

EXECUTIVE NOTE

The Contaminants in Food (Scotland) Regulations 2007 SSI/2007/29

Description

1. The above instrument was made under the powers in section 16(1)(a), (e) and (f), 17(2), 26(1)(a) (2)(e) and (3) and 48(1) of the Food Safety Act 1990 and of all other powers enabling them in that behalf, having had regard, in accordance with section 48(4A) of that Act, to relevant advice given by the Food Standards Agency and after consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council. The instrument is subject to negative resolution procedure.

Policy Objective

2. These Regulations make provision for the execution and enforcement of European Community (EC) measures contained in Commission Regulation (EC) No 1881/2006. This Regulation sets maximum levels for certain contaminants in foodstuffs 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 Commission Regulations. The Contaminants in Food (Scotland) Regulations 2007 will revoke and replace The Contaminants in Food (Scotland) Regulations 2006 (SI 2006 No 306).

Legislative Background

3. The Contaminants in Food (Scotland) Regulations 2007 will provide enforcement authorities and industry with the necessary domestic legal framework to ensure compliance with the provisions and maximum limits laid down in Commission Regulation (EC) 1881/2006 of 19/12/2006. The EC measures will apply from 1 March 2007 and repeal existing legislation on contaminants in food which currently falls under Commission Regulation (EC) 466/2001 of 8 March 2001, as amended. Commission Regulation (EC) 466/2001 which has applied since April 2002 is currently enforced in Scotland under the Contaminants in Food (Scotland) Regulations 2006. However, the consolidation and simplification of the existing EC measures has necessitated the development of a new SI.

Policy Background

4. 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 legislating for specific contaminants in food and is also of general application 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 (Commission Regulation (EC) No 466/2001 of 8 March 2001) were introduced under Regulation 315/93/EEC.

5. The intention of Commission Regulation 466/2001 was to provide consumers with an increased measure of protection by setting EC maximum limits for mycotoxins and certain undesirable process and environmental contaminants in those foodstuffs that are significant contributors to the total dietary exposure of consumers to those contaminants. The aim of the Regulation is to keep contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain.
6. In view of the requirement to protect public health by restricting contaminants to 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 since it first applied in April 2002 as new contaminants and/or new maximum limits and food commodities or revised limits or commodities are adopted. Maximum levels for aflatoxins, ochratoxin A, patulin and Fusarium toxins (mycotoxins) 3-MCPD (a process contaminant), lead, cadmium, mercury, dioxins and dioxin-like PCBs, polycyclic aromatic hydrocarbons PAHs) and nitrate (environmental chemical contaminants) and inorganic tin in canned foodstuffs have been set under this legislation.
7. It was recognised that there was a need to consolidate the existing EC measures, and Member States including the UK pressed the Commission for a new version of Commission Regulation 466/2001. As well as consolidation, the aim of Commission Regulation 1881/2006 is to simplify the legislation by removing repetition; to clarify the legal provisions and interpretation of the text; to include updated views on risk assessments; to take account of new information and developments in Codex Alimentarius and to bring the definition of the products of animal origin in line with the definitions given in Regulation EC No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. As a result, the scope of the previous legislation has been widened in some instances, there have been some changes to the existing maximum limits and certain foodstuffs have now been included or excluded from the scope of the legislation. By way of derogation, UK grown lettuce and spinach may be placed on the UK market with the intention of being consumed in the UK with nitrate levels higher than the maximum levels set out in 1881/2006 until 31st December 2008. This derogation has been granted on the basis that cloudy weather can result in occasional high levels and risk assessment has shown that this does not impact on public health.
8. The two main changes are:
 - (i) the widening of the application of the maximum level for lead in milk and milk based products to include milk from all farmed animals; there is production of milk from animals other than dairy cows in the UK albeit on a small scale
 - (ii) the inclusion of maximum limits for deoxynivalenol and zearalenone only for cereal bran marketed for direct human consumption and cereal germ. This change affects a small, specialised sector of the bran market. These new limits do not apply to bran used as an ingredient by the manufacturing industry. It was felt necessary to introduce limits for bran intended for direct consumption because Fusarium toxins if present can accumulate in the bran fraction. Furthermore, bran is habitually consumed frequently up to several times a day by high level consumers of this product who could therefore regularly exceed or come close to exceeding safety guidelines. Therefore, bran intended for direct human consumption will need to be sourced very carefully.

