

REGULATORY APPRAISAL

FOOD, WALES

THE CONTAMINANTS IN FOOD (WALES) REGULATIONS 2005

MAXIMUM LEVELS FOR TIN IN CANNED FOODSTUFFS

Background

1. Commission Regulation (EC) No 242/2004 of 12 February 2004 amending Commission Regulation 466/2001 as regards inorganic tin in foods.
2. Commission Directive 2004/16/EC of 12 February 2004 laying down the sampling methods and the methods of analysis for the official control of the levels of tin in canned foods
3. Council Regulation (EEC) No 315/93 of 8 February 1993 lays 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.
4. The intention of Commission Regulation 466/2001 is to provide consumers with an increased measure of protection by setting European Community (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 facilitating trade. Maximum limits for lead, cadmium, mercury, dioxins and nitrates (environmental chemical contaminants), 3-monochloropropane-1,2-diol (3-MCPD - a process contaminant), and aflatoxins and ochratoxin A (mycotoxins) have already been set under this legislation, and have applied since 2002.
5. 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. In Wales, provision for the enforcement and transposition of these measures is

currently under The Contaminants in Food (Wales) Regulations 2003 (SI No 1721 W.188).

6. 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. Consequently, the Commission signaled, in 2002, its intention to set maximum levels for inorganic tin in canned foodstuffs. This decision was based on the opinions of the Joint WHO/FAO Expert Committee on Food Additives (JECFA) and the European Scientific Committee on Food (SCF) on the possible health effects of tin.
7. In June 2000, JECFA reiterated its conclusion of 1989, that the limited human data available indicate that concentrations of 150 mg/kg of tin in canned beverages and 250 mg/kg in other canned foods may produce acute gastric irritation in certain individuals. The SCF concluded in its opinion of 12 December 2001, that certain levels of tin in canned foods and canned beverages may cause gastric irritation in some individuals and concurred with the JECFA conclusion. It also recorded that there was no data to determine whether infants are more sensitive than older children and adults. Copies of this document are available from the Commission's web site http://europa.eu.int/index_en.htm (document SCF/CS/CNTM/OTH/18 Final).
8. National legislation for tin in food has applied in the UK since 1992. The Tin in Food Regulations 1992 (SI 1992 No 496) apply in England, Scotland and Wales, with similar Regulations applying in Northern Ireland. The Regulations set a maximum permissible tin content of food of 200 mg/kg and prohibit the sale or import of any food containing levels of tin above this limit. Other Member States had varying national limits, with limits ranging between 50 mg/kg and 350 mg/kg. These included limits for individual foodstuffs (e.g. asparagus) and different types of food (e.g. baby food, beverages etc).

Purpose and Intended Effect of Measure

9. The purpose of this measure is to make provisions for the enforcement, in Wales of Commission Regulation 242/2004 and to transpose Commission Directive 2004/16/EC into national law. Commission Regulation 242/2004, which amends Commission Regulation 466/2001, sets a maximum level for inorganic tin in canned food, canned beverages, and canned baby and infant food. The Regulation has applied since 4 March 2004. The Regulation is supported by Commission Directive 2004/16/EC, which lays down the methods for sampling and analysis for tin in canned food for enforcement purposes. Member States are required to comply with the Directive by 31 December 2004.
10. The Contaminants in Food (Wales) Regulations 2005 will -

- (a) revoke and replace The Contaminants in Food (Wales) Regulations 2003 (SI 2003 No. 1721 W.188);
- (b) revoke in Wales, The Tin in Food Regulations 1992 (SI 1992 No. 496);
- (c) make provision for the enforcement and execution of Commission Regulation 466/2001 as amended, and continue to implement the allied sampling and analysis Directives; and bring into force Commission Directive 2004/16/EC.

11. This Regulatory Appraisal is concerned only with the provisions for the enforcement of Commission Regulation 242/2004 and the transposition of Commission Directive 2004/16/EC. The implementation of Commission Regulations 1425/2003 (patulin) 2174/2003 (aflatoxins in maize) and 684/2004 (dioxins), and their allied Directives, is addressed in the attached Regulatory Appraisals – Annexes 1A, 1B and 1D respectively. Commission Regulation 466/2001, as amended, and the allied Commission Directives (98/53/EC, 2001/22, 2002/26, 2002/27 and 2002/69) referred to in the Statutory Instrument have already been dealt with in previous Regulatory Appraisals¹.

