

dti

**THE CERAMIC ARTICLES IN
CONTACT WITH FOOD (ENGLAND)
REGULATIONS 2006**

Consultation on proposals to
implement Directive
2005/31/EC on ceramic
articles intended to come into
contact with foodstuffs

DECEMBER 2005

URN 05/1802

dti

The DTI drives our ambition of 'prosperity for all' by working to create the best environment for business success in the UK. We help people and companies become more productive by promoting enterprise, innovation and creativity.

We champion UK business at home and abroad. We invest heavily in world-class science and technology. We protect the rights of working people and consumers. And we stand up for fair and open markets in the UK, Europe and the world.

Introduction

This consultation seeks the views of businesses, manufacturers, retailers, producers and enforcement authorities on draft regulations implementing the amending Directive (2005/31/EC) on the ceramic articles that are intended to come into contact with foodstuffs. **This consultation does not seek views on the directive itself but on our proposed implementation of it.**

The Directive (at Annex C) amends Council Directive 84/500/EEC and the draft Regulations (at Annex D) will replace the Ceramic Ware (Safety) Regulations 1988. The aim of the Directive 2005/31/EC is to make it easier for producers, distributors and enforcement authorities to check that ceramic articles intended to come into contact with food comply with existing migration limits for cadmium and lead. The new provisions include a requirement that ceramic products intended for, but not yet in contact with foodstuffs, be accompanied at all marketing stages (up to and including retail) by documentation stating that they comply with the rules applicable to them. There is also now a clear obligation on producers and importers to make available to enforcement authorities (on request) documentation demonstrating compliance with migration limits. Performance criteria have now been set which analytical methodologies must comply with. The final amendment requires Member States to introduce a prohibition on the manufacture and importation of ceramic ware products that do not comply with these requirements from 20 May 2007.

Issued	6 December 2005
Respond by	28 February 2006
Enquiries to	Steve Ringer Department of Trade and Industry Consumer and Competition Policy Directorate (CCP) Bay 428 1 Victoria Street London SW1H 0ET Tel 020 7215 0359 Fax 020 7215 0339 <i>E-mail</i> ceramics.ware@dti.gsi.gov.uk

Content Page

Section 1 – Executive Summary

Section 2 – The Proposals

Section 3 – What happens next

Annex A – The Consultation Code of Practice Criteria

Annex B – List of organizations consulted

Annex C – Directive 2005/31/EC

Annex D – Draft Ceramic Articles in Contact with Food (England) Regulations

Annex E – Regulatory Impact Assessment (RIA)

Annex F – Consultation response form

1. Executive Summary

1.1. The draft Ceramic Articles in Contact with Food (England) Regulations 2006 are intended to implement Directive 2005/31/EC, which is a Directive amending Council Directive 84/500/EEC. The combined requirement of both Directives will be implemented by our Regulations.

1.2. Directive 84/500/EEC sets a limit on the levels of lead and cadmium permitted to transfer out of ceramic articles intended to come into contact with food and prescribes the methods of testing to be used to establish how much lead and cadmium is being transferred. Directive 2005/31/EC (“the Directive”) requires a declaration of compliance with these limits and introduces a performance-based approach to the analytical method of establishing the migration levels. **This consultation does not seek views on the Directive itself but on our proposed implementation of it.** Separate implementations (and consultations) will be undertaken in Scotland, Wales and Northern Ireland. The new Regulations will revoke the existing Ceramic Ware (Safety) Regulations 1988, which are no longer relevant.

1.3. The draft Regulations are being made using the powers provided in s17 of the Food Safety Act 1990, and will be enforced by the enforcement authorities named therein. The Regulations are self-contained in providing for their own offences and penalties.

1.4. The amendments introduced by the Directive, and hence the draft Regulations, apply to ceramic ware products that are intended to come into contact with foodstuffs. They introduce a new prohibition on the manufacture and import of non-compliant ceramic articles. More generally, they are geared towards making it easier for enforcement authorities, manufacturers, importers and distributors to check for compliance with existing limits on cadmium and lead migration, and provide greater certainty for consumers.

1.5. Products tested in accordance with methods complying with the performance standards set by the Directive must be allowed to be traded from 20th May 2006; while the manufacture and import of products that do not comply fully with the terms of the Directive are to be prohibited from 20th May 2007.

1.6. The transposition of this Directive has been geared towards avoiding over-implementation while maximising internal market benefits for affected exporters. To this end the new obligation to include a declaration of compliance has been aimed at enforcers and businesses in the supply chain, and should not require re-labelling of individual items. In addition, there will be a phased implementation of a 1-year voluntary period before this regulation comes into force.

How to respond

1.7. This consultation opened on 6th December 2005. The last date for responses is 28th February 2006.

Consultation responses should be sent by post, fax or e-mail to:

Steve Ringer
Department of Trade and Industry
Consumer and Competition Policy Directorate (CCP)
Bay 428
1 Victoria Street
London
SW1H 0ET

Tel 020 7215 0359
Fax 020 7215 0339
E-mail ceramics.ware@dti.gsi.gov.uk

1.8. When responding please state whether you are responding as an individual or representing the views of an organisation. If responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

1.9. A copy of the consultation response form is enclosed at Annex F. An electronic version of the consultation document and the response form is also available at <http://www.dti.gov.uk/ccp/consultations.htm>

1.10. A list of those organisations and individuals consulted is at Annex B. We would welcome suggestions for others who you think may wish to be involved in this consultation process.

Confidentiality

1.11. Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want other information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

1.12. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

1.13. The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Complaints

1.14. The code of practice criteria that this consultation should adhere to is set out in Annex A. If you have any comments or complaints about the way this consultation has been conducted, these should be sent to:

Nick Van Benschoten
Consultation Co-ordinator
Department of Trade and Industry
Bay 4110.
1 Victoria Street
London
SW1H 0ET

E-mail Nick.vanbenschoten@dti.gsi.gov.uk
Tel 020 7215 6206

ADDITIONAL COPIES

1.15. You may make copies of this document without seeking permission.

1.16. Other versions of the document in Braille, other languages or audio cassette may be obtained on request.

QUERIES

1.17. Queries on the issues raised in this consultation should be addressed to Steve Ringer, at the contact details above (1.7).

1.18. In addition to the questions raised in the consultation document we would welcome your views on the partial Regulatory Impact Assessment of these proposals particularly in relation to the cost and other burdens that business might feel would result from the implementation of these Regulations (see Annex E). It is our belief that new burdens will only apply in respect of the declaration of compliance and that these will be negligible.

1.19. If you can suggest any alternatives to regulation please do so, although we would ask that you recognise that we are required by the terms of the Directive to transpose it into UK law. If you foresee any unintended consequences or other implications of the draft Regulations please let us know what you believe these may be.

Consultation questions

1.20. This consultation does not seek views on the Directive itself but on our implementation of it.

Q1. Do you agree with our assessment that meeting the declaration of compliance requirement will entail only negligible cost to businesses? Please quantify the additional costs of compliance.