Consultation

9. In order to ensure that enforcement authorities are provided on time with the correct domestic legislation for the official control of the contaminants specified in Commission Regulation 1881/2006, a shortened consultation on the Contaminants in Food (Scotland) Regulations 2007 was carried out. Consultation in Scotland of approximately 350 interested parties for the 6 week period from 5 December 2006 produced 5 responses.

Other Administrations

10. Similar Regulations will apply in England, Wales and Northern Ireland.

Impact

11. A Regulatory Impact Assessment has been prepared and is available at the address below.
12. The impact on the public sector is believed to be minimal. Some costs to the Exchequer may arise from the costs to local authorities in carrying out the sampling and analysis requirements provided for in the Commission Regulation. However, such testing would be risk based and the overall risk in the UK is low.

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Food Standards Agency Scotland
31 January 2007

ANNEX B

PARTIAL REGULATORY IMPACT ASSESSMENT

The Contaminants in Food (Scotland) Regulations 2007 SSI/2007/29

Consolidation and replacement of Commission Regulation (EC) No 466/2001, as amended, setting maximum levels for certain contaminants in foodstuffs

New Commission Regulation repealing Commission Directive 2002/69/EC laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs

New Commission Regulation laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs

Annex B

1. TITLE OF PROPOSAL

The Contaminants in Food (Scotland) Regulations 2007

1.1 Provision for the execution and enforcement of Commission Regulation (EC) No. 1881/2006 of 19/12/2006 setting maximum levels for certain contaminants in foodstuffs. The Regulation consolidates and replaces Commission Regulation (EC) 466/2001 of 8 March 2001, as amended and will apply from 1 March 2007.

1.2 Provision for the enforcement of Commission Regulation (EC) No 1883/2006 of 19/12/2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs. The Regulation will repeal Commission Directive 2002/69/EC of 26 July 2002 and will apply from 1 March 2007.

1.3 Provision for the enforcement of Commission Regulation (EC) No 1882/2006 of 19/12/2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs. Currently this is carried out under Commission Directive 2002/63/EC. The new Regulation will apply from 1 March 2007.

2 PURPOSE AND INTENDED EFFECT

2.1 Objective

2.1.1 The purpose of this measure is to provide both industry and enforcement authorities with the necessary domestic legal framework to ensure compliance with European Community (EC) measures (Commission Regulation (EC) 1881/2006) setting maximum levels for certain contaminants in foodstuffs. The aim of the new Commission Regulation is to simplify the existing EC measures on contaminants by consolidating and replacing Commission Regulation 466/2001 which has undergone 18 amendments, whilst also taking into account new information and developments in Codex Alimentarius and where appropriate clarifying the legal provisions and interpretation of the text.

2.1.2 Commission Regulation 1883/2006 is supported by a number of allied enforcement Commission Directives and Regulations which lay down the methods for sampling and analysis for the official control of those contaminants specified in the legislation. These measures apply primarily to enforcement authorities and aim to ensure a harmonised approach to enforcement across the European Union (EU), which will help to promote consistent and effective enforcement by reducing uncertainty or dispute in interpreting results against maximum levels. The European

Commission is in the process of replacing the sampling and analysis Directives with new Commission Regulations. Consequently Commission Regulation 1883/2006 will replace and repeal Commission Directive 2002/69/EC which has applied since February 2003.

2.1.3 Commission Regulation 1882/2006 provides for maximum levels for nitrates in spinach, lettuce, baby foods and processed cereal based food for infants and young children. Fresh lettuce and spinach are very perishable products and sampling plays an important role in the precision of the determination of the levels of nitrates, as well the sample preparation procedures. It is necessary to fix general criteria which the method of analysis should comply with in order to ensure that control laboratories use methods of analysis with comparable levels of performance. Previously, the sampling and analysis used the approach set out in the pesticide Directive 2002/63/EC. These provisions have now been updated and are now more focussed for nitrate sampling in lettuce and spinach. The new Regulation will also ensure a harmonised approach across the EU to nitrate sampling.

2.1.4 A new Statutory Instrument SI (The Contaminants in Food (Scotland) Regulations 2007) is necessary to make provision for the execution and enforcement in Scotland of these new Commission Regulations. As the EC measures apply from **1 March 2007**, the new SI must come into force by that date.

