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

Guidance for business and food authorities

April 2006

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This document provides a guide to the Ceramic Articles in Contact with Food (Scotland) Regulations 2006 (SSI 2006 No 230). Its purpose is to help users of the Regulations understand their main features and the circumstances in which they apply. Those affected by the Regulations should refer to them for a full statement of the legal requirements, and in case of doubt seek legal advice on questions of interpretation. This guide has no legal force. While every effort has been made to ensure that it is correct the Food Standards Agency Scotland cannot accept liability for any errors, omissions or misleading statements in it.

The Regulations can be obtained from The Stationery Office, Publications Centre, PO Box 29, Norwich NR3 1GN, or through TSO bookshops, or online at <http://www.opsi.gov.uk>

In case of difficulty, enquires can be addressed to:

(For matters concerning food safety)

Food Standards Agency Scotland
Contaminants, Hygiene, Additives & Shellfish Branch
6th Floor, St Magnus House
25 Guild Street
Aberdeen
AB11 6NJ
Tel No 01224 285170
Fax No 01224 285168

(For matters concerning trade)

Department of Trade and Industry
Product Safety
Bay 428
1 Victoria Street
London
SW1H 0ET
Tel: 020 7215 0359
Fax: 020 7215 0357

DTI General Enquiries: 020 7215 5000

1. Introduction

- 1.1. The Ceramic Articles in Contact with Food (Scotland) Regulations 2006 (“the Regulations”) enter into force on 20th May 2006 and replace the Ceramic Ware (Safety) Regulations 1988. The Regulations are made under the Food Safety Act 1990 and transpose Council Directive 84/500/EEC, as amended by Commission Directive 2005/31/EC.

Purpose

- 1.2. Council Directive 84/500/EEC set a limit on the levels of lead and cadmium permitted to transfer out of ceramic articles intended to come into contact with food, and prescribed the method of testing to be used to establish how much lead and cadmium was being transferred. While leaving the migration limits unchanged, Directive 2005/31/EC introduces new provisions that will make it easier for the enforcement authorities and distributors to check that ceramic products comply with these migration requirements.
- 1.3. The Directive (as amended) pursues its principle objective of ensuring that no ceramic product placed on the market and intended to come into contact with food releases harmful levels of cadmium and lead by:
- Requiring manufacturers and importers to show (on request) documentation demonstrating compliance with migration limits;
 - Requiring ceramic products intended for contact with food (but not yet in contact with food) to be accompanied throughout the supply chain (including retail stage) by a written declaration that they comply with all requirements applicable to them;
 - Requiring Member States to prohibit the importation of ceramic products that do not comply with these requirements;
 - Extending the range of analytical methods that can be used to determine migration compliance by defining test method requirements in terms of performance criteria (the test method described in BS 6748:1986 remains a valid test method).
- 1.4. The Regulations implement these new provisions and will apply them as from 20th May 2007. The prohibition on the placing on the market of products that do not comply with the migration requirements set out in Schedule 1 to the Regulations (in common with the requirement under Directive 84/500/EEC) will apply from 20th May 2006.
- 1.5. As required by the Directive, products that comply with the above requirements will be allowed to trade freely from 20th May 2006.

2. Requirement for documentation demonstrating compliance with migration limits

Who does this affect

- 2.1. This requirement applies to manufacturers and importers of ceramic products intended to come into contact with food, but could also be relevant for distributors in certain circumstances. It applies to products first placed on the market on or after 20th May 2007.
- 2.2. Manufacturers would be expected to generate this documentation in the course of establishing (through testing etc) compliance with the migration limits. Importers of products originating outside of the EU would be expected to obtain the documentation from the overseas producer. If the documentation was not available the importer would be expected to test as much of the imported consignment as was necessary to indicate that it complied in its entirety with the migration requirements before the goods could be released on to the market.
- 2.3. A Distributor who did not have a declaration of compliance required under Regulation 4(1) (see below under section 3), and was unable to obtain one from the manufacturer/importer, would be expected to produce his own after having first tested the product for compliance with migration limits. This should be done before any further distribution, or supply to consumers.

What is required

- 2.4. Regulation 4(3) requires manufacturers and importers to show on request (to the enforcement authorities) documentation demonstrating that the ceramic articles they have released on to the market comply with the migration limits for cadmium and lead set out in Schedule 1 to the Regulations. The Regulation also indicates that this documentation should include (as appropriate) the test results, test conditions and contact details for the testing laboratory.
- 2.5. The documentation required will depend on whether the manufacturer has used only certified cadmium and lead-free materials, and can either demonstrate this by producing a test certificate or at the very least ensure that this is readily available from the material supplier (precisely what should be required in a given situation should be discussed with the local food authority). Where such materials have been used exclusively and there is documentation to evidence this that should normally be sufficient to satisfy the requirement. Where lead/cadmium-free materials have not been used, or where the documentation demonstrating this is not available, or is less than totally convincing as to the level of cadmium/lead content, it would be expected that compliance with migration limits would be established by testing in line with the technical requirements laid out Schedule 2 of the Regulations.

- 2.6. It is acknowledged that most ceramic manufacturers systematically test their products as part of the normal production process, or keep appropriate documentation on the use of cadmium/lead-free materials. This requirement should introduce no new burdens for these businesses.