Q2. Do you agree with our assessment that meeting the requirement to show enforcement authorities (on request) documentation demonstrating compliance with migration limits should not introduce any new costs for manufacturers or importers?

Q3. Do you agree with our assessment that a performance based approach to compliance testing methods imposes no new burden on businesses, and may well carry with it some benefit for both businesses and enforcement authorities? Please quantify the benefits.

Q4. Do you agree that we have created the correct offences and defences, and that we have set appropriate penalties?

Q5. Do you have any other comments that might aid the consultation process?

Q6. We would appreciate your general views on whether we have correctly identified the main issues in our proposals for implementation of the Directive.

2. The proposals

Introduction

2.1. The attached draft Regulations, the Ceramic Articles in Contact with Food (England) Regulations 2006, implement Commission Directive 2005/31/EC. This Directive amends Council Directive 84/500/EEC by introducing measures aimed at ensuring compliance with existing limits on cadmium and lead migration from ceramic ware (e.g. plates, cups and mugs) intended to come into contact with food and updating the test method. **This consultation does not seek views on the Directive itself but on our proposed implementation of it.**

2.2. The basis for Directive 2005/31/EC is Regulation (EC) No. 1935/2004. This Regulation, which came into force on 3rd December 2004, is the core European legislation providing the framework for controlling food contact materials and articles.

2.3. Our draft Regulations will replace the current Ceramic Ware (Safety) Regulations 1988 (which implemented Directive 84/500/EEC), and will be introduced using powers provided in s17 of the Food Safety Act 1990. The 1988 Regulations (covering the UK) were introduced by the DTI using the Consumer Protection Act 1987 (CPA). The CPA was used because food safety legislation at that time did not provide appropriate powers. Today, however, we consider the Food Safety Act to be the most appropriate primary legislation.

2.4. In recognition of its historic responsibility for these Regulations the DTI has agreed with the Food Standards Agency (FSA) that it will implement the Directive for England, and provide assistance to FSA national offices taking forward analogous implementation in Scotland, Wales and Northern Ireland. Separate implementations are required because food safety is a devolved policy area.

Declaration of compliance

2.5. Directive 2005/31/EC introduces a requirement that at all marketing stages up to and including retail, ceramic articles which are intended to come into contact with food, but are not yet in contact with food, must be accompanied by a written declaration (provided by the manufacturer or the seller) stating that they comply with all the rules applicable to them. This declaration must include: the identity and address of the manufacturer and/or importer into the Community, the identity of the product, the date of declaration, and confirmation that the product complies with the relevant requirements of Directive 2005/31/EC and Regulation (EC) No 1935/2004. The declaration is not intended for consumers but to offer re-assurance to other parties in the distribution chain and to assist the enforcement authorities with their duties.

2.6. It is already a requirement under the 1988 Regulations that such products must comply with the migration limits; only the requirement to

provide a declaration that they meet them is new. For most manufacturers and importers we believe that this will mean no more than providing a statement as part of the consignment invoice, which under other legislation must be kept for a minimum of six years. We are proposing to have this requirement come into force on 20th May 2007, and to apply only to products manufactured or imported into the Community on or after that date. This should provide businesses with plenty of time to prepare.

Q1. Do you agree with our assessment that meeting the declaration of compliance requirement will entail only negligible cost to businesses? Please quantify the additional costs of compliance.

Requirement to demonstrate compliance

2.7. Another new requirement introduced by Directive 2005/31/EC is that manufacturers and importers must show the enforcement authorities (on request) documentation demonstrating that their products comply with migration limits for cadmium and lead. This documentation will have to include the results of the analysis carried out, the test conditions and the name and address of the laboratory that performed the testing. We are proposing to bring this requirement into force on 20th May 2007

2.8. Again, this new provision should not introduce any new costs for businesses. The enforcement authorities do not have any evidence that business is currently not complying with the migration limits, and simply providing the documentation that would have been generated by testing to ensure compliance with those limits should satisfy the requirement. Importers would need to obtain this document from the overseas producer, or conduct the testing themselves, which would be consistent with what they have to do now to ensure that they are not supplying non-compliant products. However, given the new requirements, it is even more likely that importers would only buy from compliant overseas producers and ones prepared to provide the documentation to meet the new regulatory requirement.

Q2. Do you agree with our assessment that meeting the requirement to show enforcement authorities (on request) documentation demonstrating compliance with migration limits should not introduce any new costs for manufacturers or importers?

Performance criteria for analytical methodologies

2.9. Council Directive 84/500/EEC, from which the current Regulations derive, required use of an atomic absorption spectrometry methodology in testing for compliance with migration limits. The 1998 Regulations implemented this provision by requiring compliance with British Standard BS 6748:1986. Directive 2005/31/EC recognises the technological advances that have been made since the original Directive by replacing the insistence on using atomic absorption spectrometry with a set of performance criteria that analytical methodologies must meet. This, in theory, means that a variety of measurement methods can be used.

2.10. The benefit of the more flexible performance criteria approach to analysis is that there will be more opportunity to match the analytical requirements of third countries in which exporters want to trade without the need for additional testing. Also, a choice of test methods may result in quicker test-booking and may offer cheaper test options. As a consequence, the net effect of this provision should be neutral or represent a cost saving to business.

Q3. Do you agree with our assessment that a performance based approach to compliance testing methods imposes no new burden on businesses, and may well carry with it some benefit for both businesses and enforcement authorities? Please quantify and benefits.

Permitting the trade of compliant products from 20th May 2006

2.11. Although compliance with the above requirements to provide a declaration and to have available the relevant documentation will not be made mandatory until 20th May 2007, the Directive requires that Member States allow the trade in compliant products from 20th May 2006. In practice this means that from this date we will no longer be able to insist that only products which are tested in accordance with British Standard BS 6748:1986 as required by the 1988 Regulations are placed on the market, but instead permit the trade of any product tested in compliance with any of the methodologies permitted by the performance criteria.

Prohibiting the manufacture or import into the Community of non-compliant products

2.12. The Directive also requires that from 20th May 2007 Member States should prohibit the manufacture and import into the Community of products that do not meet the Directive's requirements.

New offences and penalties

2.13. As the new Regulations will be made under the Food Safety Act 1990 we can no longer link into the offences and penalties defined in the CPA, and the offences covered by the Food Safety Act are not suitable to the specific circumstances regulated by the new Directive. We are therefore proposing to create new offences in the Regulations related to breaches of the new requirements in Directive 2005/31/EC, and to set penalties that are analogous to those in other food safety legislation. It should be noted that the 1988 Regulations prohibited the "supply" of non-compliant articles (to tie in with the definition contained in the CPA) whereas the Regulations now refer to "placing on the market"

2.14. The offences are the manufacture, import or placing on the market of non-compliant articles, failure to provide a written declaration, and failure to show enforcement authorities (on request) documentation demonstrating compliance. Non-compliance means exceeding the migration limits, or failure to provide the relevant declaration, or failure to make available the relevant documentation when required. The penalties are for conviction on indictment,

a fine, or imprisonment for a term up to two years, or both, and for summary conviction, a fine, or imprisonment for a term up to six months, or both.