The Contaminants in Food (Scotland) Regulations 2007, which are made under The Food Safety Act 1990 will-

- (a) revoke and replace The Contaminants in Food (Scotland) Regulations 2006 (SI 2006 No. 306);
- (b) make provision for the execution and enforcement of Commission Regulations 1881/2006, 1882/2006 and 1883/2006; and
- (c) continue to make provision for the execution and enforcement of Commission Regulation 401/2006 and Commission Directives 2001/22/EC, 2004/16/EC and 2005/10/EC

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

2.1.5 This Regulatory Impact Assessment (RIA) is concerned only with the provisions for the enforcement of the new Commission Regulations. The allied enforcement sampling and analysis Commission Regulation and Directives referred to at point (c) above have already been dealt with in previous RIAs which are listed at Annex B.1 and are available on request.

2.2 Background

2.2.1 European Community 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 legislating for specific contaminants in food and is also of general application 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 (Commission Regulation 466/2001) were introduced 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 was 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 aim of the Regulation is to keep contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain. The Regulation also harmonises Member States' existing measures, facilitating trade. Maximum levels for lead, cadmium, mercury, dioxins and dioxin-like PCBs, polycyclic aromatic hydrocarbons (PAHs) inorganic tin, nitrate, 3-MCPD, aflatoxins, ochratoxin A, patulin, and Fusarium toxins were set under this legislation. An overview of the occurrence and effects on health of these contaminants is given at Annex B.2.

2.2.3 In view of the requirement to protect public health by keeping contaminants at levels that are toxicologically acceptable, the Commission 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 been amended 18 times since it first applied in April 2002.

2.2.4 In November 2003, the Commission produced a draft document that consolidated the text, with a further version produced in November 2005. Although these documents were available from the Commission's website they were non-binding unofficial texts and Member States including the UK pressed the Commission for a new, legally binding, consolidated version of Regulation 466/2001.

2.2.5 Discussions on a new draft Regulation which would consolidate and replace Regulation 466/2001 began at Commission level in January 2006, continuing until July, with final agreement at Standing Committee on 11 September. The aims of the exercise were to simplify the Regulation by removing repetition; to clarify the legal provisions and interpretation of the text; to include updated views on risk assessments; to take account of new information and developments in Codex Alimentarius and to bring the definition of the products of animal origin in line with the definitions given in Regulation EC No 853/2004¹. As a result the scope of the original legislation has been widened in some instances, there have been some changes to the existing maximum limits and certain foodstuffs have now been included or excluded from the scope of the legislation. A summary of the key changes is provided at Annex B3. Stakeholders were consulted throughout the

¹ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (O.J. L226/22 25.06.04 p22)

negotiations via Interested Parties letters and copies of the draft Regulations were made available. Their responses are summarised at paragraphs 3.2.1 and 3.2.2.

2.2.6 The two main changes which add to the current Regulation are –

(i) the widening of the application of the maximum level for lead in milk and milk based products to include milk from all farmed animals; there is production of milk from animals other than dairy cows in the UK albeit on a small scale.

(ii) the inclusion of maximum limits for deoxynivalenol and zearalenone only for cereal bran marketed for direct human consumption and cereal germ. This change affects a small, specialised sector of the bran market. These new limits do not apply to bran used as an ingredient by the manufacturing industry. It was felt necessary to introduce limits for bran intended for direct consumption because Fusarium toxins if present accumulate in the bran fraction. Furthermore, bran is habitually consumed frequently up to several times a day by high level consumers of this product who could therefore regularly exceed or come close to exceeding safety guidelines. Therefore, bran intended for direct human consumption will need to be sourced very carefully.

2.2.7 As stated at paragraph 2.1.2, the Commission in co-operation with Member States is replacing the existing allied Commission Directives laying down the methods for sampling and analysis for enforcement purposes with Commission Regulations. Currently official control checks for dioxins are carried out under Commission Directive 2002/69/EC which lays down the sampling methods and methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs. However, maximum levels for the sum of dioxins and dioxin-like PCBs have been set under Commission Regulation 199/2006 and apply from 4 November 2006. This change would have required amendments to Directive 2002/69/EC and consequently, for reasons of clarity, it was considered appropriate to replace the Directive with Regulation 1883/2006. Stakeholders were notified and consulted on this issue via Interested Parties letters.

