns regarding the costs of testing for traders and small businesses and commented that the impact of regulation may cause costs to be passed back up the food chain to growers, thereby affecting their business. A proportion of any increased cost which industry may face as a result of the Regulations may be passed on to the consumer in the form of higher prices for a small number of products likely to be affected. Whether this occurs or not will depend on the nature and demand for the product, the composition and level of competition in the market and the willingness of individuals to pay the premium to ensure the safety of the product. Such costs are however not expected to be significant.

Government Costs

5.3.4. The maximum limits will be enforced by local authorities and in relation to imported products from countries outside the EU by port health authorities, as is the case at present with the current maximum limits enforced under the Contaminants in Food (England) Regulations 2005. There may be some extra costs to these authorities due to the additional sampling and associated staff time that will be required to check compliance with the new limits. The cost of bulk sampling at import would be approximately £200, although the number of imports overall is low. However, local authority costs for sampling would be expected to be very much lower. In conjunction with this there will also be the cost of the charges incurred for the analysis of the sample by a public analyst. The estimated cost is anticipated to be approximately £100 - £150 per sample for each toxin depending upon the size of the sample submitted for analysis. However, the cost for each individual toxin would be less if multiple toxin analyses were carried out.

5.3.5 It is difficult to estimate the costs to the enforcement bodies without details of the precise regime that will operate; for example what proportion of an authority’s budget may be allocated for checking compliance with the new limits. The decision to undertake sampling and analysis is made by each enforcement authority on a risk assessment basis and is not dictated by the Food Standards Agency. However, there will be some additional burden on resources to ensure compliance.

5.3.6 There may also be some additional informal monitoring costs, for example the Food Standards Agency regularly carries out surveys to help protect and inform consumers, monitor trends and assess dietary exposure. They also ensure that the legislation is effective in protecting customers from exposure to harmful contaminants, such as fusarium toxins.

5.3.7 As previously stated in this RIA fusarium toxins have been implicated in a variety of detrimental health effects in humans. Any prevention of short or long term illness through introduction of the Regulations (option 2) and therefore enforcement of the new limits may thus potentially avoid more significant related additional burdens on the health services and prevent loss of productivity and consumer welfare. It is not anticipated that option 2 would have any other environmental costs, however when considering other social impacts, any indirect costs of illness, such as perhaps the loss of welfare of the families of the ill, may also be abated.

Summary of costs and benefits

	Costs	Benefits	Groups affected
Option 1	Costs associated with: <ul style="list-style-type: none"> • Infraction proceedings against the UK government • Possible adverse report from the Commission's Food & Veterinary Office • Possible financial costs to industry arising from lack of consumer confidence in the safety of the UK food supply 	None	None
Option 2	Minimal	Provide enforcement of Regulation 856/2005 and 401/2006, 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 It is not anticipated that any potential additional costs arising from checking compliance with the maximum limits will be significant to small businesses. 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. For example, this may require 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.

7. COMPETITION ASSESSMENT

7.1. Markets affected

7.1 Those involved in the cereals markets will be affected by the maximum limits as will those involved in markets for the products specified in Regulation 856/2005, including flour, bread, pastries, biscuits, breakfast cereals, pasta and foods for infants and young children. This will include growers, manufacturers, importers, traders, processors, wholesalers and retailers of these commodities or products.

7.2. MARKET CHARACTERISTICS

CEREALS

Statistics from Defra indicate that in 2004, the total area of land in the UK producing cereals was approximately 3.1 million hectares, the production volume of which amounted to over 22 million tonnes at an estimated value at market prices of £1,675 million. Imports from the EU and from the rest of the world in 2004 amounted to almost 2 million tonnes and 465,000 tonnes respectively. In economic terms wheat is the most important cereal crop in the UK, typically comprising around two thirds of the value of total cereal output.

Geographically, cereals production within the UK is heavily concentrated in England; indeed over 80% of the total UK cereals area is in England. A further 15% is found in Scotland with the remainder in Wales and Northern Ireland. Correspondingly, cereals are an important sector in economic terms in England and Scotland only, with cereals output accounting for around 16% of total gross agricultural output in each country. Within England, cereals farms are predominantly in the Eastern counties. A 1999 June census carried out by MAFF indicated a total of 20,905 cereal holdings in England, with 3428 of these classified as very small/ part time.

BREAD¹⁰.

UK retail sales of bread by volume have fallen over the last few years from 2,110,000 tonnes in 1999 to an estimated 1,987,000 in 2004. According to the same report however, the same comparison by value shows an increase from £1,791 million to an estimated £1,961 million over the same period.

The industry may be divided up into three main industry sectors: plant bakeries, in-store bakeries (ISB), and craft bakeries; the latter better known as high street retail bakeries or master bakers. The plant bakeries are accountable for the majority of bread production to the UK market, producing both finished product for retailers, as branded and own-label goods, and supplying bake-off to the in-store and craft bakeries. The share of retail value supplied by the plant manufacturers has however, grown over recent years.

