



	Guidance On The Plastic Materials And Articles In Contact With Food (England) Regulations 2009	
	Version 1 December 2008	

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Summary

Intended audience:	The aims in producing this guidance are to help those that manufacturer, use, import or sell food packaging materials and articles made from plastic for use in contact with food.
Regional coverage:	The guidance notes provide a short summary of the changes introduced by the new English Regulations only.
Legal status:	These guidance notes have been created to give informal, non-binding advice on some of the legal requirements of The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 and should be read in conjunction with the legislation itself.
Purpose:	These guidance notes provide a short summary of the changes introduced by the new Regulations.

REVISION HISTORY

Revision No.	Revision date	Purpose of revision	Revised by
1		Regulatory Guidance	

Regulatory Guidance on The Plastic Materials and Articles in Contact with Food (England) Regulations 2009

CONTENTS

INTENDED AUDIENCE	5
PURPOSE AND LEGAL STATUS	5
WHY YOU SHOULD READ THIS NOTE - COMPLIANCE	6
THE EUROPEAN LEGISLATION	7
DETAIL7	
CHANGES TO THE ENGLISH REGULATIONS	9
SUMMARY OF CHANGES	9

Regulatory Guidance on The Plastic Materials and Articles in Contact with Food
(England) Regulations 2009

INTENDED AUDIENCE

1. This guidance is aimed primarily at businesses (including SMEs, which may either use the guidance directly or learn about it via trade associations or enforcement authority contacts) that manufacture, use, import or sell materials and articles made from plastic that are intended for use in contact with food. It may also be of use to others with an interest in the legislation, such as enforcement authorities. These guidance notes provide a short summary of the changes proposed by the new Regulations in so far as they apply to England only. The devolved administrations in Wales, Scotland and Northern Ireland will make separate but parallel legislation.

PURPOSE AND LEGAL STATUS

2. These guidance notes have been produced to provide informal, non-binding advice on some of the legal requirements of The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 and should be read in conjunction with the legislation itself. The text should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power. Every effort has been made to ensure that these guidance notes are as helpful as possible. However, it is ultimately the responsibility of individual businesses to ensure their compliance with the law. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/environmental health department of the local authority.

WHY YOU SHOULD READ THIS NOTE - COMPLIANCE

3. Within the European Union, it is the responsibility of the manufacturer, importer, distributor or seller of food contact materials and articles, or those who place them in contact with food prior to sale, to ensure that their products comply with the appropriate legislation. Unlike the system administered by the Food and Drug Administration (FDA) in the United States of America that many businesses will be familiar with, there is no system of prior approval or authorisation of food contact materials within the EU. Instead of approving the product, constituents of the materials, such as monomers and other starting substances and additives used for a technical effect on the polymer, are subject to specific, conditional authorisation at EC level.
4. In the event of prosecution for an alleged offence under these Regulations, defendants may seek to avail themselves of the defence of 'due diligence' provided for at regulation 20 of the Regulations. In order to succeed, such a defence requires proof that the defendant had taken all reasonable precautions to avoid committing the alleged offence, including, probably, documentary evidence purporting to show that the goods complied with the law and on which it was reasonable for the defendant to have relied. It is in any event a legal requirement that any business which places on the market relevant goods or substances prior to the retail stage provides such documentary evidence to support the mandatory declaration of compliance with the law. The detail of this requirement is set in Schedule 4 to the Regulations, as read with regulation 14.

THE EUROPEAN LEGISLATION

5. The European Commission and the Member States of the European Union are working towards a fully harmonised set of rules that will apply to food contact materials and articles across the EU. The aim is to protect consumers from any harmful effects of eating food contaminated by chemicals that might have migrated from materials and articles with which the food had been in intentional contact or from which it might reasonably be expected that a substance might migrate into the food. In addition to protecting consumers, this harmonisation will provide businesses with one set of rules to comply with throughout the EU instead of a plethora of national rules in different EU Member States. Since the principal legislation on plastic food contact materials and articles was introduced in 1990, it has been regularly amended as better scientific understanding has developed about the nature and detection of chemical migrants from food contact materials and articles.

DETAIL

6. EC Directive 2008/39/EC (“the amending Directive”) amends Commission Directive 2002/72/EC on plastic materials and articles intended to come into contact with food (“the Directive”) for the fifth time. The amending Directive lays down the dates by which the list of additives in food contact plastics will be closed and makes interim arrangements for those additives for which an application for authorisation had been made by the deadline of December 2006. It also sets a deadline of 31st December 2009 up to which additives not on the positive list may continue to be used and prohibits their use from 1st January 2010. This period until December 2009

Regulatory Guidance on The Plastic Materials and Articles in Contact with Food (England) Regulations 2009

will enable EFSA to obtain any additional information it may need for its risk assessment of those additives on the provisional list.