2.15. There are two new statutory defences, that the non-compliant articles are intended for export to a third country which has analogous product safety legislation, or that the article was placed on the market before May 2007. In either case the matters must be proved by the defendant, which we consider to be compatible with the Human Rights Act 1998 as these are only evidential and not legal burdens.

Q4. Do you agree that we have created the correct offences and defences, and that we have set appropriate penalties?

Q5. We would appreciate your general views on whether we have correctly identified the main issues in our proposals for implementation of the Directive.

Q6. Do you have any other comments that might aid the consultation process?

3. What happens next?

3.1. We will aim to publish a summary of the views expressed by consultees, and the Department's response, on the DTI website within one month of the end of the consultation period. Thereafter, the implementing Regulations will be laid before Parliament (negative resolution) and accompanying guidance published with a view to the Regulation requiring free movement of compliant goods coming into force on 20th May 2006, and the other Regulations coming into force on 20th May 2007.

3.2. Paper copies of the summary of responses will be available on request.

The Consultation Code of Practice Criteria

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The complete code is available on the Cabinet Office's web site, address <http://www.cabinetoffice.gov.uk/regulation/consultation/index.asp>

Comments or complaints

If you wish to comment on the conduct of this consultation or make a complaint about the way this consultation has been conducted, please write to:

Nick Van Benschoten,
DTI Consultation Co-ordinator,
1 Victoria Street,
London
SW1H 0ET

Telephone Nick on 020 7215 6206
or e-mail to: nick.vanbenschoten@dti.gsi.gov.uk

List of organisations consulted

Akcros Chemicals
 Albright & Wilson Ltd
 Anglia Laboratories Ltd
 Argos Ltd
 Arjo Wiggins Ltd
 Association of British Cutlers and Allied Trades
 Association of Charity Shops
 Association for Consumer Research
 Association of London Government
 Association of Public Analysts
 Aynsley China Ltd
 Barber Index
 Belleek Pottery Ltd
 BHS Ltd
 BIBRA International
 Bird and Bird
 Black Business Association
 Bond Street Association
 Boots Group PLC
 Boots PDQ Centre
 Bridgewater Pottery Ltd
 British Association for Chemical Specialities
 British Association of Women Entrepreneurs
 British Beer & Pub Association
 British Ceramic Confederation
 British Chambers of Commerce
 British Coatings Federation Ltd
 British Colour Makers Association
 British Glass
 British Hardware Federation
 British Hardware and Houseware Manufacturers Association
 British Hospitality Association
 British Plastics Federation
 British Printing Industries Federation
 British Retail Consortium
 British Shops & Stores Association
 British Soft Drinks Association
 British Stainless Steel Association
 British Standards Institute Committee Service Centre
 British Toxicology Society
 Butterworths Law of Food And Drugs
 Cabinet Office
 Cadbury Schweppes
 Campden & Chorleywood Food Research Association
 Canadian High Commission
 Catering Equipment Suppliers Association
 Catering Industries Liaison Council
 CATRA
 Centre for Research into Information, Communication & Technology
 Ceramic Industry Forum
 Chemical Industries Association
 Chilled Food Association
 Churchill China Plc
 Clariant (UK) Ltd
 CMB Group Technology
 Coates Coatings International
 Coates Lorilleux Research
 Confederation of British Industry
 Confederation of Paper Industries
 Cookshop & Housewares Association
 Corus Packaging Plus
 Crafts Council
 Croda Adhesives Ltd
 Croda Chemicals Ltd
 Crown Corporate Technologies
 Crown Trent China Ltd
 Dairy Industry Federation
 DANI
 Denby Pottery Co. Ltd
 Department of Chemical Engineering
 Department of Constitutional Affairs
 Department for Environment, Food & Rural Affairs
 Department of Health
 Dow Corning Ltd
 Duchess China Ltd
 Dudson Ltd
 Dunoon Ceramics Ltd
 Eclipse Scientific Group
 Edwards' Analytical
 Eka Chemicals Ltd
 Elementis Specialities
 English Association of Self-Catering Operators
 European Information Centre
 Federation of European Food Additives and Food Enzymes Industries
 Federation of Small Businesses
 Federation of Townswomen Guilds
 Field Packaging
 Flint Ink
 Food Additives and Ingredients Association
 Food Additives Industry Association
 Food and Drink Federation
 Food Commission
 Food Manufacturers Federation
 Food Manufacturers Industrial Group
 FOODAWARE
 Food Standards Agency
 Foreign & Commonwealth Office

Forum of Private Business
Fresh Produce Consortium (UK)
Friends of the Earth
Greenpeace
Halton Borough Council
H J Heinz Co Ltd
Henry Cook Ltd
Hertfordshire County Council
HIPP Nutrition Ltd
House of Fraser
Hudson & Middleton Ltd
Hyperlast Ltd
ICI Packaging Coatings Ltd
ICI PLC
IGD
Industrial Packaging Association The
Industry Council for Packaging and the
Environment
Institute of Directors
Institute of Food Science and Technology
Inter-teck Testing Services
James Cropper PLC
Jamont (UK) Ltd
John Lewis Partnership PLC
John Waddington PLC
Josiah Wedgwood & Sons Ltd
JRM Associates
Kellogg's
Kenwood Ltd
Kingfisher Colours Ltd
Laser Installations Ltd
Lead Development Association
International
LGC
Linpac Plastics Ltd
LINX Printing Technologies PLC
LMG Smith Brothers
Local Authorities Co-ordinators of
Regulatory Services
Lovell White Durrant
Lyondell Chemical Europe Inc
Marks and Spencer PLC
Mason Cash & Co Ltd
Mirage Inks
Mole Valley District Council
MPMA
National Consumer Council
National Consumers' Federation
National Farmers' Union
National Federation of Consumer Groups
National Starch & Chemical
Nickel Institute
Nikken UK Ltd
Packaging Technology & Science
Paint Research Association
PERA Technology
Phase Four Technical Ltd
Pillsbury Europe
PIRA International Ltd
Portmeirion Potteries Ltd
Public Analyst Laboratory
Quest International
RDA Packaging Consultants
Reading Scientific Services Ltd
Rexam Beverage Can Europe
Rexam Plastic Packaging
RHM Technology
Robinson Brothers Ltd
Rocup
Royal Crown Derby Porcelain Co Ltd
Royal Doulton (UK) Ltd
Royal Stafford Tableware Ltd
Royal Winton
Royal Worcester Ltd
Rural Shops Alliance
Safeway Stores PLC
J Sainsburys PLC
School of Chemical Engineering
Selective Services (SSL)
Seven Seas Ltd
Shell Chemicals Europe Ltd
Sinclair International Ltd
SLF International
Small Business Service
Society of Chemical Industry
Somerville PLC
Spectra Masterbatch Ltd
Spode
Stainless Plating Ltd
Steelite International PLC
STR
SUSTAIN - National Food Alliance
Tableware Distributors Association
Tams Group Ltd
Technical Indexes
Terinex Ltd
Tesco Stores Ltd
Tile Association The
Toxicology Advice & Consulting Ltd
Trada Technology
Trading Standards Institute
Unigate
Unilever Research Colworth
United Biscuits (UK) Ltd
Univar Ltd
Vinamul Ltd
W Moorcroft PLC
W R Grace Ltd
Wade Ceramics Ltd
Weetabix Ltd
Which?
Wilsanco Plastics Ltd
World Wildlife Fund UK
Zinc Information Centre

