#### EXPLANATORY MEMORANDUM TO

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

#### 2006 No. 1179

1. This explanatory memorandum has been prepared by the Department of Trade and Industry and is laid before Parliament by Command of Her Majesty.

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

# 2. Description

- 2.1 The Order is made by the Parliamentary Under-Secretary of State for Employment Relations and Consumer Affairs, Gerry Sutcliffe, under the powers conferred on him by sections 16(2), 17(1), 26(1)(a), 2(a) and (3), and 48(1) of the Food Safety Act 1990 and section 11 of the Consumer protection Act 1987, and transposes Directive 84/500/EEC (as amended by Directive 2005/31/EC).
- 2.2 These Regulations replace the Ceramic Ware (Safety) Regulations 1988 (1988/1647) and further strengthen food contact material legislation. They do this by improving the ability of enforcement authorities and distributors to check that ceramic articles intended to come into contact with food comply with the existing migration limits for cadmium and lead.
- 3. Matters of special interest to the Joint Committee on Statutory Instruments
  - 3.1 None.

# 4. Legislative Background

- 4.1 The current Ceramic Ware (Safety) Regulations 1988 (covering the UK) implemented Council Directive 84/500/EEC (on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs) and were made under the Consumer Protection Act 1987 (CPA).
- 4.2 Commission Directive 2005/31/EC amends 84/500/EEC by introducing additional provisions to help ensure compliance with the limits for cadmium and lead transferring out of ceramic ware intended to come into contact with food that were set by the earlier Directive. The Ceramic Articles in Contact with Food (England) Regulations 2006 implement Directive 2005/31/EC and are being made under the Food Safety Act 1990, which is now seen as the most appropriate primary legislation for implementing food contact materials Directives.
- 4.3 The basis for Directive 2005/31/EC is Regulation (EC) No. 1935/2004, which came into force on 3<sup>rd</sup> December 2004 and is the core European legislation providing the framework for controlling food contact materials and articles. A transposition note is attached as Annex A.

4.4 The Ceramic Ware (Safety) Regulations 1988 will be revoked across the UK when the Ceramic Articles in Contact with Food (England) Regulations 2006 come into force on 20<sup>th</sup> May 2006.

# 5. Extent

- 5.1 This instrument applies to England only.
- 5.2 Food safety is a devolved policy area. Scotland, Wales and Northern Ireland will therefore be implementing the Directive separately.

#### 6. European Convention on Human Rights

6.1 The Parliamentary Under-Secretary of State for Employment Relations and Consumer affairs, Gerry Sutcliffe, has made the following statement regarding Human Rights:

"In my view the provisions of the Ceramic Articles in Contact with Food (England) Regulations 2006 are compatible with the Convention rights."

# 7. Policy background

- 7.1 Commission directive 2005/31/EC was adopted on 29<sup>th</sup> April 2005 and must be transposed into national law by 20<sup>th</sup> May 2006, though most of the new provisions contained within the Directive will not apply until 20<sup>th</sup> May 2007.
- 7.2 As the Department of Trade and Industry made the original Ceramic Ware (Safety) Regulations 1988 (under the CPA) it was agreed with the Food Standards Agency (FSA) that the Department would implement the Directive in England and that the FSA national offices in Scotland, Wales and Northern Ireland would implement separately based on the English legislation. Separate implementations are required because food safety is a devolved policy area and only the FSA offices can implement this Directive in the devolved regions. Once implementation of the Directive is complete the FSA will take over responsibility for all food safety aspects of the Regulations, which will complete the Agency's control of all food contact materials legislation. Revoking the Ceramic Ware (Safety) Regulations 1988 at the same time the new Regulations are introduced will meet the Government's 'one in/one out' policy objective.
- 7.3 The Directive introduces new provisions that will make it easier for enforcement authorities and distributors to check that ceramic articles intended to come into contact with food comply with the migration limits for cadmium and lead that were set in Directive 84/500/EEC. Notwithstanding that there is currently no evidence of significant non-compliance with the migration limits, the new provisions will facilitate quicker and easier investigation by the enforcement authorities by requiring manufacturers and importers (into the Community) to show on request documentation demonstrating compliance. They will also be required to generate a declaration of compliance for the products they place on the market, which must thereafter accompany the product through to the retail stage (Note. The declaration is not intended for consumers and so does not call for any changes to labelling or packaging). A specific prohibition on manufacturing and importing non-compliant products is also introduced. All of these provisions will apply from 20<sup>th</sup> May 2007.