¹⁰ Mintel, Bread, Market Intelligence 2005

The majority of bread sold in the UK is baked here, with the exception of some imported long-life speciality products and a small amount of bread produced in France and imported on a daily basis, valued at less than 1% of the market. Over three-quarters of bread sold in the UK is wrapped factory-produced loaves, the majority of which originates from a small number of large plant bakeries; the remainder comes from medium and small plants, which offer standard, speciality and ethnic bread products to the retail market.

The Federation of Bakers, a trade organisation which represents the interests of plant bakeries with a turnover of over £10 million, lists ten member companies operating 55 plants throughout the UK. The largest of these are British Bakeries Limited with 15 sites, Allied Bakeries Limited with 13 sites, Warburtons Limited with 11 sites and Rathbones Kears Limited with three sites. Allied Bakeries, British Bakeries and Warburtons together account for half of the plant bread market by value.

Breakfast Cereals¹¹

After a downturn in the late 1990s, the UK breakfast cereal market recovered and has shown slow but steady growth in volume, with an estimated 409,000 tonnes sold in 2003, equivalent to a market value of £1,117 million, the majority of which were manufactured in the UK.

The breakfast cereal market is characterised by global manufacturers operating in an oligopoly, with the largest four manufacturers in the UK estimated to share 77% of the market value. However, a variety of smaller manufacturers operate in niche sectors, with limited distribution. In 2003, accounting for 40% of market share, Kellogg was the largest manufacturer in the UK, with estimated sales of £447 million. Weetabix and Cereal Partners commanded a share of around 15% each, equivalent to around £170 million, whereas the fourth largest manufacturer was Quaker with around 6% share of the market. A further 17% of the market was comprised of own label manufacturers, of which supermarket chains had a strong presence.

Wheat and corn products are estimated to each account for 18% of the various types of breakfast cereals in the UK market, valuing both at around £190 million. A similar share of around 17% is held by bran cereals, with muesli products growing to about 10%.

In the distribution side of the breakfast cereal market, the supermarkets dominate, possessing an estimated 93% share of the market in 2003. The remainder of the market incorporates convenience and independent trade channels.

Biscuits¹²

Non-sweet biscuits

At 17% of the overall biscuit market, the non-sweet biscuit market incorporates crackers and crispbreads (77%) and savoury biscuits (23%). The largest three manufacturers of non-sweet biscuits in the UK share over two-thirds of the £285 million market. After acquiring the Jacobs brand in 2004, United Biscuits now accounts for 40% of the market, with Quaker and Ryvita accounting for 18% and 11% respectively. The majority of the

¹¹ Mintel, Breakfast Cereals, Market Intelligence 2004

¹² Mintel, Sweet Biscuits, Market Intelligence 2005; Mintel, Non-Sweet Biscuits, Market Intelligence 2005; Mintel, Cereal Bars, Market Intelligence 2004

remainder of the market includes supermarket own-label brands, although there are a large number of small artisan UK producers, and some international manufacturers competing in small niches.

With regards the distribution aspect of non-sweet biscuits, the supermarkets dominate the market, accounting for 85% of sales in 2005. The remainder of the market incorporates independent and specialist stores.

Sweet biscuits

The total biscuit market represents a value of £1.7 billion, with sweet biscuits accounting for 83% of this market. It is more diverse than the non-sweet biscuit market, although the top four manufacturers enjoyed a 58% share of the sweet biscuit market in 2005. These included United Biscuits (23%), Burton's (15%), Nestle (11%) and Fox's (9%). Other brands made up 24% of the market, and supermarket own-labels accounted for the rest (18%).

The supermarkets and co-ops account for around 86% of the sales volume in the UK, with the remainder including independent and specialist stores.

Cereal bars

The UK market of cereal bars nearly trebled between 1998 and 2003, to £182 million, of which the main players are Kellogg with a 32% market share, and Jordans with a 10% share. The rest of the market is very diverse, with a wide range of other brands, including supermarket own-label products.

As with the biscuit market, the main distributors of cereal bars are the supermarkets and co-operatives which account for about 83% of the market, with confectioners, tobacconists and newsagents and other independents accounting for the rest.

Pasta¹³

The UK market for pasta and pasta-based ready meals is diverse, with an estimated market volume of 206,000 tonnes in 2004, valued at £463 million.

The market suppliers are heavily biased towards the supermarkets who produce their own-labelled products. In 2004, dry pasta accounted for £98 million in sales, of which 67% were supermarket own-label, with Buitoni being the only major branded manufacturer in this category, possessing a 17% share of the market. For chilled pasta and pasta ready meals, sales in 2004 were £79 million and £160 million respectively, with the supermarkets' own-label share being even more pronounced at around 93%. In the other major category of frozen pasta ready meals (sales of £109 million), some branded products were present, with Birds Eye taking 24% of the market and Heinz and Findus accounting for 13% and 8% respectively. As in the other categories, the own-labels represented a large portion of the market, with a 47% share.

