

EXPLANATORY MEMORANDUM TO
THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND)
REGULATIONS 2012

2012 No. 2619

1. This explanatory memorandum has been prepared by the Food Standards Agency (FSA) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument provides for the execution and enforcement, in England, of the provisions of Commission Regulation (EU) No. 10/2011¹ (“the new EU Regulation”) of 14 January 2011, on plastic materials and articles intended to come into contact with food.

2.2 This instrument also revokes 4 sets of Regulations and consolidates into one Statutory Instrument nearly all existing national legislation on materials and articles intended to come into contact with food, with the exception of the Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011². (These Regulations put in place additional import controls for plastic kitchenware originating from China and will be periodically reviewed by the European Commission, taking into account information received from Member States.)

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The general principles governing the safety of all materials and articles intended to come into contact with foods are established in Regulation (EC) No. 1935/2004³ of the European Parliament and of the Council (“the framework Regulation”). This lays down the framework of regulation of all such materials and articles intended to come into contact with foodstuff. The new EU Regulation is a specific measure within the meaning of Article 5(1) of the framework Regulation and establishes specific rules for plastic materials and articles intended to come into contact with foods. The new EU Regulation repeals Commission Directive 2002/72/EC and all its amendments on plastic materials and articles intended to come into contact with foods. The Directive laid down the rules for the manufacture of plastic materials and articles; it has been the subject of substantial amendments spanning ten years. The Plastic Materials and Articles in Contact with Food (England) Regulations 2009⁴ implemented the provisions of Directive 2002/72/EC.

4.2 Directive 2002/72/EC was most recently amended in late November 2010 by Commission Directive 2011/8/EU, which introduced restrictions on bisphenol

¹ OJ Ref L12, 15.1.2011, pg 1-89

² SI No 2011/1527

³ OJ Ref L338, 13.11.2004 pg 4-17

⁴ SI No 2009/205

A (BPA). Once the new EU Regulation came into force it was amended by Commission Implementing Regulation (EU) No. 321/2011⁵ as regards the restriction of the use of BPA in plastic infant feeding bottles, which carried forward the restrictions originally contained in Directive 2011/8/EU. This ensured continuity of the prohibition of BPA in infant feeding bottles.

5. Territorial Extent and Application

- 5.1 This instrument applies to England only.
- 5.2 Separate but parallel legislation is being made to provide for the execution and enforcement of the new EU Regulation in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- *What is being done and why*

- 7.1 Unregulated chemical migration from food contact plastics may potentially create negative cost to others such as the National Health Service, through detrimentally affecting consumer health. Consumers are unable to assess the risks involved when consuming a product because they cannot observe the level of chemical migration and do not have full information on the production methods. Therefore, they cannot make informed choices about such risk. Legislative intervention, through European legislation that is regularly updated and implemented in the domestic law of the UK and other Member States, is necessary to reduce the risks to health and provide for consistent enforcement across the single market.
- 7.2 Providing for the execution and enforcement of the new EU Regulation provides for the continuation of consumer protection against exposure from chemicals that could migrate into food, which could carry serious long term and unacceptable risk to consumer health, particularly amongst vulnerable people. The new EU Regulation updates and replaces all the existing rules on food contact plastics into a single European Regulation.
- 7.3 The legislation also aims to protect the nature and quality of the food concerned; to provide clear and consistent conditions for the trade in goods and to provide the enforcement authorities and industry with one set of harmonised rules that apply throughout the EU, instead of a plethora of different national rules in each of the twenty seven Member States. It is also our aim to simplify the way the rules governing these materials and articles are presented in England to make them as plain as possible to those that need to refer to them.
- 7.4 This latter objective is in response to the UK Government's Red Tape Challenge (RTC) exercise, in which the Food Standards Agency (FSA) in

⁵ OJ Ref L87, 2.4.2011, p1

relation to food contact materials is committed to revoking 4 sets of Regulations and developing in England a simplified system of food safety legislation. Currently there are three separate principal SIs (and one amending SI), which contain the rules on food contact materials, which can be difficult for those that need to cross-refer to their various provision; having the rules in one SI will therefore benefit stakeholders.