2.2.8 Currently official control checks for nitrates are carried out under Commission Directive 2002/63/EC which lays down the sampling methods and methods of analysis for the official control of pesticides. In addition, amendments to Commission Regulation 466/2001 (carried forward into 1881/2006) revising the maximum levels for nitrate in vegetables have increased the need for specific methods for nitrate sampling and analysis in lettuce and spinach. Therefore, Regulation 1882/2006 will address this need for all parties concerned.

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. Failure to make these provisions will leave enforcement authorities without the necessary specific statutory legislation to ensure compliance with the Commission measures. This will have a negative impact on consumer

confidence in the safety of the UK food chain and may also lead to an adverse report from the Commission's Food and Veterinary Office which inspects the food control measures adopted in Member States of the EU and/or infraction proceedings by the Commission.

2.3.2 The existing EC measures (Regulation 466/2001) have been consolidated and will be replaced by Commission Regulation 1881/2006. A new Statutory Instrument is now necessary to make provision for the execution and enforcement of this new Commission Regulation, which itself makes directly applicable, its allied enforcement sampling and analysis Directives and Regulations. The Contaminants in Food (Scotland) Regulations 2007 has been developed for this purpose in Scotland. Similar Regulations have been developed in England, Wales and Northern Ireland. The new SIs will revoke and replace the current Contaminants in Food Regulations.

3 CONSULTATION

3.1 Regular consultations on the potential impact of the Commission's proposals to consolidate and replace Commission Regulation 466/2001 were carried out by the Agency throughout the negotiations during the Commission Working Group meetings. On each occasion, nearly 350 Scottish stakeholders including consumer groups, industry, enforcement authorities and other interested parties, including the Scottish Federation of Small Businesses were contacted via Interested Parties letters both to provide information on progress and to seek comment and information on the draft document in support of the UK negotiating position.

3.2 Within Government

Other government departments included in the informal consultation process were the Scottish Executive Environment and Rural Affairs Department and Scottish Executive Health Department. No comments were received.

3.3 Public consultation

3.3.1 Interested Parties letters dated 23 February, 13 April, 26 May, 31 July, 15 September and 9 November were distributed by the Agency.

3.3.2 The consolidation exercise was broadly welcomed by stakeholders. Comments and suggested revisions to the text submitted by stakeholders helped form the UK's response to earlier drafts of the Regulation. No concerns were raised or comments received on specific questions on the possible impact of the proposal to widen the scope of the legislation in respect to the maximum limit for lead in milk to cover all farmed animals rather than the current application to cow's milk only (letters dated 23 February, 13 April and 31 July refer). However, the proposal to revise the maximum limit for lead in fish to bring it in line with the recently agreed CODEX limit of 0.3 mg/kg was supported by stakeholders as was the proposal to exclude pine nuts from the maximum limit for cadmium in vegetables and fruit until further data

was available. No comments were received on the new nitrate sampling guidelines. A concern was raised regarding limits for bran and this issue was addressed by the Agency as well as the Commission. The principle behind the clarification of food business operators' responsibilities under Article 2, dried, diluted, processed and compound foodstuffs and Article 5, specific rules for products which can be used for feed and food or other purposes (Annex B.3 refers) was broadly accepted.

4 OPTIONS

4.1 The options are those discussed below

Option 1 Do nothing – make no provisions for the execution and enforcement of Commission Regulations 1881/2006, 1882/2006 and 1883/2006. Enforcement authorities would continue to use the Contaminants in Food (Scotland) Regulations 2006.

Option 2 - make provision for the execution and enforcement of the new Commission Regulations under The Contaminants in Food (Scotland) Regulations 2007. This will make failure to comply with the relevant Community requirements an offence under domestic law, and provide 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 England, Wales and Northern Ireland.

5. COSTS AND BENEFITS

5.1 Sectors and Groups Affected

The purpose of the Contaminants in Food (Scotland) Regulations 2007 is to give effect to EC measures which aim to provide an increased level of food safety for consumers by setting maximum levels for certain contaminants in a wide range of foodstuffs and to provide a harmonised approach to enforcement. Consequently they apply to enforcement authorities and all businesses involved in the food sector.