- 7.4 The provisions in the Directive that will apply from 20th May 2006 include the prohibition on placing non-compliant products on the market and the requirement that products that comply with the Directive's requirements be allowed to trade freely.
- 7.5 We have included appropriate enforcement provisions in the Regulations (i.e. offences and penalties) that are in line with other recent food safety legislation. The port health authorities and the FSA will examine whether there is a need for the powers of the former to be extended in order to enforce the import prohibition, with a view to introducing any necessary changes before 20th May 2007.

# 8. Impact

- 8.1 A Regulatory Impact Assessment is attached to this memorandum.
- 8.2 The impact on the public sector will be negligible and beneficial. The port health authorities will enforce the prohibition on importation during the course of their normal activities. No new burdens are being placed on the food authorities, whose investigations will be helped by the new documentation requirements.
- 8.3 The Directive's requirements were discussed with small businesses during the consultation to ensure that our implementation was proportionate. The only new burden placed on manufacturers and importers (who already comply with the existing requirements) is the need to generate a declaration of compliance with the products they release on to the market, which should need nothing more than a simple addition to invoice documentation. The need to ensure that the declaration accompanies the product at all stages of distribution effectively places a minor burden on distributors to ensure that they acquire the declaration when taking delivery of the product, and ensure that they keep a copy of this.
- 8.4 The English consultation (targeting 200+ contacts) received fewer than ten responses, though meetings were held with a group of small retailers and an accredited testing lab, and a visit was made to one large manufacturer. However, a number of additional responses were received to the Scottish consultation, which included meetings with small craft potters and their representatives. All the responses were shared to ensure maximum return from the consultation exercises. Most responses agreed that we had identified the right issues for implementation, but some small businesses highlighted the need for a proportionate approach to implementing the requirement for documentation and compliance testing, which we believe we have addressed in the accompanying guidance.

# 9. Contact

9.1 Steve Ringer at the Department of Trade and Industry (Tel: 020 7215 0359 or e-mail: steve.ringer@dti.gsi.gov.uk) can answer any queries regarding the instrument.

# The Ceramic Articles in Contact with Food (England) Regulations 2006 Full Regulatory Impact Assessment

#### 1. PURPOSE

- 1.1. The overall policy objective is further harmonisation of European food contact material safety controls.
- 1.2. The Regulations will further reduce the risk of ceramic products that release harmful levels of cadmium and lead entering the UK market, and will do this in a way that reduces the regulatory burden on enforcement authorities while ensuring that the burden placed on businesses is kept to a minimum.
- 1.3. The Regulations will meet the UK's obligation to implement Council Directive 84/500/EEC 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 regarding a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs.
- 1.4. They have been drafted to avoid over-implementation, to maximise internal market benefits for exporters, and to apply the requirements in a proportionate manner. In addition, there is a phased implementation with a 1-year voluntary period before the new requirements for producers and distributors come into force.

#### 2. INTENDED EFFECTS

- 2.1. Directive 2005/31/EC builds on the requirements of Directive 84/500/EEC by introducing provisions that will make it easier for the enforcement authorities, manufacturers, importers and distributors to check that ceramic ware (intended to come into contact with food) does not exceed existing limits for cadmium and lead migration. The Regulations implement these provisions in full.
- 2.2. Manufacturers and importers will now be required to keep and to show (on request) documentation demonstrating compliance with the migration limits. Ceramic articles intended to come into contact with (but not yet in contact with) food will have to be accompanied by a written declaration of compliance at all marketing stages up to and including retail. The declaration is not intended for consumers and therefore does not call for any changes to labelling or packaging. These requirements will enter into force on 20<sup>th</sup> May 2007 and will allow quicker and easier checking by the enforcement authorities. Distributors will also be better placed to check the compliance of products they are looking to supply.
- 2.3. Additionally, analytical testing requirements have been liberalised, with these now defined in terms of performance criteria. This will in theory allow use of alternatives to the previously prescribed atomic absorption Spectrophotometer test.
- 2.4. The Directive requires Member States to allow the free trade of products complying with these requirements from 20<sup>th</sup> May 2006, and further requires a prohibition to be placed on the manufacture and import into the Community of non-

compliant products from 20<sup>th</sup> May 2007. Again, these requirements are implemented by the Regulations. The prohibition on placing non-compliant products on the market (a requirement under Directive 84/500/EEC) will be effective from the 20<sup>th</sup> May 2006.

