Guide to United Kingdom
Legal Compliance and
Good Practice for
Business Documentation

MATERIALS AND ARTICLES IN CONTACT WITH FOOD

June 2009

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CONTACT TELEPHONE 0207 276 8553 or 8594

Summary

Intended audience:	This guide is relevant to companies that, in the course of their business, manufacture and/or use materials and articles intended to come into contact with food, or that could be brought into contact with food or that could be the source of chemical migration into food. These companies range from large to small in size and scale of operation and include material and article manufacturers, their raw material suppliers (such as those that supply polymer resins), material recyclers, converters, packers and fillers, importers and sellers on the market prior to the point of retail sale. It is also relevant to environmental and port health and trading standards officers involved in the enforcement of the law governing these materials and articles.
Regional coverage:	This guide is for those businesses and enforcement officers that operate in the United Kingdom, and refers to parallel legislation in England, Scotland, Wales and Northern Ireland where appropriate.
Legal status:	This guide is just that. It is not a legal text. It is intended to: • be used in conjunction with the regulations it names; and, • address issues of good practice as highlighted in the following pages.
Purpose:	This guide addresses • the legal requirements of Regulation (EC) No. 1935/2004 on materials and articles in contact with food in relation to business documentation as it is required in conjunction with Regulation (EC) No. 2023/2006 on good manufacturing practice; • particular requirements in specific EU measures enacted in legislation across the UK dealing with declarations of compliance as they apply to the materials that are the subject of those measures; and • good practice in this area.

FOREWORD

This guide is not a substitute for knowing what the law requires from those who enforce it and those who trade in goods that are the subject of it. It should be read in conjunction with the legislation.

The author has had the privilege of representing the UK in European negotiations on this legislation for the past nine years. He has also had the privilege of working with many British and European experts in doing so. This Guide deals with the requirements laid down by the law as it was intended at the time it was adopted by the Authorities across the European Union as the protecting and harmonising EU legislation that it is.

In producing this Guide, the author and the Food Standards Agency gratefully acknowledges the considerable time and effort taken by those who responded to the public consultation that was held from January to April 2009. Those comments have done a considerable amount to confirm the broad approach taken in providing the Guide and to improve the amount and relevance of its detail. Comments were received from the following individuals and organisations:

Enforcement Bodies

East of England Trading Standards Association
Laboratory of the Government Chemist
*Slough District Council
*Suffolk Port Health Authority
*West Wiltshire District Council / Wiltshire Council

Private Individual

Mr. Richard Armstrong

Professional Bodies & Businesses

British Ceramic Confederation
British Coatings Federation
British Glass
British Printing Industries Federation
EBLEX-BPEX
Food and Drink Federation
Metal Packaging Manufacturer's Association
Packaging and Films Association
Sun Chemicals
West Wiltshire Food Industry Technical Manager's Liaison Group

*Following a workshop for Local Authorities and businesses on Declaration of Compliance documentation, held by the Agency on 12th November 2008, these enforcement authorities ran campaigns to test business awareness of the requirements discussed in this Guide and to try the guide out in real conditions of use. We are grateful for what they have achieved in helping us to make the Guide more usable and relevant to businesses and enforcement authorities around the country.

Richard Sinclair.
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London.
June 2009.

REVISION HISTORY

Revision No.	Revision date	Purpose of revision	Revised by
1	January 2009-	Resolve legal reference mis-numbering in Annex.	Richard Sinclair
2	30March 2009	Incorporation of early consultation responses.	Richard Sinclair
3	3 April 2009	Incorporation of more consultation responses.	Richard Sinclair
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6	6 May 2009	Editorial	Richard Sinclair
7	18 May 2009	Editorial	Richard Sinclair
8	29 May 2009	Editorial and legal tables	Richard Sinclair
9	8 June 2009	Final editorial and contacts	Richard Sinclair

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LEGAL STATUS

1. You should read this guide in conjunction with the legislation itself. A table of relevant sections of the legislation is provided at Annex 3. The guide on legal requirements should not be taken as an authoritative statement or interpretation of the law, as only the courts can do this by establishing case law. It is ultimately the responsibility of individual businesses to ensure the compliance of their products with the law. Compliance with the advice on good practice in this Guide is **not** required by law, though adoption of the good practice advocated in this Guide could help minimise inspection and enforcement burdens on the business. It may also have a range of further benefits influencing, for example, customer service, trading reputation, staff commitment to the values of the business, corporate risk management and strategic planning. **To distinguish between the two types of information, all advice on good practice is in shaded boxes, with a heading of 'Good practice'.**

2. Businesses with specific queries may wish to seek the advice of their local enforcement agency, usually the trading standards/environmental or port health department of their local authority.