7. The amending Directive required that the European Commission publish its provisional list of those additives that are subject of an application for authorisation by 11th April 2008 and that the list be kept up-to-date. However, an additive will be removed from the provisional list either when it is included in the positive list, or if additional information asked for by EFSA is not provided. The list has been published and is available on the Commission's Website and can be accessed at http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm
8. For certain substances, the restrictions already established at Community level have been amended on the basis of new information becoming available. As such Annexes II, III, IVa, V and VI of Directive 2002/72/EC are amended accordingly. The amending Directive also:
 9. Permits the trade and use of plastic materials and articles intended to come into contact with food and complying with Directive 2002/72/EC, as amended by the amending Directive from 7th March 2009.
 10. Prohibits, as from 7th March 2010, the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food that do not comply with Commission Directive 2002/72/EC, as amended by the amending Directive.

CHANGES TO THE ENGLISH REGULATIONS

11. The proposed Plastic Materials and Articles in Contact with Food (England) Regulations 2009 that are the subject of this guidance, implement the amending Directive detailed above. The Regulations will revoke the Plastic Materials and Articles in Contact with Food (England) Regulations 2008 and remake them with necessary amendments. This continues our practice of ensuring that, apart from occasional short term measures, we only have one set of Regulations in relation to the law on food contact plastics in England.

SUMMARY OF CHANGES

12. The table below provides summary details of how the individual Articles in the amending Directive have been implemented in the Regulations

Articles and Annexes of Directive 2008/39/EC	Objectives	Implementation in the Plastic Materials and Articles in Contact with Food (England) Regulations 2009
Article 1(1) amending Article 4 of Directive 2002/72/EC	Article 1(1) inserts a new first paragraph at Article 4 relating to the Community list of additives which may be used for the manufacture of materials and articles, together with the restrictions and/or specifications on their use, as set out in Annex III	These provisions are implemented in Regulation 5 – paragraphs (1) and (2) have been amended (these set up a prohibition on using any additive other than one in the Community list of additives. A new paragraph (3)(a) has been added to create a time limit for materials and articles made in other MS not on the Community list may continue to be used.

Regulatory Guidance on The Plastic Materials and Articles in Contact with Food (England) Regulations 2009

<p>Article 1(2) amending Article 4a of Directive 2002/72/EC</p>	<p>Article 1(2) amends Article 4a by replacing paragraphs 3 and 4. Paragraph 3 states that a provisional list of additives that are under evaluation by the Authority shall be made public by the Commission and shall be kept updated. Paragraph 4 states that by way of derogation from the third sub-paragraph of Article 4(1), additives not included in the Community list referred in that Article may continue to be used subject to national law after 1st January 2010 for as long as they are included in the provisional list.</p>	<p>Paragraph 4 of the amended Article 4a the only provision requiring implementation here, and is implemented by Regulation 5(3)(b), which gives effect to the derogation for additives that are on the provisional list pending a decision on Community authorisation.</p>
<p>Article 1(3) and Annexes I to V amending Annexes to Directive 2002/72/EC</p>	<p>Article 1(3) Makes changes to the lists of approved substances and related specifications annexed to Directive 2002/72/EC</p>	<p>Implementation is unnecessary as the Annexes are implemented by ambulatory reference in UK legislation</p>
<p>Article 2(1)(a)</p>	<p>Article 2(1)(a) requires Member States to permit the trade in and use of plastic materials and articles intended to come into contact with food that comply with the provisions of Directive 2002/72/EC as amended by Directive 2008/39/EC from 7th</p>	<p>The coming into force of the Regulations on 7th March 2009 has the effect of meeting this requirement.</p>

	March 2009.	
Article 2(1)(b)	Article 2(1)(b) prohibits the manufacture and import into the Community from 7 th March 2010 of plastic materials and articles intended to come into contact with food and which do not comply with Directive 2002/72/EC, as amended by Directive 2008/39/EC	The provision is implemented by Regulation 5(3) as read with regulation 3(2) and Schedule 5 (transitional arrangements)

FURTHER INFORMATION

12. If you have any questions about these or any other Regulations governing food contact materials and articles, please contact:

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13. Other information about food contact materials is available from the Agency's website at:

www.food.gov.uk/industry/foodcontactmaterials

14. The information that is available includes explanatory notes and guidance notes on all food contact material legislation and United Kingdom research

Regulatory Guidance on The Plastic Materials and Articles in Contact with Food (England) Regulations 2009

and development and chemical surveillance on food contact materials.

The results of completed surveillance can be viewed from this point at:

<http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/contactmaterials/>

15. Although work predating the formation of the Agency can be accessed from the site archive, you can also access information about the work of The Working Party on Chemical Contaminants from Food Contact Materials in determining and reviewing work on research and development in this area.