¹³ Mintel, Past and Pasta-Based Meals, Market Intelligence 2005

This market profile is reflected in the make-up of the distributors of dry and fresh pasta, of which the supermarkets accounted for 88% of sales value in 2004, with co-operatives, Marks and Spencer, and independent retailers accounting for the remainder.

BABY FOODS¹⁴

The total market for baby food and drinks can be split into four main areas: milks, meals, drinks and finger foods (rusks and cereal bars). The greatest value share of the market is taken up by milks (46%) and meals (44%), with drinks (6%) and finger foods (4%) taking up a relatively small proportion. UK retail sales of baby foods in 2002 totalled around £381 million with £184 million (48% of the total) accounted for by sales of baby meals and finger foods. Imports of baby and infant foods into the UK last year were valued at approximately £195 million per annum¹⁵.

Baby meals come in two main types: wet foods including pre-cooked, pureed meals or chilled products and dry foods including meals and sauces requiring rehydration before consumption as well as cereals and baby rice. In 2002, wet meals accounted for 76% of the baby meals market compared with 24% for dry foods.

The supply structure for baby food in the UK is heavily concentrated, with a handful of manufacturers characterising the supply chain. The main companies involved are large multinational businesses with a selection of big brand names. In 2002, the three biggest companies accounted for 83% of the baby meal and finger food market, with Heinz/Farley's accounting for 47% of the market, Cow & Gate with 20% and HiPP with 16%.

The baby foods and drinks sector is characterised by a broad pattern of distribution, with sales of these products being spread amongst supermarkets, chemists, garage forecourts and motorway service areas. In 2002, supermarkets were estimated to account for around £263 million (69%) of baby foods and drinks sales.

¹⁴ Mintel report on Baby Food Drinks and Milk, October 2002.

¹⁵ Information from Infant and Dietetic Foods Association, 6 Catherine Street, London. WC2B 5JJ.

EFFECT ON COMPETITION

7.2 The Competition Filter Test has been completed and it is not anticipated that the structure of the existing sector would be significantly affected by making provisions for the enforcement of Commission Regulation 856/2005 (option 2).

7.3 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

ENFORCEMENT

8.1 Local authorities and port health authorities are responsible for enforcing a large proportion of Regulations with respect to food safety and have done so in respect to the maximum limits for contaminants in food set out in Commission Regulation 466/2001, as amended, since 2002. Thus, enforcement will be carried out using existing systems maintained in The Contaminants in Food (England) Regulations 2006.

SANCTIONS

8.2 The criminal sanctions in the current Contaminants in Food (England) Regulations 2005, would apply in the case of prosecution against those in breach of the Regulations. This is currently a fine not exceeding level 5 on the standard scale.

MONITORING

8.3 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 2006 revoke and replace the current Regulations referred to in paragraph 8.2. They make provision for the enforcement of EU measures setting maximum levels for certain contaminants in food and lay down the associated procedures and methods to be followed when conducting sampling and analysis in the course of official controls.

9.2 As highlighted in paragraph 8 above, Local Authorities and Port Health Authorities are responsible for enforcing much food safety legislation, 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 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 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 the Association of Public Analysts (the APA Liaison meetings) to help inform this review.

10.2 As stated earlier, 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 the Regulation 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.

11.2 In order to ensure a continued high level of consumer protection, 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 and the foods that are subject to control. Consequently, Regulation 466/2001 has undergone a number of amendments including most recently a new Commission Regulation setting maximum levels for fusarium toxins. The Regulation is supported by an allied Commission Regulation, which lays down the methods for sampling and analysis for the official control of those contaminants specified in the Regulation. Currently enforcement of Regulation 466/2001 is carried out under The Contaminants in Food (England) Regulations 2005 (SI 2005 No 3251).

11.4 Trichothecenes are acutely toxic to humans causing sickness and diarrhoea and in some very extreme cases death. They have also been shown to cause increased susceptibility to infections, growth retardation and reproductive effects in laboratory animals. Acute exposure is a suspected cause of alimentary toxic aleukia (ATA) in humans. Fumonisin is observed primarily as a contaminant of maize-based products and has been shown to cause kidney and liver damage in laboratory animals. High levels of exposure to fumonisins have been observed to cause liver and kidney damage in animals if consumed over long periods. Zearalenone has been shown to have oestrogenic effects on laboratory animals, as well as carcinogenic effects at higher doses.

11.5 Commission Regulations have general application and the direct force of law in all Member States and the UK has a legal obligation to ensure that provisions are in place for their enforcement. Consultation packs were circulated to nearly 800 Interested Parties; five responses were received. Of these, three were substantive and related mainly to fusarium toxins.