INTRODUCTION

3. This guide is based on the legal requirement for ensuring that only safe food contact materials and articles are placed on the market in the United Kingdom and, in a wider context, the European Union. The term 'placing on the market' is used in the wider context of making the product available to a customer, including a business customer: it is not confined to the point of retail sale. The area of the law with which this guide concerns itself lays down requirements to ensure that any migration of chemicals from food contact materials and articles into food is at levels that do not harm human health nor detrimentally affect the nature or quality of the food. It focuses on the requirements to document good manufacturing practice procedures and the legal compliance of goods down the manufacturing and supply chain. This is a principle means of control for both the business operator and for the enforcement authorities.

4. Foods come into contact with many different materials during preparation, processing, packing and transportation. These materials are used in the machinery that prepares and processes the food, packages the food and to

serve the food to the consumer. Much of the equipment used in food preparation and processing uses many materials in its construction, while packaging also often consists of several layers of different materials.

5. Within the European Union there is detailed legislation that controls the migration of chemicals into food from food contact materials and articles and that legislation is fully implemented in the United Kingdom. The legislation is routinely amended to keep it up to date as scientific understanding and laboratory techniques improve and develop. The legislation exists to ensure that the final consumer is protected from any damaging chronic effects to their health arising from ingesting food contaminated with harmful levels of chemicals that may have migrated from the materials and articles with which they have been used or in which they have been packaged. These health effects are not acute, they would not quickly be apparent, as would be the case with food poisoning arising from bacterial contamination of the food. The effects are cumulative over a lifetime and affect aspects of, for example, the development of cancers and reproductive health. The legislation also exists to ensure that the consumer can buy food that has not been adversely affected by such chemical migration, even if the levels are insufficient to harm health. Finally, the legislation ensures that businesses compete for trade throughout the EU under a single set of harmonised rules rather than a plethora of different rules in each one of the EU Member States. However, issues such as the malicious tampering of food and foreign bodies in the food are NOT dealt with by this legislation. It is essential that the requirements of the legislation governing chemical migration from these food contact materials and articles are understood by those who use them in the course of their business and those charged with their enforcement.

6. **It is the sole responsibility of business operators to make sure that the goods in which they trade comply with the law that applies to them.** It is therefore incumbent upon business operators to make sure they are aware of the requirements of the law and ensure their goods comply with it. It is essential that business operators at each stage of the manufacturing and supply chain and the chain of professional users of food contact materials, whether virgin or recycled, and the articles made from them, establish their own in-house controls to ensure the compliance of the goods they produce and/or trade in. Where specific measures apply to their materials, they must attest the compliance of their goods to their customers. It would be good business practice to provide a compliance declaration voluntarily where materials and articles are not covered by specific measures requiring one.

As well as ensuring the freedom to trade in safe, legally compliant products, in-house controls and documentation help ensure that the adventitious migration of chemicals into food is minimised through good manufacturing practice at each stage of production – and this is part of the legal requirement placed upon business operators. **The law applies to material and article manufacturers, their raw material suppliers, material converters, packers and fillers, sellers and importers.**

FOOD CONTACT MATERIALS

7. Food contact materials and articles comprise a broad and complex range of goods. Among the most widely used materials are the many types of plastic used for bottles, utensils, films and containers. There is also a wide range of paper and board products, laminates or coated materials and utensils and containers made of metal, wood, ceramics or glass. Many modern forms of packaging make use of many of these in a single packaging product and they will also contain adhesives to bond layers together and coatings that allow the packaging to protect the foodstuff under what are often physically difficult conditions during controlled processing and transportation. Increasingly, many materials can be wholly or partly made from recycled material from controlled manufacturing production scrap or post-consumer material from local recycling collection points.

8. As well as materials used for packaging the food, others are used in the equipment that prepares or processes the food. This equipment brings the food into contact with many different types of surface made from, for example, metal, plastic, wood and rubber. There are also the food surfaces and preparation equipment used in the home and in the garden, barbecues and articles such as crockery and cutlery on which and with which food is served.

9. In addition to these materials and articles, printing inks and coatings may have been used on the packaging to attract us to buy it, to inform us of the foodstuffs' ingredients and of its nutritional value to us. There may also be instructions to tell us how to treat the food safely before we consume it. Other forms of coating on the inside of containers protect the foodstuff. All materials and articles in direct contact with food or separated from it by an air or gas phase or by another material, are made from and probably treated with chemicals to help them perform their role safely and reliably.