Risk Assessment

12. The aim of Commission Regulation 242/2004 is to provide a single set of harmonised limits targeted at canned foodstuffs, which in the UK account for 98% of dietary exposure to tin. The Regulation sets a maximum level for tin in canned foods of 200 mg/kg; 100 mg/kg in canned beverages; 50 mg/kg in canned infant and baby food and 50 mg/kg in canned dietary foods for special medical purposes intended specifically for infants. The measures will provide higher levels of consumer protection and increased consumer confidence in the UK food supply.

13. The Regulation is supported by Commission Directive 2004/16/EC, which lays down harmonised methods for sampling and analysis for tin in canned foods for enforcement purposes.

Devolution

14. The implementation of Commission Regulation 242/2004 and Directive 2004/16/EC applies to the UK. The Contaminants in Food (Wales) Regulations 2005 will apply to Wales only. Corresponding Regulations will be introduced separately in Scotland, England and Northern Ireland.

Options

15. In respect of this legislation the “Do nothing option” is not an option as it would lead to infraction proceedings against the National Assembly for Wales by the European Commission.

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

16. Option 1 Make provision for the enforcement of Commission Regulation 242/2004 under The Contaminants in Food (Wales) Regulations 2005 and revoke The Tin in Food Regulations 1992, but continue to carry out enforcement under The Food Safety (Sampling and Qualifications) Regulations 1990.
17. Option 2 Implement Commission Regulation 242/2004 and Commission Directive 2004/16/EC in full as The Contaminants in Food (Wales) Regulations 2004 and revoke The Tin in Food Regulations 1992 under these Regulations. Similar Regulations would be introduced separately in Scotland, England and Northern Ireland.

Benefits

Economical

18. There would be little economic benefits arising from Option 1. Commission Regulations are directly applicable in Member States from the date that they take effect and the UK has 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 UK also has a legal obligation to implement Commission Directives. To do nothing or to partially implement the measures would leave enforcement authorities without the necessary statutory legislation to ensure compliance with the Commission measures.

Environmental

19. There would be little environmental benefits arising from Option 1. Commission Regulations are directly applicable in Member States from the date that they take effect and the UK has 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 UK also has a legal obligation to implement Commission Directives. To do nothing or to partially implement the measures would leave enforcement authorities without the necessary statutory legislation to ensure compliance with the Commission measures.

Social

20. Health effects of tin in food: 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.
21. 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. In the 2000 Total Diet Study, which is the most recently reported of the Food Standards Agency's regular surveys of metals in the UK diet, canned fruit and vegetables accounted for 98% of the average UK dietary exposure to tin.²

22. The concentration of tin in canned foods depends on a number of factors, including the type and acidity of the food, time and temperature of the storage, and the presence of air in the can headspace. Oxidising agents such as nitrates, iron and copper salts, certain pigments, and sulphur compounds all accelerate dissolution of tin. Lacquering of cans reduces corrosion and prevents de-tinning and, as a result, foods packed in lacquered cans generally contain the lowest levels of tin. A code of practice for the prevention and reduction of tin contamination in food is being developed by Codex.

Overall benefits

23. The benefits arising from Option 2 would be that the UK would fulfil its obligation to make provision for the enforcement of Regulation 242/2004 and to transpose Directive 2004/16/EC into national law. The Contaminants in Food (Wales) Regulations 2005 will promote consistent and effective enforcement by reducing uncertainty or dispute in interpreting results against limits. This will benefit industry and consumers through improved confidence in compliance testing and will increase consumer confidence in the UK food supply. Indeed, there is no reasonable alternative to introducing the proposed amending regulations since failure to do so could lead to criticism. Non-implementation would also lead to undoubtedly successful legal proceedings against the UK in the European Court of Justice, as the terms of both measures require the implementation of all their provisions. The costs of non-implementation would include the costs of infraction proceedings to the UK Government as well as any financial penalties imposed. Therefore the non-implementation of these measures is not really an option. Option 2 is therefore the preferred Option.

