

REGULATORY APPRAISAL

FOOD, WALES

THE CONTAMINANTS IN FOOD (WALES) REGULATIONS 2005

MAXIMUM LEVELS FOR DIOXINS IN FOODSTUFFS

Background

1. Commission Regulation (EC) No 684/2004 of 13 April 2004 amending Commission Regulation 466/2001 as regards dioxins in foodstuffs.
2. Commission Directive 2004/44/EC of 13 April 2004 amending 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 polychlorinated biphenyls (PCBs) in foodstuffs.
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.
5. Commission Regulation 466/2001, as amended, 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 nitrate (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.
6. The Regulation is supported by a number of allied Commission Directives, (98/53/EC, 2001/22/EC; 2001/26/EC; 2001/27/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*.

Dioxins and PCBs

7. Dioxins are toxic substances produced during various combustion and incineration processes, including household fires, and they are also unwanted by-products produced in the manufacture of certain chemicals. PCBs have been used since the early 1930s, mainly in electrical equipment, but their manufacture and general use stopped in the 1970s and is no longer permitted in the UK. Strict controls on the emissions of dioxins and PCBs from industrial processes came into effect from 1992 under Integrated Pollution Control Regulations and more recently under the Pollution Prevention and Control Regulations. The Agency is a statutory consultee under these Regulations. The only remaining use of PCBs in the UK is sealed inside some older electrical equipment but these PCBs must be phased out and destroyed under the UK PCB Regulations and must be disposed of in an environmentally sound manner.
8. Emissions of dioxins and PCBs into the environment have been reduced by about 70 per cent over the past 10 years. However, dioxins and PCBs 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.¹
9. Commission Regulation 466/2001 is amended by Council Regulation 2375/2001, which sets a maximum level for dioxins in meat, fish, eggs, milk, milk products, fats and oils. The maximum levels have applied since 1 July 2002. Specific limits for PCBs have not yet been set, but the Regulation commits the Commission to reviewing this legislation by 31 December 2004 with a view to inclusion of dioxin-like PCBs in the levels to be set. Regulation 466/2001, as amended, is supported by Commission Directive 2002/69/EC, which lays 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 Directive came into force in Wales on 30 June 2003.
10. However, because dioxins and PCBs continue to be widespread in the environment, available data indicate that free range and semi intensive eggs may contain higher levels of dioxins than battery eggs. As a result, Council Regulation 2375/2001 made provision for a transition period to enable industry to take measures to ensure that dioxin levels in these products were reduced. Free range and semi intensive eggs were required to comply with the maximum level of 3 picograms (pg) WHO-PCCD/F-TEQ/g fat as from 1 January 2004.

¹The 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

11. During a Commission Working Group meeting of 12 January 2004, some Member States indicated that more time was needed to define the possible measures that industry can take to reduce the dioxin levels in free range and semi intensive eggs, and for implementing these measures. As a result, it was agreed that it was appropriate to extend the transition period for one year; these products must now comply with the maximum level as from 1 January 2005. Commission Regulation 684/2004 has been adopted for this purpose.
12. However, results from the analysis of a limited sample of domestic free range eggs indicate that in general these products can comply with the dioxins legislation. The results from the 30 samples analysed have been published as part of a wider EU monitoring exercise under Commission Recommendation 2002/201/EC², and are available from the Agency's web site at www.food.gov.uk/news/newsarchive/eudioxins.
13. 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 and also reviews the maximum limits of those contaminants currently in the legislation. The Commission, in co-operation with Member States (within the Commission Working Group meetings) is currently carrying out a review of Commission Regulation 466/2001 and the allied sampling and analysis Directives. As part of this review, the description of the products or the parts of the product to which the maximum dioxins levels apply has been clarified (Commission Regulation 684/2004 refers). In addition, the text in Annexes I and II to Commission Directive 2002/69/EC has been amended to ensure a harmonised approach for the methods for the sampling of very large fish and the interpretation and reporting of analytical results (Commission Directive 2004/44/EC refers).

Purpose and Intended Effect of Measure

14. The purpose of this measure is to make provisions for the enforcement, in Wales, of Commission Regulation 684/2004 and to transpose Commission Directive 2004/44/EC into national law. Commission Regulation 684/2004 amends Commission Regulation 466/2001 (as amended by Council Regulation 2375/2001) in respect to the maximum level for dioxins in hen eggs and egg products. The purpose of the Regulation is to extend the transition period allowed for free range and semi intensive eggs to comply with the dioxin legislation to 1 January 2005. The Regulation, which has applied since 10 May 2004, also provides some clarification of the description of the products or the parts of the product specified in Regulation 466/2001, as amended, to which the maximum dioxin levels apply.