COMMISSION DIRECTIVE 2005/31/EC

of 29 April 2005

amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC ⁽¹⁾, and in particular Article 5(2) thereof,

Whereas:

- (1) Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs ⁽²⁾ is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004. It concerns the possible migration of lead and cadmium from ceramic articles which, in their finished state, are intended to come into contact with foodstuffs, or which are in contact with foodstuffs, and are intended for that purpose.
- (2) Article 16 of Regulation (EC) No 1935/2004 provides that the specific measures are to require that materials and articles covered by those measures are accompanied by a written declaration stating that they comply with the rules applicable to them.
- (3) That requirement has not yet been set out in Directive 84/500/EEC. There is a need to lay down that obligation for all ceramic articles which are not yet in contact with foodstuffs to clearly distinguish them from decorative articles.
- (4) The national competent authorities should have access to documents demonstrating that the ceramic articles comply with the migration limits for lead and cadmium. Therefore, the manufacturer or importer into the Community should make information concerning analysis carried out available to them on request.
- (5) Directive 84/500/EEC lays down a method for the analysis of lead and cadmium. Technological progress has been made in that area and the analytical method set out in that Directive is only one amongst several

possible methods. This Directive should take technological progress into account and establish a set of performance criteria that the analytical method must comply with having regard to Commission Directive 2001/22/EC of 8 March 2001 laying down the sampling methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs ⁽³⁾.

- (6) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring the free movement of ceramic articles intended to come into contact with foodstuffs to lay down rules for a correct enforcement of Directive 84/500/EEC. This Directive does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty.
- (7) Directive 84/500/EEC should therefore be amended accordingly.
- (8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 84/500/EEC is amended as follows:

1. The following Article 2a is inserted:

'Article 2a

1. At the marketing stages up to and including the retail stage, ceramic articles which are not yet in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council (*).

That declaration shall be issued by the manufacturer or by a seller established within the Community and shall contain the information laid down in Annex III to this Directive.

⁽¹⁾ OJ L 338, 13.11.2004, p. 4.
⁽²⁾ OJ L 277, 20.10.1984, p. 12.

⁽³⁾ OJ L 77, 16.3.2001, p. 14. Directive as last amended by Directive 2005/4/EC (OJ L 19, 21.1.2005, p. 50).

2. Appropriate documentation to demonstrate that the ceramic articles comply with the migration limits for lead and cadmium set out in Article 2 shall be made available by the manufacturer or the importer into the Community to the national competent authorities on request. That documentation shall contain the results of the analysis carried out, the test conditions and the name and the address of the laboratory that performed the testing.

(*) OJ L 338, 13.11.2004, p. 4.

2. Annex II is replaced by the text in Annex I to this Directive.
3. A new Annex III, the text of which is set out in Annex II to this Directive, is added.

Article 2

1. Member States shall adopt and publish, by 20 May 2006 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions in such a way as to:

- (a) permit the trade in and use of ceramic articles complying with this Directive, from 20 May 2006;
- (b) prohibit the manufacture and importation into the Community of ceramic articles which do not comply with this Directive, from 20 May 2007.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 April 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

ANNEX II

METHODS OF ANALYSIS FOR DETERMINATION OF THE MIGRATION OF LEAD AND CADMIUM**1. Object and field of application**

The method allows the specific migration of lead and/or cadmium to be determined.

2. Principle

The determination of the specific migration of lead and/or cadmium is carried out by an instrumental method of analysis that fulfils the performance criteria of point 4.

3. Reagents

— All reagents must be of analytical quality, unless otherwise specified.

— Where reference is made to water, it shall always mean distilled water or water of equivalent quality.

3.1. 4 % (v/v) acetic acid, in aqueous solution

Add 40 ml of glacial acetic acid to water and make up to 1 000 ml.

3.2. Stock solutions

Prepare stock solutions containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution, as referred to in point 3.1.

4. Performance criteria of the instrumental method of analysis

4.1. The detection limit for lead and cadmium must be equal to or lower than:

— 0,1 mg/litre for lead,

— 0,01 mg/litre for cadmium.

The detection limit is defined as the concentration of the element in the 4 % acetic acid solution, as referred to in point 3.1, which gives a signal equal to twice the background noise of the instrument.

4.2. The limit of quantification for lead and cadmium must be equal to or lower than:

— 0,2 mg/litre for lead,

— 0,02 mg/litre for cadmium.

4.3. *Recovery.* The recovery of lead and cadmium added to the 4 % acetic acid solution, as referred to in point 3.1, must lie within 80-120 % of the added amount.

4.4. *Specificity.* The instrumental method of analysis used must be free from matrix and spectral interferences.

5. Method**5.1. Preparation of the sample**

The sample must be clean and free from grease or other matter likely to affect the test.

Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40 °C. Rinse the sample first in tap-water and then in distilled water or water of equivalent quality. Drain and dry so as to avoid any stain. The surface to be tested is not to be handled after it has been cleaned.

5.2. *Determination of lead and/or cadmium*

- The sample thus prepared is tested under the conditions laid down in Annex I.
- Before taking the test solution for determining lead and/or cadmium, homogenise the content of the sample by an appropriate method, which avoids any loss of solution or abrasion of the surface being tested.
- Carry out a blank test on the reagent used for each series of determinations.
- Carry out determinations for lead and/or cadmium under appropriate conditions.'

ANNEX II

'ANNEX III

DECLARATION OF COMPLIANCE

The written declaration referred to in Article 2a(1) shall contain the following information:

1. the identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into the Community;
2. the identity of the ceramic article;
3. the date of the declaration;
4. the confirmation that the ceramic article meets relevant requirements in this Directive and Regulation (EC) No 1935/2004.

The written declaration shall permit an easy identification of the goods for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration of lead and cadmium.'

2005 No.**FOOD****Ceramic Articles in Contact with Food (England) Regulations
2006**

Made - - - - - ***

Laid before Parliament ***

*Coming into force (except for regulations 3(3)(a)
and (b) and 4)* 20th May 2006

Regulations 3(3)(a) and (b) and 4 20th May 2007

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by sections 17(1), 26(1)(a), 2(a) and (3), and 48(1) of the Food Safety Act 1990(a) and section 11 of the Consumer Protection Act 1987 (b);

In accordance with section 48(4A)(c) of the Food Safety Act he has had regard to relevant advice given by the Food Standards Agency and consulted as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (d);

In accordance with section 11(5) of the Consumer Protection Act 1987 he has consulted such organisations as appear to him to be representative of interests substantially affected by the proposal to revoke the Ceramic Ware (Safety) Regulations 1988(e), such other persons as he considered appropriate and the Health and Safety Commission.