Financial Implications for Wales

24. The public consultation exercise invited comments on any additional costs envisaged in implementing the Regulation. The UK has a legal obligation to ensure that provisions are in place providing for the enforcement of the maximum levels set in Commission Regulation 466/2001 as amended by Commission Regulation 242/2004. The UK must also transpose Directive 2004/16/EC into national legislation. Costs to the Exchequer arising from Option 1 would flow from infraction proceedings against the UK Government, the costs of which will be passed on to the Assembly as regards implementation in Wales. No other additional costs the Welsh Assembly Government have been identified.

² Food Survey Information Sheet 48/04, March 2004: Total diet study of twelve elements – aluminium arsenic, cadmium, chromium, copper, lead, manganese, mercury nickel, selenium and tin

25. Non implementation of the Directive would perpetrate inconsistent sampling and analysis procedures in respect to enforcement of the statutory limits for tin. If enforcement authorities do not carry out checks for compliance under the Commission Directive, the UK would receive an adverse report from the European Commission's Food and Veterinary Office. In addition, the lack of national recognition of the effectiveness of harmonised official controls is also likely to have an impact on trade. Failure to adopt harmonised limits and official controls would also undermine consumer confidence in consumer protection offered by the tin limits. It is expected that there will be minimal costs to industry arising from Option 2, which are discussed more fully below.

Compliance costs

26. Prior to the introduction of the EC maximum levels for tin in specific foodstuffs, domestic legislation (The Tin in Food Regulations 1992) set a maximum limit of 200 mg/kg for tin in food. The levels set in Commission Regulation 466/2001, as amended by Commission Regulation 242/2004, are lower than those in the national legislation for some products, however, information received from the informal and formal consultations indicated that industry could comply with the EC limits.

27. Industry should have already been carrying out checks to ensure compliance with the existing national legislation. In addition, industry should also be carrying out checks to satisfy compliance with the 'due diligence' requirement of The Food Safety Act 1990 (The Act). There is no requirement for industry to carry out additional sampling and analysis within Commission Regulation 466/2001, as amended.

28. The Commission Directive introduces guidelines for the sampling and analysis procedures for the official control of inorganic tin in foodstuffs and as such relates to enforcement testing only. The primary implications therefore, of complying with this Directive are for enforcement authorities as the procedures apply to them and those laboratories that are accredited to test for inorganic tin for enforcement purposes. Industry is not obliged to follow the sampling and analysis procedures in the Directive. However, it may wish to do so when carrying out its existing programme of checks to satisfy the 'due diligence' requirement under The Act and compliance with the maximum levels set in Commission Regulation 466/2001, as amended. The Food Standards Agency would therefore expect the costs to industry in complying with this legislation to be minimal.

Public Services Threshold Test

29. Enforcement authorities should already have been carrying out tests for tin to ensure compliance with The Tin in Food Regulations 1992 and The Food Safety Act 1990. However, information from the informal consultations indicated that there are likely to be some additional costs to enforcement authorities arising from compliance with the Directive. The perceived additional costs relate to the methods for sampling prior to analysis and where these procedures should take place. However, the Agency has not received any quantitative information on this issue.

Costs for a Typical Business

30. Typical businesses include baby food producers and manufacturers of metal packaging. As highlighted earlier in this RIA, a statutory limit for tin has applied in the UK since 1992. Information provided by these businesses has not indicated that additional costs would arise from complying with the Commission measures.

Other Costs

31. No social and environmental costs arising from the above options have been identified.

Equity and Fairness

32. Information from the informal and formal consultations indicates that the measures apply equally to industry and enforcement authorities. The Agency does not expect the implementation of the Regulation and Directive under Option 2 to have a significant impact on competition.

Consultation with Small Businesses (The Small Firms Impact Test)

33. Stakeholders including small businesses, the Small Business Service, the Federation of Small Businesses and the British Chamber of Commerce were consulted throughout the negotiations on the legislation and the formal consultation on The Contaminants in Food (Wales) Regulations 2005. The measures will affect all businesses involved in the production of canned foodstuffs; manufacturers of cans used for packing and storing food; importers; exporters; retailers and wholesalers; and enforcement authorities.

Enforcement

34. Local Authorities and Port Health Authorities are responsible for enforcing Food Safety Regulations. Local Authorities and Port Health Authorities will be responsible for enforcing The Contaminants in Food (Wales) Regulations 2005. A fine not exceeding level 5 on the standard scale will apply in the case of breaches of the main offence of placing on the market (regulation 3). Breaches of regulations 8 and 9 are liable to a fine not exceeding level 5 on the standard scale or to imprisonment for a term not exceeding three months or to both.