² Commission Recommendation 2002/201/EC of 4 March 2002 in Conjunction with Commission Regulation 466/2001, as amended and Commission Directive 2002/69/EC is part of a Commission strategy to reduce the presence of dioxins and PCBs in the environment and in food and feed. The Recommendation established action levels which 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.

15. The intention of Commission Directive 2004/44/EC, which amends Commission Directive 2002/69/EC, is to ensure a harmonised approach to sampling for the official control of dioxins in whole fish by specifying the methods for the sampling of very large fish. It also amends Annex II to Directive 2002/69/EC to ensure a harmonised enforcement approach to the reporting and interpretation of analytical results. Member States are required to comply with the Directive by 10 May 2005.
16. 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, continue to implement the allied sampling and analysis Directives; and bring into force Commission Directive 2004/44/EC.
17. This Regulatory Appraisal is concerned only with the provisions for the enforcement of Commission Regulation 684/2004 and the transposition of Commission Directive 2004/44/EC. The implementation of Commission Regulations 1425/2003 (patulin), 2174/2003 (aflatoxins in maize) and 242/2004 (tin), and their allied Directives, is addressed in the attached Regulatory Appraisals – Annexes 1A, 1B and 1C, 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 Appraisals³.

Risk Assessment: Health effects of dioxins and PCBs in food

18. Dioxins and PCBs have no immediate effect on health, even at the highest levels found in foods. The potential risks to health come from long-term exposure to high levels. They can cause a wide range of effects in animals, including cancer and effects on the immune and reproductive systems. However, it appears people may be less sensitive.

Devolution

19. The implementation of Commission Regulation 684/2004 and Directive 2004/44/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.

³ 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)

Options

20. These Regulations implement EC Decisions. There is no reasonable alternative to introducing the proposed 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. Implement Commission Regulation 684/2004, and Commission Directive 2004/44/EC in full as The Contaminants in Food (Wales) Regulations 2005. Similar Regulations would be introduced in Scotland, England and Northern Ireland.

Benefits

Environmental

21. 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. Non implementation would leave enforcement authorities without the necessary statutory legislation to ensure compliance with the Commission measures.

22. The benefits arising from implementing these Regulations would be that the UK would fulfil its legal obligations to transpose Directive 2004/44/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.

Financial Implications for Wales

23. 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 Commission Regulation 466/2001 as amended. The UK must also transpose Directive 2004/44/EC into UK national legislation. Non implementation of the Directive would perpetuate inconsistent sampling and analysis procedures across the EU in respect to enforcement of the statutory limits for dioxins in fish. Non implementation of the Directive may also lead to an adverse report from the Food and Veterinary Office. In addition, the lack of national recognition of the effectiveness of harmonised methods for taking samples from very large fish and harmonised procedures for the reporting and interpretation of analyses is also likely to have an impact on trade.

24. It is expected that there will be some costs to industry and to the Exchequer arising from the implementation of these Regulations, which are discussed more fully below.

Compliance costs

25. The levels of dioxins and PCBs present in food reflect current and historical emissions of these contaminants from industrial and other sources both man made and natural. The extension of the transition period for free range and semi intensive eggs allows Member States more time to investigate the possible measures industry can take to reduce the levels of dioxins in these products and for implementing these measures. Whilst the costs to industry in complying with Commission Regulation 466/2001, as amended by Commission Regulation 684/2004, are expected to be minimal, it is possible that industry may incur some costs as it takes steps to ensure that products comply with the dioxins legislation by 1 January 2005. However, results from a limited monitoring exercise carried out by the Agency indicated that in general free range and semi intensive eggs in the UK comply with the current maximum level. To date, the Agency has not received quantitative information on this issue.
26. The Commission Directive introduces harmonised methods for sampling very large fish for the official control of dioxins in these products. 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 dioxins for enforcement purposes. There is no requirement for industry to carry out additional sampling and analysis within Commission Regulation 466/2001, as amended nor is it 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 Food Safety Act 1990 and compliance with the maximum levels set in Commission Regulation 466/2001, as amended by Council Regulation 2375/2001. The costs of complying with the dioxins legislation were explored fully in earlier Regulatory Appraisals (footnote 1 refers). However, the Agency acknowledges that the costs for analysis for dioxins remains high at around £400 - £500 per sample, although some screening methods, at around £150 per sample may be used for screening purposes.