Citation, Commencement, Extent and Revocation

1.—(1) These Regulations may be cited as the Ceramic Articles in Contact with Food (England) Regulations 2006 and shall come into force on 20th May 2006 except for regulation 3(3)(a) and (b) and 4 which shall come into force on 20th May 2007.

(2) These Regulations extend only to England.

(3) The Ceramic Ware (Safety) Regulations 1988 are revoked.

(a) 1990 c.16.

(b) 1987 c.43.

(c) Subsection (4A) was inserted by para. 21 of Sch. 5 to the Food Standards Act 1999 (c.28).

(d) OJ No L 31, 1/2/2002, p.1.

(e) 1988 No. 1647.

Interpretation

2. In these Regulations —

“ceramic article” means an article—

- (a) manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. Such an article is first shaped and the shape thus obtained is permanently fixed by firing. It may be glazed, enamelled and/or decorated;
- (b) which, in its finished state, is intended to come into contact with foodstuffs, or which is in contact with foodstuffs, and is intended for that purpose;

but does not include articles which are supplied as antiques.

“import” means the release into the UK for free circulation in the Community;

“place on the market” means the holding of ceramic articles for sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves;

Limits on the transfer of lead and cadmium

3.—(1) The quantities of lead and cadmium transferred from a ceramic article shall not exceed the limits laid down in Schedule 1.

(2) Whether a ceramic article complies with paragraph (1) shall be determined by means of the test, the conditions of which are specified in Part 1 of Schedule 2 and which uses the methods of analysis described in Part 2 of that Schedule.

(3) No person may —

- (a) manufacture,
- (b) import, or
- (c) place on the market,

a ceramic article which does not comply with the requirements in paragraph (1).

Declaration of Compliance

4.—(1) A manufacturer or seller of a ceramic article which is not yet in contact with food shall provide a written declaration to accompany the article at the marketing stages up to and including the retail stage.

(2) The declaration shall be issued by the manufacturer or by a seller established within the Community and shall contain the information laid down in Schedule 3.

(3) The manufacturer or importer into the Community shall on request make available to an enforcement authority specified in regulation 5 appropriate documentation to demonstrate that the ceramic articles comply with the migration limits for lead and cadmium set out in Schedule 1.

(4) That documentation shall contain:

- (a) the results of the analysis carried out;
- (b) the test conditions;
- (c) the name and the address of the laboratory that performed the testing.

(5) This regulation does not apply to a ceramic article which is second-hand.

Enforcement

5. The following authorities shall execute and enforce these Regulations —

- (a) each food authority in its area;

- (b) each port health authority in its district.

Offences and penalties

6.—(1) A person who contravenes a provision of regulations 3(3) or 4(1) or (3) is guilty of an offence

(2) A person guilty of an offence under paragraph (1) is liable

- (a) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both; or
- (b) on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both..

(3) Where it is alleged in proceedings for an offence under paragraph (1) that a ceramic article failed to meet the requirements specified in regulation 3(1) or to be accompanied by a declaration of compliance it shall be a defence for the person charged to prove that the article was intended for export to a state outside the Community which has legislation analogous to these Regulations and that the article complied with such legislation.

(4) In proceedings for an offence in respect of failure to comply with regulation 4 it shall be a defence to prove that the ceramic article to which the offence relates was first placed on the market in the Community before 20 May 2007.

Application of the Food Safety Act 1990

7.—(1) The following provisions of the Food Safety Act 1990(a) apply for the purposes of these Regulations, with reference in those provisions to the Act or a Part of it being construed as a reference to these Regulations –

- (a) section 20 (offences due to fault of another person);
- (b) section 21(1), (5) and (6) (defence of due diligence);
- (c) section 33 (obstruction etc of officers);
- (d) Section 34 of the Food Safety Act 1990 (time limit for prosecutions) applies to offences under regulations 6 as it applies to offences punishable under section 35(2) of the Act.
- (e) section 35(1)(b) (punishment of offences) in so far as it relates to offences under section 33 as applied by this regulation;
- (f) section 35(2) and (3)(b) in so far as it relates to offences under section 33(2) as applied by this regulation;
- (g) section 36 (offences by bodies corporate);
- (h) section 36A(c) (offences by Scottish partnerships);
- (i) section 44 (protection of officers acting in good faith).

SCHEDULE 1

Regulation 3(1)

Maximum quantities of lead and cadmium which may be transferred from a ceramic article

The quantity of lead and/or cadmium extracted during the test carried out under the conditions laid down in Parts 2 & 3 of Schedule 2 shall not exceed the following limits:

(a) 1990 c.16.

(b) Section 35(1) is amended by Sch. 26 para. 42 of the Criminal Justice Act 2003 (c.44) from a date to be appointed.

(c) Section 36A was inserted by Sch. 5 para. 16 of the Food Standards Act 1990.

	<i>Lead</i>	<i>Cadmium</i>
Category 1: articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm	0.8 mg/dm ²	0.07 mg/dm ²
Category 2: All other articles which can be filled	4.0 mg/l	0.3mg/l
Category 3: Cooking ware; packaging and storage vessels having a capacity of more than three litres	1.5 mg/l	0.1 mg/l

Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead and/or cadmium limit which may not be exceeded (mg/dm² or mg/litre) shall be that which applies to the vessel alone. The vessel alone and the inner surface of the lid shall be tested separately and under the same conditions; the sum of the two lead and/or cadmium extraction levels obtained shall be related as appropriate to the surface area or the volume of the vessel alone.

Where a ceramic article does not exceed the above quantities by more than 50%, that article shall nevertheless be recognised as satisfying the requirements of these Regulations if at least three other articles with the same shape, dimensions, decoration and glaze are subjected to a test carried out under the conditions laid down in Parts 1 and 2 of Schedule 2 and the average quantities of lead and/or cadmium extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50%.

SCHEDULE 2

Regulation 3(2)

PART I

BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM

1. Test liquid (“simulant”)

4% (v/v) acetic acid, in a freshly prepared aqueous solution.

2. Test conditions

2.1 carry out the test at a temperature of $22 \pm 2^\circ$ for a duration of 24 ± 0.5 hours.

2.2 When the migration of lead is to be determined, cover the sample by an appropriate means of protection and expose it to the usual lighting conditions in a laboratory.

When the migration of cadmium or of lead and cadmium is to be determined, cover the sample so as to ensure that the surface to be tested is kept in total darkness.

3. Filling

3.1 Samples which can be filled

Fill the article with a 4% (v/v) acetic acid solution to a level no more than 1mm from the overflow point; the distance is measured from the upper rim of the sample.

Samples with a flat or slightly sloping rim should be filled so that the distance between the surface of the liquid and the overflow point is no more than 6mm measured along the sloping rim.

3.2 *Samples which cannot be filled*

The surface of the sample which is not intended to come into contact with foodstuffs is first covered with a suitable protective layer able to resist the action of the 4% (v/v) acetic acid solution. The sample is then immersed in a receptacle containing a known volume of acetic acid solution in such a way that the surface intended to come into contact with the foodstuffs is completely covered by the test liquid.