Summary Costs and Benefits Table

OPTION	Total benefit per annum: economic, environmental, social	Total cost per annum: <ul style="list-style-type: none"> • economic, environmental, social • policy & administrative
1 – Do Nothing	None	<ul style="list-style-type: none"> • Infraction proceedings against the UK government • Possible adverse report from the Commission’s Food & Veterinary Office • Possible financial costs to industry arising from lack of consumer confidence in the safety of the UK food supply
2 – Make provision for the enforcement & enactment of the EC measures under The Contaminants in Food (England) Regulations 2006	<ul style="list-style-type: none"> • Fulfils the UK’s legal obligations to make provision for the enforcement of EC Regulations • Continued high level of public health safety & consumer confidence in compliance testing • 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’. 	<ul style="list-style-type: none"> • No quantified information received by the Agency in respect to costs arising from the EC legislation. There are likely to be some costs arising from the costs of sampling & 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. • It was agreed that the new Regulation would apply from 1 July 2006 to allow industry time to implement the new measures.

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

The Contaminants in Food (England) Regulations 2006 will provide enforcement authorities with the necessary powers to effectively enforce the provisions and maximum limits set in Commission Regulation 466/2001, as amended. The Regulations will revoke and replace The Contaminants in Food (England) Regulations 2005 (SI 2004 No 3251). The Agency is developing Guidance Notes on the legislation.

12. DECLARATION AND PUBLICATION

Declaration

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

Signed: Caroline Flint

Date: 5th June 2005

Minister of State, Department of Health.

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FINAL REGULATORY IMPACT ASSESSMENT

The Draft Contaminants in Food (England) Regulations 2006

Maximum levels for dioxins and dioxin-like polychlorinated biphenyls

1. TITLE OF PROPOSAL

The Contaminants in Food (England) Regulations 2006

1.1 Provision for the enforcement of Commission Regulation (EC) No. 199/2006 of 3 February 2006 amending Commission Regulation (EC) 466/2001 as regards dioxins and dioxin-like polychlorinated biphenyls (PCBs) in foods.

2. PURPOSE AND INTENDED EFFECT

2.1 Objective

2.1.1 The purpose of this measure is to provide enforcement authorities with the necessary powers to ensure that food business operators comply with European Community (EC) measures (Commission Regulation (EC) No 466/2001 of 8 March 2001 as most recently amended) setting maximum levels for certain contaminants in food. 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. The Regulation has recently been amended by Commission Regulation 199/2006, as regards maximum levels for dioxins and dioxin-like PCBs. Commission Regulation 199/2006 will apply from 4 November 2006.

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

2.1.3 Maximum levels for dioxins in food have existed across the EU since 1 July 2002 (Council Regulation (EC) No 2375/2001 amending Regulation 466/2001 refers). Compliance with these limits is currently enforced in England under the Contaminants in Food (England) Regulations 2005 (SI 2005 No 3251). However, Commission Regulation 199/2006 sets new maximum levels for the sum of dioxins and dioxin-like PCBs as well as maintaining, for a transitional period, the existing dioxins limits. Consequently, a new SI (The Contaminants in Food (England) Regulations 2006) is necessary to make provision for the enforcement and execution in England of Regulation 466/2001 as amended. The methods for sampling and analysis for the official control of dioxins and dioxin-like PCBs will continue under Commission Directive 2002/69/EC, which has applied since February 2003.

2.1.4 This Regulatory Impact Assessment (RIA) is concerned only with the provisions for the enforcement of Commission Regulation 199/2006. The provisions for the enforcement and enactment of Commission Regulation 856/2005 (setting maximum levels for Fusarium toxins) and Commission Regulation 401/2006 (laying down the methods for sampling and analysis for the official control of mycotoxins in foodstuffs) are addressed in a separate RIA at Annex 1A. Commission Regulation 466/2001, as previously amended and the

allied Commission Directives referred to at point 2.1.2 above have already been dealt with in previous RIAs¹⁶.

2.1.5 The draft Contaminants in Food (England) Regulations 2006, which are made under The Food Safety Act 1990 will-

- (a) revoke and replace The Contaminants in Food (England) Regulations 2005 (SI 2005 No. 3251);
- (b) make provision for the enforcement and execution of Commission Regulation 466/2001 as amended, and continue to implement the allied enforcement Directives;
- (c) make provision for the enforcement and enactment of Commission Regulations 199/2006, 856/2005; and
- (d) ensure the observance by enforcement authorities of Commission Regulation 401/2006

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

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 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 relating to specific contaminants were introduced in Commission Regulation 466/2001, made under 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 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, nitrate, 3-MCPD, aflatoxins, ochratoxin A, patulin, polycyclic aromatic hydrocarbons (PAHs) and inorganic tin have already been set under this legislation.