Public Services Threshold Test

27. The maximum levels for dioxins have applied since 2002, and enforcement authorities should already be carrying out checks to ensure compliance with the Commission legislation and with The Food Safety Act 1990. However, as noted above, the cost for analysis for dioxins is high. Commission Directive 2004/44/EC introduces specific provisions for the sampling of lots containing very large whole fish and a harmonised enforcement approach to the reporting and interpretation of analytical results. From the information received during the informal and formal consultations, the Agency expects the cost of compliance to be minimal.

Costs for a Typical Business

28. A typical business would be a farm producing free range eggs. As highlighted earlier in this Regulatory Appraisal, a transition period for these products has existed since 2002. Information to date indicates that in general, free range and semi intensive eggs in the UK can comply with the

current dioxin limits. The Agency has received insufficient information from these businesses on this issue to include an estimate of total costs.

Business sectors affected

29. The Contaminants in Food (Wales) Regulations 2005 primarily affect producers of free range and semi intensive eggs and enforcement authorities.

Issues of equity and fairness

30. The Agency expects the measures to impact equally across industry and enforcement authorities.

Consultation with Small Businesses (The Small Firms Impact Test)

31. 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 Regulations.

Competition Assessment

32. From the information available, the Agency does not expect the implementation of the Regulation and Directive to have a significant impact on competition.

Enforcement and Sanctions

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

34. 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

35. Both informal and formal consultations have occurred.

Public Consultation

36. 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. Stakeholders, industry and consumer groups, were informed of the intention to extend the transition period for free range and semi intensive eggs and the proposed sampling arrangements for fish via information letters. The Agency in

England received one response in relation to the sampling proposals, which was specific to the definition of the Limit of Quantification in Annex II to the draft Directive.

37. 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 and the formal consultation undertaken from 19 July to 30 September. Assembly Members were included in the list of stakeholders who were consulted

With Subject Committee

38. 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 (item no FSA 61(03)) on the Food Standards Agency schedule) and in successive meetings but was not identified for scrutiny.

Summary and Recommendation

39. Commission Regulation 466/2001 as amended by Council Regulation 2375/2001, sets maximum levels for dioxins in certain foodstuffs including hen eggs and egg products. The maximum levels have applied since 1 July 2002.
40. However, dioxins and PCBs are persistent organic pollutants that degrade only slowly and so are widespread in the environment. Available data indicated that free range and semi intensive eggs may contain higher levels of dioxins than battery eggs, and, as a result, Council Regulation 2375/2001 made provision for a transition period to enable industry to take measures to ensure that dioxin levels in these products were reduced. Free range and semi intensive eggs were required to comply with the maximum level of 3 pg WHO-PCCD/F-TEQ/g fat as from 1 January 2004.
41. During a Commission Working Group meeting on 12 January 2004, Member States expressed concerns that these products may still have difficulty complying with the maximum level. It was agreed that more time was needed to define the possible measures that industry can take to reduce the dioxin levels in these products, and for implementing these measures. As a result, Commission Regulation 684/2004, amending Regulation 466/2001, has been adopted. The Regulation extends the transition period for one year to 1 January 2005. Results from a recent monitoring exercise under the provisions of Commission Recommendation 2002/201/EC indicate that in general, free range and semi intensive eggs produced in the UK would be able to comply with the current limit.
42. The Commission is currently carrying out a review of Regulation 466/2001 and the allied sampling and analysis Directives. As part of this review, the description of the products or the parts of the product to which the maximum dioxin levels apply has been clarified under Commission

Regulation 684/2004. In addition, the text in Annexes I and II to Commission Directive 2002/69/EC has been amended by Commission Directive 2004/44/EC to ensure a harmonised approach for the methods for the sampling of very large fish and the interpretation and reporting of analytical results.

43. The proposed will continue to provide enforcement authorities with the necessary provisions to effectively enforce Commission Regulation 466/2001 as amended by Commission Regulation 684/2004 and will fulfil the UK's legal obligation to transpose Directive 2004/44/EC into national legislation.

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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