7.5 The England national Regulations being revoked are

- a) The Plastic Materials and Articles in Contact with Food (England) Regulations 2009⁶
- b) The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011⁷
- c) The Materials and Articles in Contact with Food (England) Regulations 2010⁸;
- d) The Ceramic Articles in Contact with Food (England) Regulations 2006⁹, which implement the provisions of Council Directive 84/500/EEC¹⁰, as amended by Commission Directive 2005/31/EC¹¹

8. Consultation outcome

Informal Consultation

- 8.1 During the course of negotiations with the Commission, FSA officials have frequently conveyed information to interested organisations, including, industry, research institutes, consumer groups, enforcement bodies, public analysts and others with an interest in policy issues related to food contact materials. Consultations on the harmonised rules on food contact plastics have been conducted in seven recent years; 2002, 2004, 2005, 2006, 2007, 2008, 2009 and 2011, when the rules on food contact plastics were last amended.
- 8.2 Two informal consultations on the proposed new EU Regulation were carried out; the first in 2004 and the second in 2009. Industry welcomed the proposed consolidation of the plastics legislation into a single European Regulation, simultaneously applicable in all Member States, noting that the process of compliance demonstration would become much simpler. They also welcomed the introduction of the text in Article 18 of the new EU Regulation, which recognises the use of internationally recognised scientific principles for risk assessment of non-intentionally added substances and non-listed substances. This would result in industry possibly being able to use exposure-based risk assessments.

⁶ SI 2009 No. 205

⁷ SI 2011 No. 231

⁸ SI 2010 No. 2225

⁹ SI 2006 No. 1179

¹⁰ Council Directive 84/500/EEC on the approximation of laws of the Member States relating to Ceramic articles intended to come into contact with foodstuffs

¹¹ Commission 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.

- 8.3 Any comments received from interested organisations have, where appropriate, been incorporated into the UK's negotiating line.

Formal Public Consultation

- 8.4 The FSA conducted a formal public consultation from 10th January to 3rd April 2012, seeking comments on the draft consolidated instrument. Eighty two stakeholders were consulted on these proposals; these included food industry organisations, sector specific organisations, consumer groups, non-government organisations, local enforcement authorities (including port health authorities), public and independent laboratories and others with an interest in food contact materials legislation.
- 8.5 The FSA received 9 responses to the consultation, from Port Health Authorities (PHAs), Trading Standards Institute (TSI), one from the Government Chemist and five from industry. Comments mainly focused on the estimated costs associated with the draft consolidated Regulations, as reflected in the Impact Assessment (IA).
- 8.6 There were several comments on the draft Regulations from Port Health Authorities (PHAs) and industry on drafting detail and these have been acted upon where necessary.
- 8.7 Stakeholders were asked to comment on whether the proposed consolidated food contact materials (FCM) Regulations would make it easier for businesses and other stakeholders to find the legislation that affects them and if new entrants to the FCM sector will benefit from these proposals. Enforcement authorities and industry were generally in support of the proposed consolidation of nearly all the FCM national legislation into a single statutory instrument. They also agreed that new entrants to the FCM sector will benefit from the consolidation of several pieces of legislation. The ceramics sector felt however, that it will not make it easier for businesses to refer to a single set of Regulations, as they would still need to refer to the two different documents rather than one, as the verification of compliance of their products is contained in the original EU legislation and not the consolidation Regulations. However, the need to cross-refer to EU legislation is the case with all sectors of the FCM manufacturing industry and is unavoidable.
- 8.8 There was a general consensus amongst industry that familiarisation costs highlighted in the IA were a reasonable assessment, adding that a small number of businesses may ask their FCM suppliers for new declarations of compliance (DoC) that make specific references to the new consolidated Regulations; however, the majority of food packaging manufacturers are content to accept DoCs that refer to EU legislation only.
- 8.9 Comments received from enforcement bodies indicated that 2 hours was a reasonable estimate for familiarisation and for the dissemination of information on the Regulations, but PHAs observed that more time may be required for internal procedures/document changes; should these be required and that staff may need further time to understand the changes. Even when legislation is simplified, there is a familiarisation cost for enforcement bodies. Consideration needs to be given as to what is covered by the new legislation and which legislation previously covered it.