5.1.2 Impact on Race Equality

The Regulations are not considered to have any race equality impacts.

5.1.3 Impact on Sustainability

The Regulations will not have a specific impact on sustainability. However, these issues are taken into consideration during the negotiations and consultations, and limits are set at a level which balances the ability of businesses to provide the items subject to limits with a continued high level of consumer health protection, consumer confidence in the safety of the UK food chain and consumer choice. Where a problem is identified such as the original maximum limit for cadmium in swordfish or the proposed limit for PAH in bivalve molluscs (where limits excluded products from the market whilst providing little apparent benefit in food safety; see RIA for The Contaminants in Food (Scotland) Regulation 2005 for details) the limits are revised to a more appropriate and proportionate level.

5.2 Analysis of Costs and Benefits

The potential impact on food business operators, the public sector and on the Government is discussed below.

Option 1: Costs and Benefits

5.2.1 Costs

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 Contaminants in Food (Scotland) Regulations 2007 has been developed for this purpose. To do nothing will incur infraction proceedings on the UK from the EC. To follow this option will also hamper enforcement authorities carrying out their duties to protect public safety.

5.2.2 Benefits

This option represents the status quo. Therefore there would be no incremental benefits from following this option.

Option 2 Costs and Benefits

5.2.3 Costs

Food business operators have general responsibilities and should already be taking all reasonable precautions such as carrying out checks for example applying Hazard Analysis Critical Control Point (HACCP) principles which are risk based or sourcing foodstuffs from suppliers that are accredited and/or complying 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.

Food Businesses

No comments on the specific additional costs to food business operators (FBOs) and enforcement authorities arising from these Regulations were received by the Agency during the informal consultation. The main aim of the new Commission Regulation is to simplify the application of the legislation by consolidating Regulation 466/2001 which has been amended 18 times as new contaminants and/or new limits and food commodities or revised limits and commodities are adopted.

Commission Regulation 1881/2006 consolidates and replaces existing EC measures on maximum levels for certain contaminants in foodstuffs. The potential costs of analysis for the contaminants specified in the new Regulation were discussed in detail in earlier RIAs (Annex B.1). However, it should be noted that although food business operators and enforcement authorities should be carrying out checks to ensure compliance with the Commission measures, neither Commission Regulation 1881/2006 nor the allied enforcement sampling and analysis Regulations and Directives prescribe the number of checks that should be carried out. This is at the discretion of the operators and enforcement authorities. During the consultations throughout the negotiations, the Agency received no information on the potential costs to industry and enforcement authorities arising from the new Commission Regulations.

5.2.4 Benefits

The Contaminants in Food (Scotland) Regulation 2007 will continue to ensure a 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 1881/2006.

The consolidation and replacement of Regulation 466/2001 as amended has been broadly welcomed by stakeholders as it goes some way to simplifying the impact on industry when applying the legislation. The new enforcement sampling and analysis Regulation 1883/2006 takes account of the new EC measures for dioxins and dioxin-like PCBs which are not covered by the existing legislation (Directive 2002/69/EC) and consequently do not fall under the Contaminants in Food (Scotland) Regulations 2006.

Additionally, the new sampling and analysis of nitrate Regulation 1882/2006 will allow control laboratories to use methods of analysis for nitrate that will enable levels of performance to be compared. These new procedures are not currently covered by Directive 2002/69/EC so reliability of nitrate analysis under the new Regulations is more reliable and robust.

The Agency believes that for businesses there will be a benefit from having to spend less time reading and interpreting the consolidated regulation. The Agency has been advised that it currently takes internal experts in food businesses two hours to read and understand the current EC measures and the Contaminants in Food (Scotland) Regulations 2006 (SI 2006 No 306) at a total cost of £36.00 per business. It is estimated that the new regulation will only take one hour to read and understand,

representing a saving of one hour or £18 for each business. Such businesses may represent a tiny and unknown proportion of the 346,000 food businesses as defined in Regulation 178/2002.

An Administrative Burdens Measurement Exercise carried out across Government in 2005 measured the administrative burden of regulations in force at May 2005. The exercise did not identify any administrative burden on business arising from either the Commission Regulations or the Contaminants in Food (Scotland) Regulations 2004. We believe that the consolidated regulations impose no administrative costs beyond that already incurred during the normal course of business.