- 2.5. 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.
- 2.6. Responses to the public consultations carried out in England, Scotland, Wales and Northern Ireland acknowledged that our approach to implementation had picked up on all the key issues addressed in Directive 2005/31/EC and reinforced our view that any new burden introduced by the new Regulations would 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 significant non-compliance with the migration limits.

#### 3. RISK ASSESSMENT

- 3.1. The Regulations are considered uncontroversial. In implementing Directive 2005/31/EC they will introduce measures for ceramic ware articles that are in line with the general requirements of Regulation (EC) 1935/2004.
- 3.2. The burdens on businesses introduced by the new Regulations will be negligible, and could only derive from the need to provide a declaration of compliance. No new burdens are being placed on the enforcement authorities, who already have responsibility for enforcing law in this area. They will not be called upon to undertake 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.
- 3.3. The new requirements will make it easier for businesses to identify when goods are not compliant and to understand the consequences of non-compliance. There are provisions 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.

# 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 29<sup>th</sup> April 2005, and has to be implemented by 20<sup>th</sup> 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 3<sup>rd</sup> 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 require little more than simple compliance with a British technical standard, a requirement that would be incompatible with the Directive's

more flexible analytical requirements. 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 food contact material Directives.

#### 5. CONSULTATION

# **Consultation within Government**

- 5.1. Consultation within central government was carried out primarily with the Food Standards Agency (FSA), which leads on food contact materials generally and will be taking over responsibility for food safety aspects of the new legislation once it comes into force. The Agency's input has helped to ensure that the Regulations are consistent with other food safety legislation and are proportionate in their implementation of the Directive's provisions. We also consulted and cooperated closely with the FSA national offices in Scotland, Wales and Northern Ireland, who are taking forward analogous legislation based on the English Regulations.
- 5.2. Local government interests were explored in consultation with Lacors (the Local Authorities Coordinators of Regulatory Services) and with the Association of Port Health Authorities, who will have responsibility for enforcing the import ban.
- 5.3. The Port Health Authorities (PHAs) have been seeking an extension of their existing powers in relation to materials and articles intended to be brought into contact with food, and have raised this again in relation to ceramic materials and articles. However, this is an overarching issue for all imported food contact materials and articles and it is the Food Standards Agency that leads in that case. The Agency has therefore invited the PHAs to provide evidence as to why the present powers provided in the current legislation do not provide adequate safeguards for public health. Consideration of this will be taken forward separately from the current implementation exercise with a view to resolving any difficulties before 20<sup>th</sup> May 2007, when the prohibition on importing non-compliant products comes into force.

#### **Public consultation**

- 5.4. A formal public consultation was carried out in England between 6<sup>th</sup> December 2005 and 28<sup>th</sup> February 2006 (separate consultations took place in Scotland, Wales and Northern Ireland over roughly the same period). Over two hundred organisations, trade associations and businesses were contacted, but less than ten of these responded. In general, the responses either confirmed our view that the Regulations would not introduce any significant new burdens or indicated a misunderstanding of what was intended. It was nevertheless valuable to see where additional clarification would be helpful.
- 5.5. A meeting was also held with a group of small retailers, whose input helped us to shape a proportionate implementation of the 'declaration' requirement.
- 5.6. The drafting of the Regulations and accompanying guidance also benefited from feedback from the Scottish consultation, particularly so in respect of the views of small manufacturers (e.g. craft potters and one-man operations).