- 8.10 Industry was also asked to comment on whether the number and types of businesses identified in the IA were an accurate reflection, of those that are likely to be impacted by the new consolidated Regulations. Although industry agreed that the assessment was an accurate reflection, they felt that perhaps end-users, such as fillers and packers should also be included. Since food packers using plastic materials or articles need compliance documentation from their suppliers. If these categories were included, the number of businesses affected by the proposals would increase from the number identified in Table 4 of the IA.
- 8.11 Stakeholders were also asked to comment on the omission of regulations 11 and 12 and regulations 8 and 9 of the current 2010 Regulations from the proposed consolidated Regulations, as they are considered to have become obsolete. Enforcement bodies concurred that regulations 11 and 12 and 8 and 9 were no longer necessary and could be omitted from the consolidated Regulations. However, whilst industry in general agreed that regulations 11 and 12, and regulation 9 could be omitted, some of those responding suggested that the omission of regulation 8 may prevent the FSA or enforcement bodies from taking action on the use of vinyl chloride in certain circumstances and requested that the FSA reconsider the removal of the legal limits transposed from Directive 78/142/EEC, which are currently laid down in regulation 8.
- 8.12 Following comments from stakeholders on the omission, a different approach has been taken and only regulation 9 has been omitted from the consolidated Regulations, with regulation 8¹² being re-enacted in a modified form.
- 8.13 Stakeholders were asked to provide evidence to support their views in relation to additional costs, over and above their normal commercial activities, of the proposed Regulations. However, none were able to quantify the additional costs in their comments or provide evidence to support their views.
- 8.14 Comments received in response to the consultation have been reflected, where necessary, in the Impact Assessment attached to this memorandum.
- 8.15 A full summary of the comments received in response to the consultation will be published on the FSA's website.

9. Guidance

- 9.1 The European Commission has produced Guidance on the new EU Regulation to assist businesses and enforcement bodies. The Guidance, when published will be available on the Commissions website at:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

10. Impact

- 10.1 As set out in the Impact Assessment, the proposed consolidated Regulations will affect UK manufacturers of plastic materials and articles intended to come into contact with food (including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment).

¹² Note: the FSA will review this in the near future, as and when the Commission decides to repeal Council Directive 78/142/EEC and will take appropriate action.

They will also affect importers, retailers, including retailers of food beverage products, supermarkets, food stalls, food markets, as well as retail of food and beverages in specialised stores. For this sector, there will be a one-off cost for reading and familiarising with the new consolidated Regulations and the requirements of the new EU Regulation.

- 10.2 Local Authorities (LAs), PHAs and official control laboratories (OCLs) will also be affected by this policy as they will be required to read and familiarise themselves with the new EU Regulations, since they are responsible for enforcing food safety legislation in their respective areas or districts. There will be a one-off cost for this.
- 10.3 In addition, there will be a one-off cost to OCLs also for reading and familiarising with the changes to testing requirements, as outlined in the requirements of the new EU Regulation.
- 10.4 There is no particular impact on charities or voluntary bodies, rural areas or on members of the ethnic communities of any particular racial group that can be identified. No comments were received from such bodies on the effects of the proposal on them.
- 10.5 As regards the public sector, there may be an impact on Enforcement Authorities and the FSA in the form of administrative costs associated with intervention in support of businesses achieving compliance with the EU Regulation.
- 10.6 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11 Regulating small business

- 11.1 The instrument will apply to all businesses, small and large.

12 Monitoring & review

Monitoring

- 12.1 The Agency will work with Local Authorities and Port Health Authorities where problems arise or suspected infringements of the instrument arise. The effectiveness of the instrument will be also be monitored via general feedback from industry and Enforcement Authorities.

Statutory Review

- 12.2 The FSA is required to carry out a review of this instrument every five years. The review period begins when this instrument comes into force.
- 12.3 In carrying out the review, the FSA is required to produce a report that sets out the objectives of this instrument, the extent to which they have been achieved and whether they could be achieved by means that impose less regulation. Information gathered via the activities described in paragraphs 11.1 above will inform the review.

13 Contact

- 13.1 Nasreen Shah at the Food Standards Agency, Tel: 020 7276 8538, Email: nasreen.shah@foodstandards.gsi.gov.uk, can answer any queries regarding the instrument.