¹⁶ 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 nitrate);
- (ii) The Contaminants in Food (England) Regulations 2003 in February 2003 (dioxins sampling & analysis Directive);
- (iii) The Contaminants in Food (England) Regulations 2004 in June 2004 (tin, patulin, dioxins and aflatoxins); and
- (iv) The Contaminants in Food (England) Regulations 2005 in July 2005 (heavy metals in fish, PAH and ochratoxin A)

2.2.3 Commission Regulation 199/2006 amends Regulation 466/2001 as regards maximum levels for dioxins and dioxin-like PCBs in meat, fish, milk, eggs and products thereof and oils and fats. The Regulation, which will apply from 4 November 2006, sets new maximum levels for the sum of dioxins and dioxin-like PCBs in foodstuffs based on the Total Toxic Equivalent (expressed in WHO-TEQ)¹⁷. This is considered to be the most appropriate approach from a toxicological point of view. The existing maximum levels for dioxins, set under Regulation 466/2001 as amended by Council Regulation 2375/2001 will continue to apply for a transitional period. Food business operators will need to ensure that during this period, foodstuffs placed on the market comply with the maximum levels for dioxins and with the maximum levels for the sum of dioxins and dioxin-like PCBs.

2.2.4 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. It also reviews the maximum levels for those contaminants currently in the legislation and the foods that are subject to control. Consequently, Commission Regulation 466/2001 has undergone 18 amendments including these recent measures on dioxins and dioxin-like PCBs since it first applied in April 2002. An overview of the background to the development of the dioxins and dioxin-like PCBs legislation and the health effects of these contaminants is given below.

Dioxins and dioxin-like PCBs

2.2.5 As noted earlier in this RIA, maximum levels for dioxins were set under Commission Regulation 466/2001 as amended by Council Regulation 2375/2001 and have applied across the EU since 1 July 2002. The Food Standards Agency consulted widely on the proposals to set maximum levels for these contaminants during the negotiations. Although from a toxicological point of view any level set should apply to both dioxins and dioxin-like PCBs, the limited data available at that time meant specific limits for dioxin-like PCBs could not be set. However, the Regulation committed the Commission to reviewing the legislation by 31 December 2004 with a view to including dioxin-like PCBs in the limits to be set.

2.2.6 Discussions on this issue began in January 2004 when the Commission presented the preliminary results of a report that considered the possible impact of introducing maximum levels for dioxin-like PCBs into the legislation. Discussions continued throughout 2004 and 2005, with final agreement and adoption in November 2005 of Commission Regulation 199/2006. The Agency consulted widely on the proposals on several occasions during the negotiations.

2.2.7 As dioxins and dioxin-like PCBs have similar toxicological properties it was agreed to set a limit for the sum of dioxins and dioxin-like PCBs and not for the two classes of chemicals separately. In order to ensure a smooth transition, the Regulation makes provision for a transitional period where the existing limits for dioxins will continue to apply in addition to the newly set levels for the sum of dioxins and dioxin-like PCBs. In addition, Member States agreed that the new the Regulation would apply nine months after the date of publication in the Commission's Official Journal to allow industry time to

¹⁷ Dioxins and PCBs are found as mixtures of chemicals with differing toxicity – the sum of these chemicals, weighted on the basis of the most toxic dioxin, gives the Toxic Equivalent (TEQ). The Toxic Equivalent system devised by the World Health Organisation (WHO) is used, so the figures are referred to as WHO TEQs.

implement the new measures. The Commission has a general commitment to review the maximum levels set under Commission Regulation 466/2001. Consequently Commission Regulation 199/2006 will be reviewed with the view to establishing maximum levels for other foodstuffs including specific lower limits for infant and baby food and dispensing with the separate maximum levels for dioxins.

2.2.8 In addition to the statutory limits, 'action levels' have been established under Commission Recommendation 2002/201/EC as amended. The Recommendation in conjunction with Commission Regulation 466/2001 and Commission Directive 2002/69/EC is part of a Commission strategy to reduce the presence of dioxins and dioxin-like PCBs in the environment, food and feed. The 'action levels' are a tool for 'early warning' which trigger a proactive approach from competent authorities and operators to identify sources and pathways for contamination and to take measures to eliminate them. Member States are requested to carry out national monitoring programmes against these non-statutory action levels. The results of a monitoring exercise carried out under this Recommendation were published in June 2004 and are available from the Agency's website. Further monitoring is underway and results will be published in due course.

Health effects

2.2.9 The term dioxins refers to two groups of closely related compounds, individually referred to as congeners. There are 75 polychlorinated dibenzo-p-dioxins (PCDDs) and 135 polychlorinated dibenzofurans (PCDFs). Dioxins have developmental effects on young children and are believed to disrupt the endocrine systems in humans and wildlife. Of the PCDD and PCDF groups, 17 are of toxicological concern. One of the compounds, 2,3,7,8-tetrachlordibenzo-p- dioxin (TCDD) may cause cancer in humans and also has endometriosis, neurobehavioural and immunosuppressive effects. Polychlorinated biphenyls (PCBs) are a group of 209 different congeners. A few exhibit toxicological properties similar to dioxins and are therefore described as being 'dioxin-like'.