Monitoring and Review

35. 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.

Consultation

36. Both informal and formal consultations have occurred.

Public Consultation

37. An informal consultation on the draft Directive was carried out in September 2003. Comments from the Local Authorities Co-ordinators of Regulatory Services (LACORS) were that there would be some minor

costs to Local Authorities if sampling officers were required to homogenise material prior to division and distribution of the samples. If Public Analyst Laboratories carried out this process, the laboratories would incur costs in returning a sample portion to the vendor. However, information provided to the Food Standards Agency to date has not been sufficient to include estimates of total costs.

38. Government Departments including the Department for Environment Food and Rural Affairs, the Department of Health, the Department of Trade and Industry, the National Assembly and the Cabinet Office were included in the informal and formal consultations.
39. The Food Standards Agency Wales carried out a formal consultation from 19 July 2004 to 30 September 2004. Stakeholders included Assembly Members, consumer and industry representative bodies (a full list of consultees is at Appendix A). They were invited to comment on the draft Regulations and any costs associated with the implementation of the Regulations. No comments were received. Parallel consultations were carried out in England, Scotland and Northern Ireland.
40. During the course of the negotiations with the European Commission, the Agency carried out regular informal consultations with stakeholders including consumer groups, industry, research institutes, enforcement organisations and other interested parties, through regular information letters.
41. Concerns raised during this period generally related to the proposed maximum limits. These concerns were presented to and discussed with the Commission and other Member States. The main concern raised by industry related to an initial proposal for a maximum level for canned beverages of 50 mg/kg in particular in respect to certain fruit juices. These fruit juices are packaged and processed in plain internal tins and it was believed that they would not be able to meet the proposed level. It was noted however, that these products are imported and that domestic products are routinely packaged in lacquered cans and would be able to meet this proposed level. The Agency raised the potential impact to importers with the Commission and an alternative level of 100 mg/kg was put forward for consideration. Member States accepted this higher level.

With Subject Committee

42. There has been no prior scrutiny of the proposed Instrument by the Health and Social Services Committee. However, the Instrument has been notified to the Committee via the list of forthcoming legislation, put to the Committee on 3 March 2004 (item No FSA 61(03) on the Food Standards Agency schedule) and in successive meetings but was not identified for scrutiny..

Summary and Recommendation

43. As discussed in this Regulatory Appraisal, the intention of Commission Regulation 466/2001, as amended, is to protect public health by providing

a single set of harmonised levels targeted at those foods that make a significant contribution to consumer exposure of those contaminants specified in the legislation. The Regulation aims to exclude grossly contaminated food from entering the food chain and harmonise Member States' existing measures, facilitating trade.

44. Following the most recent opinions of the JECFA and SCF, the Commission introduced measures setting maximum levels for inorganic tin in canned food; canned beverages and canned infant and baby food. These maximum limits have applied since 4 March 2004. Prior to the introduction of these measures the UK had national legislation in place, The Tin in Food Regulations 1992, which set a maximum level of 200 mg/kg for tin in food. Although Commission Regulation 466/2001 as amended by Commission Regulation 242/2004 introduces specific, lower, limits for canned infant food and canned beverages, industry has indicated that in general it can comply with the limits set in the EC legislation.
45. The Regulation is supported by Commission Directive 2004/16/EC, which lays down the sampling and analysis procedures for enforcement purposes. Member States must comply with the Directive by 31 December 2004. The options for the UK are those identified above.
46. It is recommended that Option 2 is supported. This Option will provide enforcement authorities with the necessary provisions to effectively enforce the limits set in Commission Regulation 466/2001, as amended, and will fulfil the UK's legal obligation to transpose Directive 2004/16/EC, which lays down harmonised statutory official controls, into national legislation. Revoking The Tin in Food Regulations 1992 would prevent having two independent sets of regulatory limits.