6 SMALL FIRMS IMPACT TEST

6.1 Stakeholders including the Scottish Federation of Small Businesses and the Scottish Chamber of Commerce were consulted throughout the negotiations on the EC measures. 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 regardless of size and is proportionate to the size of the business.

7 'TEST RUN' OF BUSINESS FORMS

7.1 There are no forms associated with this piece of legislation.

8 COMPETITION ASSESSMENT

8.1 The Contaminants in Food (Scotland) Regulations 2007 apply to all businesses involved in the food industry and enforcement authorities. A competition filter has been completed. Given that no additional costs to businesses from the enforcement of the limits set under Commission Regulation 1881/2006 have been identified during the negotiations on the Commission measures, there are no anticipated effects on competition.

9 ENFORCEMENT, SANCTIONS AND MONITORING

9.1 Enforcement

Local Authorities are responsible for enforcing Food Safety Regulations.

9.2 Sanctions

Local Authorities will be responsible for enforcing the Contaminants in Food (Scotland) Regulations 2007. A fine not exceeding level 5 on the standard scale will apply in the case of breaches of the main offence of placing contaminated food on the

market, using contaminated food in the manufacture of other foodstuffs, or chemically detoxifying food containing mycotoxins (regulation 3).

9.3 Monitoring

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.

10 IMPLEMENTATION AND DELIVERY PLAN

10.1 As highlighted in paragraph 9 above, Local Authorities are responsible for enforcing much of the 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 (APHA) 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.

11 POST IMPLEMENTATION REVIEW

11.1 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), LACORS and APHA to help inform this review.

11.2 FSA will continue to consult with Local Authorities, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation. In accordance with the Scottish Executive's IRIS unit guidelines, this RIA will be reviewed, as appropriate, in order to establish that it is "fit for purpose". Therefore not adding any additional burdens to businesses. In line with Scottish Executive guidance we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed with 10 years.

11.3 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 to gather 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.

12 SUMMARY AND RECOMMENDATION

12.1 European Community measures (Commission Regulation 466/2001) setting maximum levels for certain contaminants in foodstuffs have applied since 2002. The

aim of the new Commission Regulation (1881/2006) is to simplify the existing EC measures on contaminants by consolidating and replacing Commission Regulation 466/2001 which has undergone 18 amendments, whilst also taking into account new information and developments in Codex Alimentarius and where appropriate clarifying the legal provisions and interpretation of the text. Commission Regulations (EC) No. 1882/2006 – laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs and 1883/2006 – laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin like PCB's in certain foodstuffs make up the entirety of the Contaminants in Food Regulations 2007.

12.2 Existing maximum levels for lead, cadmium, mercury, dioxins and dioxin-like PCBs, polycyclic aromatic hydrocarbons (PAHs) inorganic tin, nitrate, 3-MCPD, aflatoxins, ochratoxin A, patulin, and Fusarium toxins covered under 466/2001 and its 18 amendments are now consolidated under the new regulation 1881/2006. The two main changes are-

- (i) the widening of the application of the maximum level for lead in milk and milk based products to include milk from all farmed animals; there is production of milk from animals other than dairy cows in the UK albeit on a small scale.
- (ii) the inclusion of maximum limits for deoxynivalenol and zearalenone only for cereal bran marketed for direct human consumption and cereal germ. This change affects a small, specialised sector of the bran market. These new limits do not apply to bran used as an ingredient by the manufacturing industry. It was felt necessary to introduce limits for bran intended for direct consumption because Fusarium toxins if present accumulate in the bran fraction. Furthermore, bran is habitually consumed frequently up to several times a day by high level consumers of this product who could therefore regularly exceed or come close to exceeding safety guidelines. Therefore, bran intended for direct human consumption will need to be sourced very carefully.

Currently official control checks for dioxins are carried out under Commission Directive 2002/69/EC which lays down the sampling methods and methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs. However, maximum levels for the sum of dioxins and dioxin-like PCBs have been set under Commission Regulation 199/2006 and applied from 4 November 2006. This change would have required amendments to Directive 2002/69/EC and consequently, for reasons of clarity, it was considered appropriate to replace the Directive with Regulation 1883/2006.