2.2.10 Dioxins are unintentionally produced in small amounts during most combustion processes, both industrial and domestic and may be formed as unwanted by-products in the manufacture of certain chemicals. Unlike dioxins, PCBs were manufactured and are found in a wide range of applications from the early 1930s. However, they are no longer produced in the UK and have no significant uses. Emissions of dioxins and PCBs into the environment have reduced by about 70% over the past 10 years and average adult dietary intakes by 87% between 1982 and 2001¹⁸. However these contaminants do not degrade easily and so continue to be widespread in the environment. They tend to bio-accumulate and are generally present at low concentrations in most foods especially fat containing foods such as milk, meat, fish and eggs. A recently published Food Standards Agency survey on dioxins and dioxin-like PCBs in farmed and wild fish and shellfish show that levels of these contaminants in most fish are continuing to fall¹⁹.

¹⁸ The Food Standards Agency's Food Survey Information Sheet No 38/03, July 2003 – Dioxins and dioxin-like PCBs in the UK diet: 2001 Total Diet Study Samples.

Available from the Agency's website at www.food.gov.uk/science/surveillance

¹⁹ The Food Standards Agency's Food Information Sheet No. 03/06 – Dioxins and dioxin-like PCBs in farmed and wild fish and shellfish.

Available from the Agency's website at www.food.gov.uk/science/surveillance

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 2005 (SI 2005 No 3251). Similar Regulations apply in Northern Ireland, Scotland and Wales. A new Statutory Instrument is now necessary to additionally make provision for the execution and enforcement of Commission Regulation 199/2006. The draft Contaminants in Food (England) Regulations 2006 has 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, which will have a negative impact on consumer confidence in the safety of the UK food chain. In addition it may also lead to an adverse report from the Commission's Food and Veterinary Office who inspect the food control measures adopted in Member States of the EU.

3 CONSULTATION

3.1 Formal Consultation on the draft Regulations

3.11 The Contaminants in Food (England) Regulations 2005 included references to the criteria and requirements for the various enforcement sampling and analysis Directives. However, the Agency's revised view is that these need not and should not be implemented in the SI because their observance is already a directly applicable requirement of Commission Regulation 466/2001. Consequently all references relating to these provisions are now mentioned in the Explanatory Note to the SI only. The Agency sought comments and views from interested parties, in particular from enforcement authorities, on this significant change to the Contaminants in Food (England) Regulations. A consultation package was distributed to over 700 interested parties including consumer groups, industry (including Trade Associations) and enforcement authorities. Five responses, of which three were substantive, were received. Details of the comments are at Annex 3. The substantive comments related mainly to the maximum levels for Fusarium toxins (Annex 1A). In its response, the Association of Port Health Authorities highlighted the cost of sampling and analysis of foodstuffs for dioxins and dioxin-like PCBs and that there are few laboratories in the UK accredited to carry out official analyses for this contaminant.

3.12 The Agency acknowledges that analysis for dioxins is expensive and that Public Analysts Laboratories are currently unable to carry out the work themselves. The Agency highlighted these issues in earlier RIAs on The Contaminants in Food (England) Regulations 2002. (SI 2002 No 1923) and The Contaminants in Food (England) Regulations 2003 (SI 2003 No 1478). We consulted widely throughout the negotiations on the maximum limits for dioxins and dioxin-like PCBs and requested information from

enforcement authorities on the implications of these proposals but received no quantified information. Maximum limits for dioxins have applied since 1 July 2002 and the costs of analysis and the current situation with the Public Analyst service would apply irrespective of whether provisions were made for the enforcement of Commission Regulation 199/2006 or not.

3.2 Informal consultations during the negotiations with the European Commission

3.2.1 Regular informal consultations on the potential impact of the Commission's proposals were carried out by the Agency throughout the negotiations during the Commission Working Group meetings. On each occasion, nearly 400 stakeholders including consumer groups, industry, enforcement authorities and other interested parties were contacted via information letters both to provide information on progress and to seek comment and data to help inform the UK's negotiating position. The following paragraphs summarise the outcome of these consultations.

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

3.2.3 Information letters distributed by the Agency dated 27 January, 8 July and 2 August 2004 and 5 January, 31 January and 24 February 2005 requested views and comments on the Commission's proposals from stakeholders covering industry, enforcement and consumer interests. The letter of 24 February 2005 included an initial RIA that sought comments and views from stakeholders on the potential costs, impact on competition and any other potential costs arising from complying with the proposed measures. No comments on these issues were received.

3.2.4 Interested parties have been aware since 2001 that in order to maintain a high level of consumer health protection maximum levels for dioxin-like PCBs would be included in the dioxins legislation. Consequently the main focus of the negotiations, and comments received, related to the technical detail on how PCBs might be brought into the legislation and the various options regarding setting limits for dioxin-like PCBs. A central issue was whether the new Regulation would contain separate limits for dioxins and dioxin-like PCBs or a limit on the Total TEQ. Responses indicated the preference to maintain the existing dioxins limits and add on an increment for dioxin-like PCBs but only regulate on the basis of Total TEQ.

4 OPTIONS

4.1 The options are those discussed below

Option 1 Do nothing – make no provisions for the enforcement and enactment of Commission Regulation 466/2001 as amended by Commission Regulation 199/2006.