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APPENDIX A

LIST OF CONSULTEES

A J Craske	Abergavenny Fine Foods
Cate Barrow - Food Business Development Manager	ADAS Wales
Paul Lenartowicz - Vice President	The Association of Public Analysts
Mr Mark Dukes	Bar and Restaurant Foods Ltd
Colin Hunt	Biotrace Limited
Ms A Gabe	Carmarthenshire County Council
Ceri J Baillie	Clark's Original Pies
Wendy Cave	Co-operative Group (CWS) Ltd
Mr Arwyn Owen, Director of Policy	Farmers' Union of Wales
Lynn Hoskins	Food Quality Panel
Mr R Dailley	Food Safe
The Secretary	G C Hahn & Co Ltd
Mr K F Powell	Good Food Distributors
Elizabeth Williams	Halo Foods Ltd
Peter Lee	Iceland Frozen Foods
Ms Susan Perkins	LACORS (Welsh Officer)
Mrs Brenda Davies	Meridian Foods
Mrs Mary James	National Farmers Union (Wales)
David Jackson	Peters Food Service Ltd
Joanna Tett	Rachel's Dairy
Mr J Frow	RCT Trading Standards Dept
R A Ennion	Ruddock & Sherratt
Professor G Coleman	School of Environmental Sciences
Mr Lester Lewis	Society of Directors of Public Protection
Kevin P Jones, Panel Chairman	Society of Directors of Public Protection - North Wales
Steve Delahaye, Secretary	Society of Directors of Public Protection Wales - Trading Standards Group
Mr P Chaplin	T/A Source Foods
Mr Gareth Rowlands	The Organic Working Group
Chris Price-Jones	The Speciality Sauce Co. Ltd
Mr T B Dickens	Tillery Valley Foods Ltd
Eurwyn Harries	Tovali Ltd
Lowri Jones	Wales Young Farmers' Club
Viv Sugar, Chair	Welsh Consumer Council
Mr Paul Handby, Development Co-ordinator	Chartered Institute of Environmental Health in Wales
Mr Norman Biggs	Welsh Food Laboratories
Mrs Ceri Edwards, Secretary	Welsh Food Microbiological Forum
Mr Wynfford James, Director	WDA Food Directorate
Gerry Devine	Zorba Foods
Charles Stevens	PRP Training Ltd
Ffion Roberts, Public Protection Manager	Gwynedd CC
Mr Richard Wood	British Retail Consortium

Professor James Parry	Member - Welsh Food Advisory Committee
Dr Robert Bell	Member - Welsh Food Advisory Committee
Mrs Dilwen Phillips	Member - Welsh Food Advisory Committee
Mrs Gilli Davies	Member - Welsh Food Advisory Committee
Professor Robert Pickard	Member - Welsh Food Advisory Committee
Professor SM Griffiths	Member - Welsh Food Advisory Committee
Dr David Casemore	Member - Welsh Food Advisory Committee
David Hill	Kwik Save Group Ltd
Mr Sandy Blair	Welsh Local Government Association
Brian Davies, Principal EHO	Ceredigion County Council
David Hughes, Chief Public Protection Officer	Blaenau Gwent CBC
Malcolm Evans,	Cardiff County Council
Mr Mathew Frankcom, Principal Food Safety Officer	Conwy County Borough Council
A Jenkins, Director of Consumer Services	Neath Port Talbot CBC
Stephen Davison	Newport CBC
CJ Taylor, Head of Public Protection	Powys CC
Mrs Reena Owen, Director of Environment	City and County of Swansea
Mr S J Whitehouse, Env Management Dept	Torfaen CBC
Philip Walton, Director of Environmental Services	Wrexham CBC
Sue Redding, Head of Trading Law	Sainsbury's Supermarkets Limited
Dr Donald Ribeiro	PHLS in Wales
Mr Trevor Jones	Conwy Mussel Company
Sylvia Portbury, Food Safety Manager	Flintshire County Council
Mr David Smith	Member - Welsh Food Advisory Committee
Allan Bennett, Head of Public Protection	Pembrokeshire County Council
Norman Gatehouse, Chief Environmental Health Offic	Caerphilly CBC
David Dier, Head of Public Health	Merthyr Tydfil CBC
Jean Sullivan	Welsh Food Alliance
Graham Gubb, Env Health Officer	Bridgend County Borough Council
T E Johnson	Minton, Treharne & Davies Ltd
Mr M Williams	Cardiff Scientific Services
Julie Barratt, Director	Chartered Institute of Environmental Health in Wales