4. **Determination of the surface area**

The surface area of the articles in category 1 is equal to the surface area of the meniscus formed by the free liquid surface obtained by complying with the filling requirements set out in paragraph 3 above.

PART 2

METHODS OF ANALYSIS FOR DETERMINATION OF THE MIGRATION OF LEAD AND CADMIUM

1. **Object and field of application**

The method allows the specific migration of lead and/or cadmium to be determined.

2. **Principle**

The determination of the specific migration of lead and/or cadmium is carried out by an instrumental method of analysis that fulfils the performance criteria of point 4.

3. **Reagents**

— All reagents must be of analytical quality, unless otherwise specified.

— Where reference is made to water, it shall always mean distilled water or water of equivalent quality.

3.1. *4 % (v/v) acetic acid, in aqueous solution*

Add 40 ml of glacial acetic acid to water and make up to 1 000 ml.

3.2. *Stock solutions*

Prepare stock solutions containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution, as referred to in point 3.1.

4. **Performance criteria of the instrumental method of analysis**

4.1. The detection limit for lead and cadmium must be equal to or lower than:

— 0,1 mg/litre for lead,

— 0,01 mg/litre for cadmium.

The detection limit is defined as the concentration of the element in the 4 % acetic acid solution, as referred to in point 3.1, which gives a signal equal to twice the background noise of the instrument.

4.2. The limit of quantification for lead and cadmium must be equal to or lower than:

— 0,2 mg/litre for lead,

— 0,02 mg/litre for cadmium.

4.3. *Recovery*. The recovery of lead and cadmium added to the 4 % acetic acid solution, as referred to in point 3.1, must lie within 80-120 % of the added amount.

4.4. *Specificity*. The instrumental method of analysis used must be free from matrix and spectral interferences.

5. Method

5.1. Preparation of the sample

The sample must be clean and free from grease or other matter likely to affect the test.

Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40 °C. Rinse the sample first in tap-water and then in distilled water or water of equivalent quality. Drain and dry so as to avoid any stain. The surface to be tested is not to be handled after it has been cleaned.

5.2. Determination of lead and/or cadmium

— The sample thus prepared is tested under the conditions laid down in Schedule I.

— Before taking the test solution for determining lead and/or cadmium, homogenise the content of the sample by an appropriate method, which avoids any loss of solution or abrasion of the surface being tested.

— Carry out a blank test on the reagent used for each series of determinations.

— Carry out determinations for lead and/or cadmium under appropriate conditions.

SCHEDULE 3

Regulation 4

DECLARATION OF COMPLIANCE

The written declaration referred to in article 4(1) shall contain the following information:

1. the identity and address of the company which manufactured the finished ceramic article and (if applicable) of the importer who imports it into the Community;
2. the identity of the ceramic article;
3. the date of the declaration;
4. confirmation that the ceramic article meets the relevant requirements in:
 - (j) this Regulation; or
 - (k) Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs as amended by Commission Directive 2005/31/EC of 29 April 2005; and
 - (l) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC^(a).

The written declaration shall permit an easy identification of the goods for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration of lead and cadmium.

(a) OJ L338, 13/11/2004 p.4-14.

EXPLANATORY NOTE

(This note is not part of the Order)

The Ceramic Articles in Contact with Food (England) Regulations 2006

Partial Regulatory Impact Assessment

1. PURPOSE

1.1. The overall policy objective is to further reduce the risk of unsafe levels of the harmful metals, cadmium and lead, passing from (migrating from) the glaze on ceramic ware into food.

1.2. The specific purpose of these UK regulations is to implement the provisions of Commission Directive 2005/31/EC (amending Council Directive 84/500/EEC). Directive 84/500/EEC sets a limit on the levels of lead and cadmium permitted to transfer out of ceramic articles intended to come into contact with food and prescribes the methods of testing to be used to establish how much lead and cadmium is being transferred. Directive 2005/31/EC requires a declaration of compliance with the migration limits to accompany ceramic articles intended to come into contact with food, and sets performance criteria for the analytical method used to test for compliance. It also requires provisions to be made for enforcement, with effective penalties that are in line with other food safety legislation.

1.3. The transposition of this Directive has been geared towards avoiding over-implementation while maximising internal market benefits for affected exporters. To this end the new obligation to include a declaration of compliance has been aimed at enforcers and businesses in the supply chain, and should not require re-labelling of individual items. In addition, there will be a phased implementation of a 1-year voluntary period before this regulation comes into force.

2. INTENDED EFFECTS

2.1. Directive 2005/31/EC is an amending Directive. It builds on the requirements of its predecessor by introducing provisions that will make it easier for enforcement authorities, manufacturers, importers and distributors to check that ceramic ware intended to come into contact with food does not exceed the limits governing the migration of cadmium and lead migration from the ceramic glaze into food.

2.2. All parties involved in the manufacture, import and distribution of ceramic ware intended to come into contact with food will be affected to a greater or lesser extent by the implementing proposal, though it will be the manufacturers and the importers who are principally affected. The impact of any additional burdens and costs introduced by the proposal on business will be negligible. The impact on enforcement authorities should be to make enforcement more efficient, though in overall terms the benefit will be small since there is no evidence of current non-compliance with the migration limits.

2.3. In line with the requirements of the core European legislation controlling food contact materials - Regulation (EC) No. 1935/2004 (on materials and articles

intended to come into contact with food) - responsibility is placed on producers and other parties involved in the distribution of ceramic ware intended to come into contact with food to indicate compliance with the Directive's requirements by including with the product, at all marketing stages up to and including retail, a written declaration stating that it complies with the rules applicable to it. Producers, or importers into the Community, must additionally (on request) show the enforcement authorities documentation demonstrating this compliance (including results of laboratory analysis etc).

2.4. In acknowledgement of advances in analytical technology made since the adoption of Directive 84/500/EEC, the testing method for migration compliance stipulated in that Directive is no longer insisted upon. Instead, performance criteria have now been set that analytical methodologies must meet, thus allowing a range of methodologies to be used.

2.5. The Directive requires that Member States must allow the trade in products complying with these requirements from 20th May 2006, and further requires a prohibition to be placed on the manufacture and import into the Community of non-compliant products from 20th May 2007.

2.6. Since the current Ceramic Ware (Safety) Regulations 1988 do little more than require compliance with technical standard BS 6748:1986 (which uses the analytical methodology required by Directive 84/500/EEC) they do not meet the objectives of Directive 2005/31/EC and will need to be revoked, though the migration limits will be re-enacted as part of the implementation.

3. RISK ASSESSMENT

3.1. The proposed Regulations are considered uncontroversial and make provisions for food authorities in England to enforce the provisions implementing Directive 2005/31/EC, and for the courts to impose penalties on those convicted of an offence under the Regulations that are in line with those elsewhere in our food law. The new requirements will also make it easier for businesses to understand the consequences of non-compliance and to identify when goods are not compliant.