#### 6. OPTIONS

Two main options for implementation were considered:

# Option 1 – Take no action

6.1. This option would have contradicted the Government's commitment to meeting its EU obligations and its policy on consumer protection in this area. It would also have risked 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 have left UK law out of step with the law in the rest of the EU, and UK manufacturers would still have needed to comply with the harmonised rules if they wanted to sell their products in the EU market. This option was therefore 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. While the CPA was technically still available as a possible basis for making the new UK Regulations, we concluded that the subject matter (food safety) was devolved in respect of Scotland, Wales and Northern Ireland, and that the most appropriate primary legislation was now the Food Safety Act.
- B Implementing using s2(2) of European Communities Act (ECA)
- 6.3. This option bore similar consideration to Option 2 in that while the powers available in the ECA allow the making of Regulations covering the UK, the subject matter is nevertheless properly devolved. Cabinet Office guidance also advises strongly against use of the ECA where more appropriate powers are available. Again, this option was 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 was the recommended option in the consultation and was not opposed in any of the comments we received. The implementing Regulations have therefore been drafted in line with this option.
- 6.5. In recognition of the DTI's historic ownership of this legislation, and taking account of current resources, the DTI agreed with the Food Standards Agency (FSA) that it would implement for England, and that FSA national offices would implement separately for Scotland, Wales and Northern Ireland. It was further agreed that once implementation had been completed across the UK, the FSA would take over responsibility for all food safety aspects of the new Regulations.
- 6.6. The current Ceramic Ware (Safety) Regulations 1988 will be repealed at the same time the new Regulations come into force.

# 7. DEVOLUTION

7.1. The Regulations will cover only England. The implication of using the Food Safety Act is that the DTI cannot introduce regulations for Scotland, Wales and

Northern Ireland. Food safety, including food contact materials, was delegated to Scottish and Welsh Ministers. Northern Ireland is not covered by the Food Safety Act and must implement under the Food Safety (Northern Ireland) Order 1991.

#### 8. COSTS AND BENEFITS

# Option 1

8.1. This option would have placed no direct burdens or costs on businesses, though declarations of compliance would still have been needed if businesses wished to trade elsewhere in the EU. Moreover, the UK Government would have risked substantial infraction penalties for failure to implement. Also, enforcement activity would not have benefited from the availability of documentation required by the Directive (e.g. declaration of compliance and requirement to show documentation demonstrating compliance), which would have meant 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 have been the same for each of these sub-options, and are explained below. Option 'A' would have avoided much of the costs the devolved administrations are now facing in taking forward separate implementations.

#### **Economic**

- 8.3. These Regulations will affect all businesses involved in the manufacture, importation and supply of new ceramic ware intended to come into contact with food.
- 8.4. The British Ceramics Confederation estimates that there are around 400 or so producers of ceramic table and ornamental ware in the UK, with around 40 of these trading internationally. It is unlikely however that these figures take into account all the small craft potters, nor the occasional non-business producers, such as evening classes, schools etc. The number of retailing outlets who sell ceramic ware covered by the Regulations is vast but unquantifiable, ranging from supermarkets and departments stores to 'everything for a pound' shops. The sale of UK produced ceramic tableware in 2004 was in the order of £380 million (at ex-factory prices).
- 8.5. The Regulations will introduce no significant new burdens for businesses or the enforcement authorities. There is already a legal requirement to comply with migration limits for cadmium and lead (limits which remain unchanged by these Regulations) and the steps one would take to ensure this testing against British Standard BS 6748:1986, or using only certified lead/cadmium-free glazes and decoration materials would generate documentary evidence sufficient to meet the new requirement to demonstrate compliance. Importers would need to obtain this from the overseas producer.
- 8.6. Lacors reports little evidence of non-compliance with existing ceramic ware legislation. Indeed, large and medium-sized producers in the UK generally test their products as part of the normal production process, with most of the exporting businesses testing to the far more stringent requirements set by California's Proposition 65. Nevertheless, it is accepted that there are probably some producers and importers who are not doing all they should to ensure compliance and will not

therefore have the documentary evidence needed to satisfy the new requirements. For these people the cost of testing might well be faced for the first time. But even in such cases the 'new' cost burden should be slight as tests typically cost in the region of £25 (plus p&p) per product and the results can be taken to apply (within reason) to as many of the manufacturer's products as use the same materials (glazes and decoration) and firing process.