Currently official control checks for nitrates are carried out under Commission Directive 2002/63/EC which lays down the sampling methods and methods of analysis for the official control of pesticides. In addition, amendments to Commission Regulation 466/2001 (carried forward into 1881/2006) revising the maximum levels for nitrate in vegetables have increased the need for specific methods for nitrate sampling and analysis in lettuce and spinach. Therefore, Regulation 1882/2006 will address this need for all parties concerned.

12.3 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 350 Interested Parties; 4 responses were received.

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
2 – Make provision for the enforcement & enactment of the EC measures under The Contaminants in Food (Scotland) Regulations 2007	<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 is recommended that Option 2 is supported.

The Contaminants in Food (Scotland) Regulations 2007 will provide enforcement authorities with the necessary powers to effectively enforce the provisions and maximum limits set in Commission Regulation 1881/2006. They will also revoke the Contaminants in Food (Scotland) Regulations 2006 - S.I. 2006 No 306.

13 DECLARATION AND PUBLICATION

Declaration

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

Signed by the responsible Minister _____

Date _____

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LIST OF RELEVANT RIAs

Consultation on:

The Contaminants in Food (Scotland) Regulations 2006 (April 2006)

Commission Regulation 856/2005 setting maximum limits for Fusarium toxins in certain foodstuffs

Commission Regulation 199/2006 setting maximum limits for the sum of dioxins and dioxin-like PCBs in certain foodstuffs

Commission Regulation 401/2006 laying down the methods for sampling and analysis for the official control of aflatoxins, ochratoxin A, patulin and Fusarium toxins

The Contaminants in Food (Scotland) (Amendment) Regulations 2005 (September 2004)

Commission Regulation 655/2004 setting a maximum limit for nitrates in foods for infants and young children

Commission Regulation 683/2004 setting a maximum limit for aflatoxins and ochratoxin A in foods for infants and young children

The Contaminants in Food (Scotland) Regulations 2005 (July 2005)

Commission Regulation 78/2005 amending the lists of fish species covered by the maximum limits for lead, cadmium and mercury and revising the limit for lead in tuna and cadmium in swordfish

Commission Regulation 123/2005 setting maximum limits for ochratoxin A in wine, coffee and grape juices

Commission Regulation 208/2005 setting maximum limits for polycyclic aromatic hydrocarbons (specifically benzo(a)pyrene) in certain foodstuffs

Commission Regulation 1822/2005 extending the derogation period for nitrate in fresh spinach and fresh lettuce in certain Member States

The Contaminants in Food (Scotland) Regulations 2004 (June 2004)

Commission Regulation 1425/2003 setting maximum limits for patulin in certain foodstuffs

Commission Regulation 2174/2003 setting maximum limits for aflatoxins in raw maize

Commission Regulation 242/2004 setting maximum limits for inorganic tin in canned foodstuffs, canned beverages and canned infant and baby foods

Commission Regulation 684/2004 extending the derogation period for dioxins in free range and semi intensive eggs

The Contaminants in Food (Scotland) Regulations 2003 (February 2003)

Commission Directive 2002/69/EC laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs

The Contaminants in Food (Scotland) Regulations 2002 (March 2002)

Commission Regulation 466/2001 setting maximum limits for aflatoxins, ochratoxin A, lead, cadmium, mercury, nitrate and 3-MCPD and allied enforcement sampling and analysis Directives

Commission Regulation 221/2001 amending Regulation 466/2001 in regards to the maximum limit for lead in bivalve molluscs and revising the list of fish species covered by the maximum limits for heavy metals

Council Regulation 2375/2001 amending Regulation 466/2001 as regards setting maximum limits for dioxins

Commission Regulation 472/2002 setting maximum limits for aflatoxins in spices (consultation carried out July 2002)

Commission Regulation 472/2002 setting maximum limits for ochratoxin A in certain foodstuffs (consultation carried out December 2001)

ANNEX B.2

Summary of Health Effects

MYCOTOXINS

Aflatoxins

Aflatoxins are toxic compounds produced by species of moulds/fungi of the genus *Aspergillus*; mould species that grow in warm humid conditions. Aflatoxin B₁, the most toxic aflatoxin, is a potent carcinogen in laboratory animals and there is evidence that it is a genotoxic human carcinogen i.e. it can cause cancer by reacting with genetic material. Aflatoxins occur mainly in commodities imported from third countries, in particular groundnuts (peanuts), edible nuts and their products, dried figs and dried fig products, spices, and maize.