3.2. The new burdens placed on businesses by the new Regulations will be negligible, and could only derive from the need to provide a declaration of compliance. The same is true for the enforcement authorities, who already have responsibility for enforcing law in this area. They will not be called upon to undertake any action over and above what they currently do, or to introduce any new procedures. The changes will be of benefit to them by aiding the efficiency of any checks or enforcement action they may take.

4. BACKGROUND

4.1. Directive 2005/31/EC ("amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs") was adopted on 29th April 2005, and has to be implemented by 20th May 2006. This is an amending Directive, having the effect of amending Council Directive 84/500/EEC, from which the current Ceramic Ware (Safety) Regulations 1988 derive.

4.2. The basis for Directive 2005/31/EC is Regulation (EC) No. 1935/2004. This Regulation, which came into force on 3rd December 2004, is the core European legislation providing the framework for controlling food contact materials and articles.

4.3. The changes introduced by Directive 2005/31/EC go beyond what can sensibly be implemented via amendments to the current Ceramic Ware (Safety) Regulations 1988. These current Regulations require little more than simple compliance with a British technical standard, which would itself be an inappropriate restriction on the new Directive's more flexible performance criteria approach to defining allowable measurement methodologies. Also, the current Regulations link into the offences and penalties contained within the Consumer Protection Act 1987 (CPA), which is no longer the most appropriate primary legislation under which to implement these Directives.

5. CONSULTATION WITH SMALL BUSINESS

5.1. The companies involved in this area are represented through their national trade bodies to those that represent them at European level. Although initial soundings indicate no significant impact on small firms, we have included small firm trade bodies in the distribution list for this consultation and encourage small firms to contribute their views. If there is sufficient interest we will be happy to conduct a small firms focus group. We have consulted the Small Business Service, who are content with our approach.

6. OPTIONS

Two main options have been considered:

Option 1 – Take no action

6.1. This option contradicts the Government's commitment to meeting its EU obligations and its policy on consumer protection in this area. It would also risk the UK being cited in infraction proceedings for failing to implement or provide the means to enforce harmonised provisions that it had supported during European negotiations and subsequent adoption. Taking no action would also leave UK law out of step with the law in the rest of the EU. Manufacturers in the UK would still need to comply with the harmonised rules that apply in the rest of the EU if they sought to sell products in the EU market. This option has therefore been rejected.

Option 2 – Implementing by means of Secondary Legislation

A – Implementing under the Consumer Protection Act 1987 (CPA)

6.2. The 1988 Regulations were introduced by the DTI using powers available under the CPA because the food safety legislation in force at the time did not provide appropriate powers. We have concluded that the subject matter of the Regulations is devolved in respect of Scotland, Wales and Northern Ireland and that the proper powers to use are the specific ones in the Food Safety Act covering food contact materials.

6.3. The choice between amending and making new Regulations would be theoretical only. The very nature of the current Regulations, a simple requirement to comply with a technical standard, would not be compatible with the more flexible approach to defining acceptable analytical methodologies in the new Directive. Most of the wording in the current Regulations would have to be amended. For these reasons, this option has also been rejected.

B – Implementing using s2(2) of European Communities Act (ECA)

This option bears similar consideration to Option 2 in that whilst the powers extend to making Regulations covering the UK nevertheless the subject matter is properly devolved. Cabinet Office guidance advises strongly against use of the ECA where more appropriate powers are available. Again, this option has been rejected.

C – Implementing using s17 of the Food Safety Act 1990

6.4. The Food Safety Act provides the most appropriate powers for implementing the provisions of Directive 2005/31/EC. It specifically covers food contact materials (s17) and has been the basis for all food contact materials legislation in Great Britain in recent years. This is the preferred option.

6.5. In recognition of the history of this legislation the DTI has agreed with the Food Standards Agency (FSA) that it will implement for England, and that FSA national offices will implement for Scotland, Wales and Northern Ireland. It has been further agreed that once implementation has been completed across the UK, the FSA will take over responsibility for all food safety aspects of the new Regulations. We will be working closely with the FSA throughout this exercise.

6.6. If new Regulations were introduced as recommended, the current Ceramic Ware (Safety) Regulations 1988 would be repealed at the same time, which would be in line with the Government's one in/one out policy.

7. DEVOLUTION

7.1. This implementation will apply to England only. The implication of using the Food Safety Act is that the DTI cannot introduce regulations for Scotland and Northern Ireland. Food safety, including food contact materials, was delegated to Scottish and Welsh Ministers, and so Directive 2005/31/EC will require separate Scottish and Welsh implementation under the Food Safety Act (a joint SI would not be possible). Northern Ireland is not covered by the Food Safety Act and so would have to implement separately, under the Food Safety (Northern Ireland) Order 1991.

8. COSTS AND BENEFITS

Option 1

8.1. This option would place no new direct burdens or costs on businesses, but they would still need to provide declarations of compliance if they wanted to trade elsewhere on the Community market. And Community importers and manufacturers in other Member States would have to continue to use the BS 6748:1986 method of analysis to be able to sell in the UK. Moreover, the UK Government would risk

substantial infraction penalties for failure to implement. Also, enforcement activity would not benefit from the availability of documentation required by the Directive (e.g. declaration of compliance and requirement to show documentation demonstrating compliance), which would mean more time consuming investigations for both enforcement authorities and businesses.

Options 2 A, B & C

8.2. The costs and benefits for businesses and enforcement would be the same for each of these sub options, and are explained below. Although A would avoid much of the central Government costs that the authorities in Scotland, Wales and Northern Ireland would otherwise meet in taking forward separate devolved implementations.

Economic

8.3. All businesses involved in placing new ceramic ware not yet in contact with foodstuffs on the market or supplying such products (manufacturers, importers, distributors and retailers) will be affected by these regulations, just as they are by the current Ceramic Ware (Safety) Regulations 1988.

8.4. The British Ceramics Confederation advises that there are around 400 or so producers of ceramic table and ornamental ware in the UK, with around 40 of these trading internationally. The sale of UK produced ceramic tableware in 2004 was in the order of £380 million (at ex-factory prices).

8.5. Since Lacors reports no evidence of non-compliance with migration limits there should be little or no additional costs associated with meeting the existing requirements as a result of this implementation, or providing evidence of same on request. The only change introduced by the implementation that could have any cost implication is the requirement to provide with the product a declaration stating that it complies with all the rules applicable to it, but this arguably is counter-balanced by a reduction in the burden of demonstrating compliance in the case of individual enforcement investigations. In practice, manufacturers could choose to meet this requirement in a number of ways. For example, they could choose to include a sheet of paper (or add wording to an existing sheet) within the product packaging, or they could choose to make the declaration on the packaging. However, as this declaration is not intended for the consumer, but rather for other parties in the distribution chain and for the enforcement authorities, it is more relevant that manufacturers and importers include the declaration as part of the consignment invoice which in any case must be kept for a minimum of 6 years under tax law. The costs associated with doing this would be minimal, with the set-up requiring only the modification of mostly electronic document formats and the paper to print it on. We propose to introduce this requirement from 20th May 2007 and to have it apply only to products first placed on the market on or after that date.