- 8.7. Some small producers (including craft potters and one-man operations) did express concern that the new requirement might call for a greater incidence of testing than was currently the case, and some who worked exclusively with lead/cadmium-free glazes and colours feared that testing would become a mandatory requirement for them for the first time. The guidance to the Regulations will make clear that where there is convincing documentary evidence (including analytical evidence) that only lead/cadmium free materials are used this would be sufficient to satisfy the enforcement authorities. The European Commission has approved this interpretation of the Directive's requirements. Where use of such materials cannot be demonstrated we would consider it reasonable and proportionate to expect a smaller potter to select one or two representative samples from his production for testing.
- 8.8. The new requirement for declarations of compliance would constitute a new burden for all businesses involved in the manufacture, import and distribution of these products, but the effect of this would be negligible. The requirement would be met in the first instance by the manufacturer (or the importer) adding a simple written statement of compliance to the automatically generated invoice documentation, which would require only basic IT skills to set up. Smaller less automated operations would rely instead on simple word-processing/printing solutions in line with their current document generating practices. Thereafter, the requirement on distributors would simply be to ensure that they receive and keep a copy of the document, and that they provide a copy of this with any further distribution of the product. A distributor receiving the product without the declaration would have to produce his own (after confirming the compliance of the product) before he could continue the supply.
- 8.9. Some small retailers were worried that expecting them to obtain declarations of compliance for each product they bought from cash and carry outlets would be a disproportionate implementation of the Directive. We have agreed with Lacors that small retailers in the habit of acquiring small quantities of goods in this way should not need to obtain declarations so long as they keep records of where they obtained the products, and in acquiring the products took reasonable steps to ensure that they were compliant. This would allow the authorities to maintain local contact with a documentary trail leading back to the manufacturer.
- 8.10. The liberalisation of analytical requirements will introduce no new costs for businesses or enforcement authorities. Indeed, the element of choice could well make for easier, quicker and possibly cheaper compliance testing.
- 8.11. The changes introduced by the Regulations will make it easier for the enforcement authorities to check for compliance, which they will continue to do in the course of their normal activities.

#### **Environmental**

8.12. 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

8.13. There are unlikely to be any social costs arising from the Regulations. 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**

8.14. There will be little change in respect of additional costs and burdens to the enforcement authorities. Lacors have 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, there is 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. The declaration requirement will apply to all businesses involved in the manufacture, importation, distribution and retail, though less so for the smaller retailers who source products from cash and carry outlets. 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. SMALL FIRMS IMPACT TEST

10.1. The small businesses covered by these Regulations (manufacturers and distributors) are largely represented through a variety of trade bodies, and a number of these were contacted directly about the English consultation. Others were similarly contacted under the Scottish, Welsh and Northern Irish consultations. The responses received were shared between the implementing authorities. In addition, a number of face-to-face meetings were conducted with small businesses (including small craft potters and small retailers). We consulted the Small Business Service, who acknowledged our approach. Generally, the feedback received from small businesses confirmed our view that no significant new burdens would be introduced as long as a proportionate approach to implementation was adopted.

# 11. COMPETITION ASSESSMENT

11.1. Large-scale manufacture is mainly centred in and around Stoke-on-Trent (the Potteries) but medium/small scale production is more evenly spread around the

country. Distribution of these products involves a vast number of businesses, principally retailers (ranging from department stores to 'everything for £1' shops). The majority of non-EU imports originate from China and will more often than not enter the country via Felixstowe.

- 11.2. The only indicator triggered in the competition filter test was market share, where some manufacturing companies like Wedgwood are prominent. But given that the new requirements will have negligible impact generally there will be no distortion of competition. The provision of enforcement powers to the proper authorities 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.
- 11.3. 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.