Enforcement authorities would continue to use the Contaminants in Food (England) Regulations 2005.

Option 2 make provision for the execution and enforcement of Commission Regulation 199/2006 under The Contaminants in Food (England) Regulations 2006. Thus providing enforcement authorities with the powers to take samples and request the analysis of foodstuffs to check compliance with the new EC legislation and to take appropriate action where foodstuffs are found to be non-compliant. 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 Contaminant in Food (England) Regulations 2006 apply to enforcement authorities and all businesses involved in the food sector and provide a measure of increased food safety for consumers. As stated earlier in this RIA, the draft Regulations will revoke and replace the previous 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) apply various sections of the Food Safety Act 1990; 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 Impact on Race Equality

The purpose of the draft Contaminants in Food (England) Regulations 2006 is to provide enforcement authorities with the appropriate powers to carry out their official control responsibilities. The draft Regulations make provision for the enforcement and enactment of EC measures which aim to provide a high level of consumer protection by setting maximum levels for certain contaminants in a wide range of foodstuffs. Consequently the draft Regulations are not considered to have any race equality impacts.

5.1.4 Impact on Sustainability

The draft Regulations will not have a specific impact on sustainability. However, the maximum levels set under Commission Regulation 199/2002 may have an impact on the sustainability of some fish. As discussed in paragraph 2.2.10, dioxins and dioxin-like PCBs tend to accumulate in the body fat of fish in particular oily fish such as salmon and mackerel. Consequently older, larger fish will have higher levels of these contaminants than younger, smaller fish. In order to comply with the maximum levels it is possible that younger fish will be taken and this could potentially have a negative impact on the long-term sustainability of some species. This will also have an impact on consumer choice.

5.1.5 No comments on the specific costs to industry arising from these Regulations were received by the Agency. The potential impact on the public sector is discussed 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 2006 have been developed for this purpose.

5.2.2 To follow this option may maintain an unacceptable risk to human health, would disadvantage UK food producers operating in an international market, would hamper enforcement authorities carrying out their duties to protect public safety and would incur infraction proceedings against the UK from the EC. There are no benefits arising from this option.

Option 2 Costs and Benefits

Benefits

5.2.3 The draft Contaminants in Food (England) Regulation 2006 will, if made, ensure a continuing high level of consumer health protection by providing enforcement authorities with the necessary provisions for the enforcement of the maximum levels set under Commission Regulation 466/2001 as amended by Regulation 199/2006. The Regulations will also benefit food business operators through continued consumer confidence in the safety of the UK food chain.

Costs

5.2.4 Food business operators have general responsibilities and should already be taking all reasonable precautions such as carrying out checks, sourcing foodstuffs from suppliers that are accredited and/or comply with the various industry standards of Quality Control and Assurance Schemes to ensure compliance with general food law (Regulation (EC) 178/2002 and The Food Safety Act 1990 requirements. Enforcement authorities should be carrying out checks to ensure compliance with food safety requirements as part of their official control responsibilities.

5.2.5 Commission Regulation 199/2006 introduces new statutory limits for the sum of dioxins and dioxin-like PCBs and industry and enforcement authorities should check compliance with the legislation. The cost of analysis for dioxins and PCBs in foodstuffs is currently around £600 to £700 per sample and this is not significantly different whether

dioxins alone or dioxins and dioxin-like PCBs are analysed. Although food business operators and enforcement authorities should be carrying out checks to ensure compliance with the Community measures, neither Commission Regulation 466/2001, as amended, nor the allied enforcement sampling and analysis Directive prescribe the number of checks that should be carried out. This is at the discretion of the operators and enforcement authorities and firms already operating a risk based testing system as standard are not expected to incur significant extra operating costs. During the informal consultations, the Agency received no information on the potential costs to industry and 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. Small businesses were invited to comment on the potential impact of these measures during the informal consultation of 24 February 2005. No comments on the Commission's proposals were received from these organisations. The obligation to provide safe food in compliance with food law applies equally to all food business operators. Compliance with the legislation will facilitate trade and ensure consistency throughout the EU.

7 COMPETITION ASSESSMENT

7.1 The draft Contaminants in Food (England) Regulations 2006 apply to all businesses involved in the food industry and enforcement authorities. A competition filter has been completed. Comments on the likely impact of the proposals on competition were specifically requested during the informal consultation of 24 February 2005 but no comments were received. Given that no costs to businesses from the enforcement of Commission Regulation 199/2006 have been identified during the negotiations on the Commission measures, there are no anticipated effects on competition.

8 ENFORCEMENT AND SANCTIONS

8.1 Enforcement

Local Authorities and Port Health Authorities are responsible for enforcing a large proportion of food safety legislation.

8.2 Sanctions

Local Authorities and Port Health Authorities will be responsible for enforcing the Contaminants in Food (England) Regulations 2006. A fine not exceeding level 5 on the standard scale will apply in the case of conviction for an offence under the Regulations.