8.6. We also propose to introduce on the 20th May 2007 the requirement to show enforcement authorities (on request) documentation demonstrating compliance. Simply providing the documentation that must have been generated in meeting the current requirement to ensure compliance with migration limits will meet this requirement. Importers will need to obtain this from the overseas producer, or

conduct the testing themselves, which is no different from what they would currently be expected to do in ensuring that they did not supply non-compliant products.

8.7. The 'liberalisation' of analytical requirements will introduce no new costs for businesses or enforcement authorities. Indeed, the element of choice should make for easier, quicker and possibly cheaper compliance testing. We propose that the new Regulations allow the free trade of products complying with the Directive's requirements from 20th May 2006 (as the Directive requires).

8.8. The changes are principally intended to make it easier for manufacturers, importers and distributors to satisfy the enforcement authorities and to some extent consumers (although they will obviously be the beneficiaries of compliant products) that their goods are compliant, and make it easier for the enforcement authorities to enforce the requirements. In addition, greater consistency in the application of penalties for offences relating to breaches of food safety regulations will be introduced.

Environmental

8.9. Environmental costs arising from this proposal are likely to be negligible. Indeed, as these provisions are intended to make enforcement of the requirements easier it can be expected that fewer ceramic products with cadmium and lead migration above permitted levels will be allowed to release these materials into the environment, principally land fill.

Social

8.10. There are unlikely to be any social costs arising from this proposal. Consumer protection will continue in an area of food control where inadequate controls would have serious long-term implications for the prevention of human cancers, gene mutation and reproductive defects arising from the ingestion of cumulative amounts of substances known to carry, or seriously suspected of carrying, an unacceptable risk to consumer health, particularly among more vulnerable people.

Other Costs

8.11. There should be little change in respect of additional costs and burdens to the enforcement authorities. Lacors has already indicated that there should be no new burdens for the local authorities. Indeed, the changes proposed should enable non-compliant ceramic ware to be more readily identifiable, leading to more efficient enforcement. Though, as has already been said, they see no evidence of widespread non-compliance with the migration limits.

9. ISSUES OF EQUITY AND FAIRNESS

9.1. The testing provisions apply principally to manufacturers and importers of ceramic ware intended to come into contact with foodstuffs. Manufacture of these products in England is mainly centred in Staffordshire. The requirement to ensure that products affected by the proposals are accompanied by documentation stating that they comply with all requirements will apply to everyone in the distribution chain

up to and including retail. Rural areas and members of ethnic communities are not discriminated against or specifically adversely affected by the proposal. Both the DTI and the Food Standards Agency believe that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework that removes trade barriers and allows for technological innovation.

10. COMPETITION ASSESSMENT

10.1. The provision of enforcement powers to the proper authorities in England does not place any hindrance on the competitiveness of businesses, nor do the realignment of penalties for offences with those that apply elsewhere in our food law.

10.2. Industry has been closely involved at European level, principally through representation by British business, in the development of the harmonised EU rules that these proposals relate to and has not raised any issues that indicate a disadvantage to any business sector.

11. ENFORCEMENT AND SANCTIONS

11.1. The enforcement of the Ceramic Articles in Contact with Food (England) Regulations 2006 will be the responsibility of the enforcement authorities

12. MONITORING AND REVIEW

12.1. Member States are obliged under the provisions of Regulation (EC) No. 1935/2004 to ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with the Regulation. After the new Regulations have come into force the Food Standards Agency will routinely survey materials and articles on the market to ensure compliance with the Regulations and work with enforcement authorities where problems or suspected infringements of the Regulations arise. They will also routinely talk to industry to ensure that no unforeseen difficulties connected with food safety arise from these Regulations.

Consultation on proposals to implement Directive 2005/31/EC on ceramic articles intended to come into contact with foodstuffs

Consultation Response Form

The closing date for this consultation is 28/02/2006

The Department may, in accordance with the Code of Practice on Access to Government information, make available, on public request, individual consultation responses. This will extend to your comments unless you inform us that you wish them to remain confidential.

Name _____

Organisation (if applicable) _____

Address _____

Return completed forms to:

Steve Ringer
Department of Trade and Industry
Consumer and Competition Policy Directorate
Bay 428
1 Victoria Street
London SW1H 0ET

Telephone: **00 44 (0) 20 7215 0359**

Fax: **00 44 (0) 20 7215 0339**

email: ceramics.ware@dti.gsi.gov.uk

Respondents should be asked to tick one box from a list of options that best describes them at a respondent. This enables views to be presented by group type. A box for 'others' should always be included. For example:

	Small to Medium Enterprise
	Representative Organisation
	Trade Union
	Interest Group
	Big Business
	Local Government
	Central Government
	Other (please describe):

Questionnaires need careful design so as not to encourage a biased response (contact the Operational Research Unit in the Strategy Unit for help and information). Responses in other forms, and on different but relevant questions should always be accepted. A mix of open and closed questions

seems to work well and the sample questionnaire provided uses a selection of different approaches to question setting, all of which have been effective. The use of tick-boxes enables teams to gauge the strength of feeling behind proposals and present quantitative analysis. However, space for comments should always be added, whether questions are open or closed, offering respondents the opportunity to qualify their choices. Issues arising in narrative should form the framework for qualitative analysis of responses.

This draft questionnaire is intended as a “pull out” design as part of a consultation document.

Question 1.

**Do you agree with our assessment that meeting the declaration of compliance requirement will entail only negligible cost to businesses?
Please quantify the additional costs of compliance.**

Yes

No

Not sure

Comments:

Question 2.

Do you agree with our assessment that meeting the requirement to show enforcement authorities (on request) documentation demonstrating compliance with migration limits should not introduce any new costs for manufacturers or importers?

Yes

No

Not sure

Comments:

Question 3.

Do you agree with our assessment that a performance based approach to compliance testing methods imposes no new burden on businesses, and may well carry with it some benefit for both businesses and enforcement authorities? Please quantify the benefits.

Yes

No

Not sure

Comments:

Question 4.

Do you agree that we have created the correct offences and defences, and that we have set appropriate penalties?

Yes

No

Not sure

Comments:

Question 5.

Do you have any other comments that might aid the consultation process?

Yes

No

Not sure

Comments:

Question 6.

We would appreciate your general views on whether we have correctly identified the main issues in our proposals for implementation of the Directive.

Yes

No

Not sure

Comments:

Thank you for taking the time to let us have your views. We do not intend to acknowledge receipt of individual responses unless you tick the box below.

Please acknowledge this reply

(Respondents should be thanked for their views and we should say whether we will acknowledge individual responses. Acknowledging responses can help foster good relations with new partners, however, most of the Department's stakeholders are regular contributors to consultations and would probably consider acknowledgements to be an unnecessary expense. Current practice is to acknowledge on request only, actioned by a tick on the questionnaire using letter, postcards or e-mails)

Here at the Department for Trade and Industry we carry out our research on many different topics and consultations. As your views are valuable to us, would it be okay if we were to contact you again from time to time either for research or to send through consultation documents?

Yes

No