

**EXPLANATORY MEMORANDUM TO**  
**THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2004**  
**2004 No.3062**

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Description**

2.1 The Regulations make provision for the implementation of EU measures setting maximum levels for certain contaminants in foodstuffs and implement allied enforcement Commission Directives. The Regulations will revoke and replace The Contaminants in Food (England) Regulations 2003 (SI 2003 No 1478) and revoke in England, The Tin in Food Regulations 1992 (SI 1992 No 496).

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

3.1 None

4. **Legislative Background**

4.1 The Instrument is made under The Food Safety Act 1990. The new Regulations make provision for the enactment of various European Commission Regulations which set maximum limits for patulin in foodstuffs, aflatoxins in raw maize, inorganic tin in canned foods and extend a transition period for free range and semi intensive eggs to comply with the current dioxins legislation. The Regulations will also transpose four allied Directives on enforcement methods (2003/78/EC (patulin), 2003/121/EC (aflatoxins), 2004/16/EC (tin) and 2004/44/EC (dioxins)) into national legislation. A Transposition Note is attached to this memorandum.

4.2 The Commission Regulations amend Commission Regulation EC No 466/2001 of 8 March 2001, which sets maximum limits for certain contaminants in foodstuffs and has applied since 2002. Commission Regulation 466/2001 is supported by a number of enforcement Commission Directives, which lay down the methods for sampling and analysis for the official control of those contaminants specified in the legislation. In England provision for the enforcement and transposition of these measures is currently under The Contaminants in Food (England) Regulations 2003.

4.3 A national limit of 200 mg/kg for tin in food has applied in the UK since 1992. The Tin in Food Regulations 1992 apply in England, Wales and Scotland, with similar Regulations applying in Northern Ireland. However, the EC measures for tin set specific lower limits for canned infant and baby food and canned beverages. Industry has indicated that it can comply with the limits set in the EC legislation and as a result it is recommended that in order to prevent having two independent sets of regulatory limits, that the national legislation is revoked.

## **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 Not applicable.

## **7. Policy background**

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

7.2 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, which has undergone a number of amendments, aims to exclude grossly contaminated food from entering the food chain and harmonises Member States' existing measures, thus facilitating trade.

7.3 Maximum limits for lead, cadmium, mercury, dioxins and nitrates (environmental chemical contaminants), 3-monochloropropane-1,2-diol (3-MCPD a process contaminant), aflatoxins and ochratoxin A (mycotoxins) have already been set under this legislation, and have applied since 2002. The Regulation is supported by a number of allied Commission Directives, (98/53/EC, 2001/22/EC, 2002/26/EC, 2002/27/EC and 2002/69/EC) which lay

down the sampling methods and the methods of analysis for the official control of those contaminants specified in the legislation.

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

- (i) Commission Regulation (EC) No 1425/2003 of 12 August 2003, as amended by Commission Regulation (EC) No. 455/2004 of 12 March 2004, setting maximum levels for patulin in foodstuffs. The Regulation is supported by Commission Directive 2003/78/EC. Member States were required to comply with the provisions in this Directive by 1 September 2004.
- (ii) Commission Regulation (EC) No 2174/2003 of 12 December 2003 setting maximum levels for aflatoxins in maize. The Regulation is supported by Commission Directive 2003/121/EC. Member States are required to comply with the provisions in this Directive by 31 October 2004.
- (iii) Commission Regulation (EC) No 242/2004 of 12 February 2004 setting maximum levels for inorganic tin in food. The Regulation is supported by Commission Directive 2004/16/EC. Member States must comply with the provisions in this Directive by 31 December 2004.
- (iv) Commission Regulation (EC) No 684/2004 of 13 April 2004 extending the transition period for free range and semi-intensive eggs to comply with the maximum level for dioxins to 1 January 2005. A transition period until 1 January 2004 was originally provided for in Council Regulation (EC) No 2375/2001, which amended Commission Regulation 466/2001 in respect to dioxins and applied from 1 July 2002.
- (v) Commission Directive 2004/44/EC amending Commission Directive 2002/69/EC laying down the methods for sampling and analysis for the official control of dioxins and the determination of dioxin-like polychlorinated biphenyls (PCBs) in foodstuffs. The Directive specifies the methods for sampling very large fish and harmonises the reporting and interpretation of analytical results. Member States must comply with the provisions in this Directive by 10 May 2005.

7.5 Informal and formal consultations have been carried out on the measures and information on the benefits and costs of the legislation to public health and businesses including enforcement authorities is included in the attached Regulatory Impact Assessments. Consultation in England of nearly 700 interested parties including consumer groups, industry, enforcement

authorities and other government departments, in the 12 weeks from 24 June 2004 produced 8 responses. Comments raised were mainly in respect to the complexity of the Regulations and the need to read the Regulations together with the Commission Regulations. The text of the Regulations is in line with legal officers' advice on apparent description of the scope of the EU Regulations.

7.5 Information received during the informal consultations indicated that industry could comply with the proposed limits for tin although there were some initial concerns regarding the proposed limit for canned beverages. It was believed that certain imported fruit juices would not be able to comply with the proposed limit. The UK successfully negotiated for a revised higher limit. No comments were received in respect to the extension of the transition period for free range and semi intensive eggs. Concerns were raised by industry that the limit initially proposed for patulin in apple juice was too low. It believed that producers of fresh pressed apple juice would not be able to comply with the proposed limit at certain times of the year. The UK successfully negotiated for a revised higher limit.

## **8. Impact**

8.1 Regulatory Impact Assessments have been placed in the Libraries.

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

## **9. Contact**

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