9 IMPLEMENTATION AND DELIVERY PLAN

9.1 The Contaminants in Food (England) Regulations 2006 revoke and replace the Contaminants in Food (England) Regulations 2005. They make provision the enforcement

of EU measures setting maximum levels for certain contaminants in food, and ensure the observance by enforcement bodies of a Commission Regulation and a number of Directives laying down the prescribed methods of sampling and analysis to be followed when enforcing those maximum levels.

9.2 As highlighted in paragraph 8 above, Local Authorities and Port Health Authorities are responsible for enforcing much of the food safety legislation in England, 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 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 As part of the Commission's review of the dioxins' legislation by December 2008, the Agency will consult with enforcement, industry and other stakeholders to evaluate the effectiveness of and experience with and impact of the legislation. As part of this process, the Agency meets regularly with representatives from the Association of Public Analysts (the APA Liaison meetings) to help inform this review.

10.2 As stated earlier, 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 the Regulation 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 thus facilitating trade.

11.2 In order to ensure a continued high level of consumer protection, 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 and the foods that are subject to control. Consequently, Regulation 466/2001 has undergone a number of amendments and a new Commission Regulation setting maximum levels for the sum of dioxins and dioxin-like PCBs has been adopted. Regulation 466/2001 is supported by various allied Commission Directives and a Regulation, which lay down the methods for sampling and analysis for the official control of those contaminants specified in the Regulation. Currently enforcement of these measures is carried out under The Contaminants in Food (England) Regulations 2005 (SI 2005 No 3251).

11.3 Maximum levels for dioxins have applied since July 2001 (Council Regulation 2375/2001 amending Regulation 466/2001 refers) but due to the limited data available at that time specific limits for dioxin-like PCBs could not be set. However, the Regulation committed the Commission to reviewing the legislation by 31 December 2004 with the view to including dioxin-like PCBs in the limits to be set. Discussions on this issue began in January 2004 and continued throughout 2004 and 2005, with final agreement and adoption of Commission Regulation 199/2006 in November 2005.

11.4 Dioxins have developmental effects on young children and are believed to disrupt the endocrine systems in humans and wildlife. One (2,3,7,8-tetrachlordibenzo-p- dioxin (TCDD)) may cause cancer in humans and also has endometriosis, neurobehavioural and immunosuppressive effects. Certain PCBs exhibit toxicological properties similar to dioxins and are therefore described as being ‘dioxin-like’. As dioxins and dioxin-like PCBs have similar toxicological properties it was agreed, following consultation, to set a limit for the sum of dioxins and dioxin-like PCBs with a transitional period where the existing limits for dioxins will continue to apply in addition to the new Regulation.

11.5 Commission Regulations have general application and the direct force of law in all Member States and the UK has a legal obligation to ensure that provisions are in place for their enforcement. Consultation packs were circulated to nearly 800 Interested Parties; five responses were received. Of these, three were substantive and related mainly to Fusarium toxins (Annex 1A) although the Association of Port Health Authorities did raise the issue of the high cost of analysis for dioxins and the limited official control laboratory provision. No quantified information from stakeholders on the costs or benefits of these measures was received by the Agency. The table below provides a qualitative summary of the options for the UK.

Summary Costs and Benefits Table

OPTION	Total benefit per annum: economic, environmental, social	Total cost per annum: <ul style="list-style-type: none"> • economic, environmental, social • policy & administrative
1 – Do Nothing	None	<ul style="list-style-type: none"> • Infraction proceedings against the UK government • Possible adverse report from the Commission’s Food & Veterinary Office • Possible financial costs to industry arising from lack of consumer confidence in the safety of the UK food supply
2 – Make provision for the enforcement & enactment of the EC measures under The Contaminants in Food (England) Regulations 2006	<ul style="list-style-type: none"> • Fulfils the UK’s legal obligations to make provision for the enforcement of EC Regulations • Continued high 	<ul style="list-style-type: none"> • No quantified information received by the Agency in respect to costs arising from the EC legislation. There are likely to be some costs arising from the costs of sampling & analysis but these

	<p>level of public health safety & consumer confidence in compliance testing</p> <ul style="list-style-type: none"> • The new Regulations will ensure that measures, which are applicable to all member states, are in place, thereby facilitating trade and ensuring consistency throughout the EU. 	<p>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.</p> <ul style="list-style-type: none"> • It was agreed that the new Regulation would apply nine months after the date of publication in the Commission's Official Journal to allow industry time to implement the new measures.
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It is recommended that **Option 2 is supported.**

The Contaminants in Food (England) Regulations 2006 will provide enforcement authorities with the necessary powers to effectively enforce the provisions and maximum limits set in Commission Regulation 466/2001, as amended. The Regulations will revoke and replace The Contaminants in Food (England) Regulations 2005 (SI 2005 No 3251). The Agency is developing Guidance Notes on the legislation.

12 DECLARATION AND PUBLICATION

Declaration

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

Signed: Caroline Flint

Date: 5th June 2005

Minister of State, Department of Health.

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