How much testing is expected

- 2.7. As a general principle, each product in a manufacturer's range that uses glazes and/or decorating materials different from those already tested should be tested, and in each case 'worst case' samples should be selected for testing. That is to say samples that have the greatest surface area and the greatest area of decoration. A different firing setting or changes to the production process should also be considered a prompt for additional testing. The use of different under-glaze materials should not necessitate extra testing.
- 2.8. The expectation for the very small producers (e.g. the craft potter, one-man operations etc) is more flexible and proportionate. These businesses, whose production processes, product ranges and use of materials is typically more varied than that of the larger producer, would find testing to the frequency indicated above disproportionately burdensome. For this reason the Agency has agreed with the enforcement authorities that the very small producers, particularly those producing experimental designs and those who mix their own glazes and colours, should be expected to test a small representative sample of their work each year. In some case (best discussed with the local food authority) one sample might be deemed to be sufficient.
- 2.9. For some non-business producers who produce small quantities on a part-time/ad hoc basis and occasionally make these available for sale, such as schools and evening classes, testing is likely to be both financially burdensome and less likely to convince in terms of it being representative of all production. For these producers it would probably be more sensible to use only certified lead/cadmium-free materials.

Who can carry out testing

- 2.10. Testing for lead/cadmium migration can be carried out at any accredited test laboratory, and at the time of writing (April 2006) tests typically costs in the region of £25-£30 (+p&p) per product. For up to date information on the facilities providing this service in the UK contact:

United Kingdom Accreditation Service (UKAS)
21-47 High Street
Feltham
Middlesex
TW13 4UN

Tel: +44(0) 20 8917 8400
Fax: +44(0) 20 8917 8500
Email: info@ukas.com

3. Requirement for Declaration of Compliance

Who does this affect

- 3.1. This requirement applies to manufacturers, importers, distributors and retailers of ceramic products intended to come into contact with food.

What is required

- 3.2. The declaration is not intended for consumers and so does not call for any changes to labelling or packaging. Its purpose is to provide the enforcement authorities and distributors with the means to check that ceramic products comply with lead/cadmium migration requirements.
- 3.3. Manufacturers and importers would be expected to produce a declaration in line with the requirements set out in Annex A, and to provide this with every consignment of the covered products released on to the market. The declaration could cover as much of the manufacturers product range as uses the same materials and firings.
- 3.4. Distributors (including retailers) should ensure that they obtain a valid declaration(s) with every delivery, and should provide a copy of this when supplying to other distributors or retailers.
- 3.5. For some smaller retailers who obtain their stock from cash and carry businesses the requirement to obtain and keep declarations for every range of product would be disproportionately burdensome. It has therefore been agreed with the enforcement authorities that in these instances a declaration would not be required as long as the retailer took reasonable steps to ensure that the products were compliant (e.g. asking to see declarations) and kept records of where they obtained the goods. The latter would enable the authorities follow a document trail back to the manufacturer.
- 3.6. Other instances when a declaration would not be needed include where a declaration for the same product (or product range) was already held, and within a retail chain the documents were held centrally.

4. Other information

Second-hand products

- 4.1. The Regulations do not apply to second-hand products (i.e. articles that are at the second point of retail).

Enforcement

- 4.2. The enforcement of the Regulations will be the responsibility of the Food Authorities identified in Part 1, section 5 of the Food Safety Act 1990.

Offences and Penalties

- 4.3. The Regulations introduce sanctions for non-compliance, which are in line with other recent food safety legislation.
- 4.4. From 20th May 2006, it will be an offence to place on the market products that do not comply with the migration limits for cadmium and lead. From 20th May 2007, it will be an offence to manufacture or import non-compliant products. From the same date it will also be an offence if a manufacturer or a supplier 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.
- 4.5. 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 £5,000, or to a term of imprisonment not exceeding 6 months, or to both.
- 4.6. In proceedings for an offence in respect of failure to produce on request documentation demonstrating compliance, or of failing to accompany an article with a declaration of compliance, it will be a defence to prove that the article was first placed on the market in the Community before 20th May 2007. Additionally, and in reference to Article 12 of Regulation (EC) No 178/2002, where it is alleged in proceedings for an offence that a ceramic article already in contact with food failed to meet the migration requirements specified in Regulation 3(1), or failed to be accompanied by a declaration of compliance, the person charged may raise the defence (under Regulation 6A of the General Food Regulations 2004 as amended) that the article was intended for export to a state outside of the Community which has legislation analogous to the these Regulations and that the article complied with such legislation. This latter defence, however, does not extend to ceramic articles that are not yet in contact with food.

Changes to existing legislation

- 4.7. These Regulations, and their equivalent in England, Wales and Northern Ireland, replace the Ceramic Ware (Safety) Regulations 1988, which are revoked for the whole of the UK.
- 4.8. In the Official Feed and Food Controls (Scotland) Regulations 2006, sub-paragraph (b) of Schedule 3 (Definition of relevant food law) is amended by the omission of the words “except in so far as it involves the regulation of food contact materials under the Ceramic Ware (Safety) Regulations 1988”.

Declaration of Compliance

The written declaration referred to in Regulation 4(1) of the Ceramic Articles in Contact with Food (Scotland) Regulations 2006 shall contain the following information:

1. the name 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:
 - a) Regulation 4 of the Regulations; or
 - b) 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
 - c) Regulations (EC) 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.

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