#### 12. ENFORCEMENT AND SANCTIONS

- 12.1. The enforcement of the Ceramic Articles in Contact with Food (England) Regulations 2006 will be the responsibility of the food authorities and the port health authorities. The Food Standards Agency will have overall enforcement responsibility.
- 12.2. The Regulations will introduce sanctions for non-compliance that are in line with other recent food safety legislation. In particular, it will be an offence to manufacture, import or place on the market products that do not comply with the migration limits for cadmium and lead. It will also be an offence if a manufacturer or seller fails to provide a declaration of compliance with the product at all marketing stages up to retail, or if a manufacturer or importer fails on request to make available to the authorities documentation demonstrating compliance with migration limits. A person guilty of an offence is liable on conviction on indictment to a fine, or to imprisonment for a term not exceeding two years, or to both. Summary conviction carries the penalty of a fine not exceeding the statutory maximum, or to a term of imprisonment not exceeding 6 months, or to both.
- 12.3. There is little evidence of non-compliance with migration limits (which will remain unchanged) under the current Ceramic Ware (Safety) Regulations 1988, and we have no records of any recent prosecutions in this area.

#### 13. MONITORING AND REVIEW

13.1. 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.

#### 14. IMPLEMENTATION AND DELIVERY PLAN

14.1. The Regulations are being made using powers available in the Food Safety Act 1990 and will replace the current Ceramic Ware (Safety) Regulation 1988 when

they enter into force on 20<sup>th</sup> May 2006. Because food safety is a devolved policy area these Regulations can only cover England. Separate and analogous legislation is being introduced in Scotland, Wales and Northern Ireland. The Food Standards Agency will take over responsibility for all food safety aspects of the legislation when the implementation of the Directive has been completed for the whole of the UK.

14.2. From the 20<sup>th</sup> May 2006 all products complying with the Regulations must be allowed to trade freely. However, the new requirements on businesses – not to manufacture or import non-compliant products, to provide a written declaration of compliance with the product and to show on request documentation demonstrating compliance – will not come into force until 20<sup>th</sup> May 2007, as required by the Directive.

#### 15. SUMMARY AND RECOMMENDATION

15.1. The new Regulations are the most effective means of implementing the amendments to Directive 84/500/EEC and will have negligible impact in terms of new costs and burdens. The Regulations should be approved in time for their entry into force on 20<sup>th</sup> May 2006.

# **16. DECLARATION**

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

# Signed Gerry Sutcliffe

# Date 24th April 2006

Parliamentary Under-Secretary of State for Employment Relations and Consumer Affairs, Department of Trade and Industry Contact point

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

#### TRANSPOSITION TABLE

These Regulations do what is necessary to implement the Directive, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply. These Regulations only apply to England (except in so far as they repeal the previous UK wide implementation of Directive 84/500/EEC). Separate regulations are being made for Northern Ireland, Scotland and Wales.

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 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.

Articles	Objectives	Implementation	Responsibility
Article 1(1) and (2)	Reference to Directive 76/893/EEC and scope of application	Do not require transposition	Secretary of State
Article 1(3)	Defines "ceramic articles"	Regulation 2 – definition of ceramic article	
Article 2(1) and (3) to (5)	Limits on the quantities of lead and cadmium which may be transferred from ceramic articles	Regulation 3(1) and Schedule 1	
2(2) and Annexes I and II (Annex II is replaced by Annex I to 2005/31/EC)	Art 2(2) requires the quantity of lead and cadmium transferred to be determined by a test, the conditions of which are specified in Annex I, using the method of analysis in Annex II	Regulation 3(2) and Schedule 2 Parts 1 and 2	
Article 2a inserted by 2005/31/EC	Requires ceramic articles which are not yet in contact with foodstuffs to be accompanied at the marketing stages by a written declaration containing the information in Annex III.	Regulation 4 and Schedule 3	
Article 3	Procedure for amendment to the Annexes	Does not require implementation	

Articles	Objectives	Implementation	Responsibility
Article 4	Provisions in respect of future work in this field	Does not require implementation	
Article 5	Original implementation dates and transitional provisions	Does not require implementation	
Article 2 of 2005/31/EC	Requires implementing laws to be published by 20 May 2006 and trade in and use of compliant ceramic articles to be permitted from that date and prohibits manufacture and importation in to the Community of non-complaint articles from 20 May 2007	Regulation 4 requires ceramic articles to comply with the Directive's requirements from 20 May 2006. Regulations 3(3)(a) and (b) and 4, which come into effect on 20 May 2007, prohibit manufacture and importation of noncompliant articles and require articles to be accompanied by the declaration of compliance from that date.	