

## EXECUTIVE NOTE

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

S.S.I. 2006/230

#### Description

1. *The above instrument was made under the powers in section 6(4), 16(2), 17(1), 26(1)(a) 2(a) and (3), 31 and 48(1) of the Food Safety Act 1990, section 11 of the Consumer Protection Act 1987 and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency. The instrument is subject to negative resolution procedure.*

#### Policy Objective

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.*

#### Legislative Background

3. 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. 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 (Scotland) Regulations 2006 implement Directive 84/500/EEC as amended and are being made under the Food Safety Act 1990, which is now the most appropriate primary legislation for implementing food contact materials Directives.
5. 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.
6. *The Ceramic Ware (Safety) Regulations 1988 will be revoked when the Ceramic Articles in Contact with Food (Scotland) Regulations 2006 come into force on 20<sup>th</sup> May 2006.*

## **Policy Background**

7. *Commission Directive 2005/13/EC was adopted on 29 April 2005 and must be transposed into national law by 20 May 2006, though most of the new provisions contained within the Directive will not apply until 20 May 2007.*
8. *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.*
9. *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.*
10. *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 enabling products that comply with the Directive's requirements to trade freely.*
11. *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.*

## **Consultation**

12. *Informal and formal consultations have been carried out on the measures and information on the benefits and costs of the legislation to public health and businesses including enforcement authorities is included in the attached Regulatory Impact Assessments. England, Wales and Northern Ireland have carried out their own parallel consultation exercise.*

13. *Consultation in Scotland of around 130 organisations, trade associations and businesses were contacted and 6 responses were received. 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.*

#### **Other Administrations**

14. Similar Regulations will apply in England, Wales and Northern Ireland.

#### **Impact**

15. The impact on the public sector will be negligible and beneficial. No new burdens are being placed on the food authorities, whose investigations will be helped by the new documentation requirements.
16. 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.
- 17 A Regulatory Impact Assessment has been prepared and is available at the address below.

#### **Food Standards Agency Scotland 27 April 2005**

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# **THE CERAMIC ARTICLES IN CONTACT WITH FOOD (SCOTLAND) REGULATIONS 2006            S.S.I. 2006/230G**

## **1. Title of Proposal**

1.1. These Regulations are to be known as The Ceramic Articles in Contact with Food (Scotland) Regulations 2006.

## **2. Purpose and Intended Effect**

### **The Objective**

2.1. The overall policy objective is further harmonisation of European food contact material safety controls.

2.2. 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.

2.3. 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.

2.4. 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.

### **The Effect**

2.5. 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.

2.6. 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.

2.7. 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.

2.8. 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.

2.9. 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.

2.10. Responses to the public consultations carried out in Scotland, England, 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.

### **Other Administrations**

2.11. The Regulations relate to Scotland only. England, Wales and Northern Ireland will make separate, parallel legislation.

### **The Background**

2.12. 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.

2.13. 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.

2.14. 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.

### **Rationale for Government Intervention**

2.15. These proposals fulfil the Government's policy objectives of meeting its EU obligations; of keeping food safe by reducing the risks to consumers from chemical migration; of meeting the Lisbon agenda to improve the competitiveness of businesses in Europe by providing harmonised rules within which business compete; and, of simplifying the laws in Scotland.

2.16. The Food Standards Agency (FSA) believes that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework and ensures consumer protection in relation to food safety.

2.17. Doing nothing would mean that the Government would have failed to implement these policies. It would also create potential for the UK to become liable for infraction proceedings and it would not be possible to implement only parts of this proposal. Businesses in Scotland would have to comply with the proposals being made here if their goods were legally compliant elsewhere in the EU.

## **3. CONSULTATION**

### **With Government**

3.1. Other government departments within the Scottish Executive were made aware of negotiations relating to the Directive through Commission Working Group and Standing Committee meeting.

### **Public consultation**

3.2. A formal public consultation was carried out in Scotland between 19 December 2005 and 14 March 2006 (separate consultations took place in England, Wales and Northern Ireland over roughly the same period. Around 130 organisations, trade associations and businesses were contacted and 6 responses were received. 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.

3.3. A meeting was also held with a group of manufacturers (e.g. craft potters and one-man operations), whose input helped us to shape a proportionate implementation.