Fusarium Toxins

Fusarium toxins belong to a group of chemicals called mycotoxins, produced by mould species that grow in temperate climates with lower temperatures and humidity. 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.

Patulin

Patulin is a toxic compound produced by a number of fungi/mould species in the genera *Penicillium*, *Aspergillus* and *Byssochlamys* of which *Penicillium expansum* is probably the most commonly encountered species. Patulin has been found as a contaminant in many mouldy fruits, vegetables, cereals and other foods, however, the major sources of contamination are apples and apple products such as apple juice. There is no clear evidence that patulin is carcinogenic, however, it has been shown to cause immunotoxic effects and is neurotoxic in animals.

Ochratoxin A

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

PROCESS CHEMICAL CONTAMINANTS

3-MCPD

Chloropropanols are a group of chemical contaminants. The most commonly identified of these in food is 3-MCPD. 3-MCPD has most frequently been found at high levels in soy sauces and the savoury food ingredient, acid-hydrolysed vegetable protein (acid-HVP). It has also been quantified at low levels in many foods and food ingredients as a result of processing. 3-MCPD can cause cancer in laboratory animals when fed large amounts over their lifetime. 3-MCPD could potentially have similar effects in humans.

ENVIRONMENTAL CHEMICAL CONTAMINANTS

Cadmium

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

Dioxins and PCBs

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'. 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 2001. 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.

Lead

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

Mercury

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

Nitrate

Nitrate (NO_3^-) is a form of nitrogen (N) that is found naturally in soil, water and food. During the nitrogen cycle, bacteria convert nitrogen to nitrate, which is taken up by plants and incorporated into plant tissues. It is therefore a natural component in all fruit and vegetables, especially green leafy vegetables such as lettuce and spinach, which contain relatively high concentrations compared to other foods, and may constitute a significant source of nitrate to the consumer. Nitrate *per se* is of relatively low toxicity and has no immediate effect on health, even at the highest levels found in foods. The potential risks to human health therefore come from its conversion to nitrite, which can cause a form of anaemia, especially in infants and young children. There is also uncertainty about the potential endogenous formation of nitrosocompounds, which in the long-term could be linked to increased risk of gastric cancer.

PAH

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

OTHER

Tin

High concentrations of tin in food irritate the digestive tract and may cause stomach upsets in sensitive people at tin concentrations above 200 mg/kg, with some increased risk of effects at concentrations above 250 mg/kg. These effects, the symptoms of which include fever, headache, nausea, vomiting, diarrhoea, abdominal cramps and bloating are short-term with recovery expected soon after exposure. There are no long-term health effects associated with occasional intakes from tin in the diet even at the higher level. Most foods contain very low concentrations of tin, usually below 10 mg/kg. However, canned foods can contain higher concentrations, which may

increase with time as a result of the gradual dissolution into the food of the tin coating used on the inside of some food cans to protect the steel body of the can from corrosion. As a consequence, canned foods make the biggest contribution to dietary intakes of tin.

SUMMARY OF KEY CHANGES

ARTICLES

Article 2: Dried, diluted, processed and compound foodstuffs

- The specific concentration or dilution factors shall be provided and justified by the food business operator.

Article 5: Specific rules for products which can be used for feed and food or other purposes

- Groundnuts, derived products thereof and cereals must be clearly labelled indicating their intended use.

ANNEX: maximum levels for certain foodstuffs

Section 2: Mycotoxins

i) Deoxynivalenol

- Limits now apply to cereal bran marketed for direct human consumption and germ

ii) Zearalenone

- Limits now apply to cereal bran marketed for direct human consumption and germ

Section 3: Heavy Metals

i) Lead

- Milk – extended from just cow's milk to cover all farm animals
- Muscle meat of fish – all species now fall under one limit of 300 µg/kg instead of 200 or 400 according to species.

ii) Cadmium

- Liver and kidney – extended to include horse
- Vegetables and fruit – pine nuts are excluded

Section 5: Dioxins and dioxin-like PCBs

- Meat and meat products – farmed game now excluded
- Liver & derived products, and fat – limit applies only to bovines, sheep, poultry, pigs