## **4. OPTIONS**

Two main options for implementation were considered:

### **Option 1 – Take no action**

4.1. 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 the law in Scotland out of step with the law in the rest of the EU, manufacturers in Scotland 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)**

4.2. 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 as the subject matter was food safety, the most appropriate primary legislation was now the Food Safety Act., which is devolved in respect of Scotland, Wales and Northern Ireland.

#### **B – Implementing using the Section 2(2) of European Communities Act (ECA)**

4.3. This option bore similar consideration to Option A in that whilst 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 Section 17 of the Food Safety Act 1990**

4.4. The Food Safety Act provides the most appropriate powers for implementing the provisions of Directive 2005/31/EC. It specifically covers food contact materials (section 17) 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.

4.5. In recognition of the Department of Trade and Industry's (DTI) historic ownership of this legislation they agreed with the FSA that they would implement in

England. Separate implementation is required because food safety is a devolved matter therefore FSA Scotland will implement the Directive in Scotland. It was agreed that once this had been completed across the UK, the FSA would take responsibility for all food safety aspects of the new Regulations.

4.6. The current Ceramic Ware (Safety) Regulations 1988 will be repealed at the same time the new Regulations come into force.

## **5. Costs and Benefits**

### **Sectors and groups affected**

5.1. The testing provisions apply principally to manufacturers and importers. The declaration requirement will apply to all businesses involved in initial manufacture, importation, distribution and initial retail sale. Rural areas and members of ethnic communities are not discriminated against or specifically adversely affected by the proposal. Both the DTI and the FSA believe that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework ensures food safety and allows for technological innovation.

#### **5.2. Option 1**

5.3. This option would have placed no direct burden 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 2A, B & C**

5.4. The costs and benefits for businesses and enforcement would have been the same for each of these sub options, and are explained below.

### **Economic**

5.5. These Regulations will affect all businesses involved in the manufacture, importation and supply of new ceramic ware intended to come into contact with food.

5.6. The British Ceramics Confederation estimates that there are around 400 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).



5.7. 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.

5.8. 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.

5.9. 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 Regulations and Guidance 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.

5.10. 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 by the manufacturer (or the importer) providing a simple statement of compliance. Thereafter, the requirement on distributors would be to ensure that they retain a copy of the document, and that they provide a copy of this with any further distribution of the product up to the point of initial point of initial retail sale.

5.11. 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 acquiring small quantities of goods 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.

5.12. 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.

5.13. 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**

5.14. 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**

5.15. There are unlikely to be any social costs arising from the Regulations. Consumer protection will continue in an area of food safety where inadequate controls would have serious long-term implications for human health.

### **Costs**

5.16. There will 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, there is no evidence of widespread non-compliance with the migration limits.

## **6. Small Firms Impact Test**

6.1. Many small businesses (manufacturers and distributors) covered by these Regulations are represented through a variety of trade bodies, and a number of these were contacted directly about the Scottish consultation. Others were similarly contacted under the English, Welsh and Northern Irish consultations. The responses received were shared between the implementing authorities. In addition, a number of meetings were conducted with small businesses (including small craft potters and small retailers). We consulted the Scottish Federation of Small Businesses, 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.

## **7. “Test Run” of business forms**

7.1. No specified form required.

## **8. Competition Assessment**

8.1. 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.

8.2. 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.

8.3. 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.

## **9. Enforcement, Sanctions and Monitoring**

9.1. The enforcement of the Ceramic Articles in Contact with Food (Scotland) Regulations 2006 will be the responsibility of the Local Authorities. The Food Standards Agency will have overall enforcement responsibility.

9.2. 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 found 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.

9.3. 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.

9.4. 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 FSA will 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 talk to industry to ensure that no unforeseen difficulties connected with food safety arise from these Regulations.

## **10. Implementation and Delivery Plan**

10.1. 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 Scotland. Separate and analogous legislation is being introduced in England, 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.

10.2. 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.

## **11. Post-implementation Review**

11.1. FSA will continue to consult with Local Authorities, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation. In accordance with the Scottish Executive's IRIS unit guidelines, this RIA will be reviewed, as appropriate, in order to establish that it is "fit for purpose". Therefore not adding any additional burdens to businesses. In line with Scottish Executive guidance we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed with 10 years.

## **12. Summary and Recommendation**

12.1. 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.

## **13. DECLARATION AND PUBLICATION**

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

**Signed by the responsible Minister** .....

**Date** .....

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