LEGISLATION

10. Throughout the EU the main legislation controlling all food contact materials and articles is European Regulation (EC) number 1935/2004. This Regulation came into force in 2004 and replaced Council Directive 89/109/EEC that had been in place for fifteen years. The European Regulation is directly and fully applicable in all EU Member States. National regulations in each of the countries of the United Kingdom were put in place to establish the means of enforcing the EU Regulation. These national regulations also create offences for failing to comply with the European Regulation and defences against some alleged offences, along with the penalties that may be imposed by the Courts upon conviction for an offence. These penalties include fines and terms of imprisonment.

11. The European Regulation applies to all materials and articles which, in their finished state, are intended to come into contact with food, including so-called 'active' and 'intelligent' food contact materials and articles (see paragraph 16).

12. Two other types of materials and articles are also within the scope of the Regulation. The first are those materials and articles that can reasonably be expected to be brought into contact with foods, for example the linings inside refrigerators. The second are those that can reasonably be expected to transfer their constituents to food, for example, printing inks and coatings as components that form part of the final packaging and adhesive labels that may be used on packaging.

13. However, it specifically excludes covering or coating substances that are part of the food and that may be eaten with it, such as sausage skins and edible cheese rinds. Also excluded are materials and articles supplied as antiques that may have been manufactured and placed on the market before 1st January 1980, when the first EU-harmonised rules on food contact materials and articles came into effect. Materials and articles that are used in fixed public and private water supply systems are also excluded from this Regulation. This includes water mains and the piping that brings the supply into a building.

14. The Regulation requires that all food contact materials and articles should be manufactured using good manufacturing practice (this is discussed in more detail later in this guide). In normal use, they may not transfer their

constituents to food in quantities that could endanger human health or cause unacceptable changes in the composition of food or a deterioration of its taste, texture, aroma and appearance.

15. Whilst this encompasses the traditional provision dealing with the adventitious migration of substances from food contact materials and articles, this Regulation also makes a failsafe provision for instances of intended migration that arise in the case of active food contact materials and articles. These are intended to release substances onto the food or the atmosphere surrounding the packaged food. This is done to improve the quality of the food or to increase its shelf life. It also requires that the labelling, advertising and presentation of a material or article shall not mislead the consumer. That is to say that the labelling, advertising and presentation should not give the impression that the material or article can achieve things that it cannot. For instance, if a material has a substance in it that destroys some bacteria that may develop in the microscopic fissures on the surface of the material, the description should be clear and specific about what the substance actually does. It should not, for instance, infer that all bacteria are destroyed. Where active bacteria remain, in spite of the presence of the substance in the material, consumers should be made aware.

BUSINESS DOCUMENTATION

16. The legal requirement for business documentation concerns the presence and use of that documentation up and down the manufacturing and supply chain prior to the point of retail sale. It is based on two sets of needs and they are both rooted in legal requirements laid down in the European legislation: namely, Regulation (EC) No. 2023/2006 on good manufacturing practice, and Regulation (EC) No. 1935/2004 on materials and articles in contact with food.

17. This latter Regulation is given further elaboration in Directives on specific materials. These are

- Directive 2002/72/EC on plastic materials and articles in contact with food (enacted in the UK by The Plastic Materials and Articles in Contact with Food (England) Regulations 2009, The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009, The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2009, and The Plastic Materials and Articles in Contact with Food (Scotland)

Regulations 2009); [N.B. This Directive and these Regulations are likely to change in the near future when a European Regulation is adopted.]

- 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; and,

- Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. (These Directives are enacted in the UK by The Materials and Articles in Contact with Food (England) Regulations 2007, The Materials and Articles in Contact with Food (Wales) Regulations 2007, The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007 and The Materials and Articles in Contact with Food (Scotland) Regulations 2007).

18. Many businesses whose products are the subject of the requirements of the Directives on specific materials will have access to guidance and documentation provided by their representative associations. That guidance and documentation will have been devised quite specifically to help them meet their obligations arising under the requirements of the Directives and will include guidance on particular issues that may not be addressed in this more generic guide. Where this is the case, the business is able to follow the advice and guidance that best meets its compliance needs.

19. The first of the two sets of needs for business documentation is for the business to ensure the consistent standards of its own processes and procedures through the documentation, application and review of good manufacturing practice. The second is the need for the business to provide adequate documentation to help its downstream customers meet their legal obligations through the provision of comprehensive compliance declarations that address all the legal requirements that pertain to their product(s). These requirements are part of a total approach to safe, consistently manufactured, formed and used products. Each part complements the other.

20. In this latter case, it is clearly the intention from Regulation (EC) No. 1935/2004 that all food contact materials and articles should be accompanied by a declaration of compliance, but it requires specific legal measures to say in detail how this must be done. So far such specific measures deal with food contact plastics, ceramics and regenerated cellulose film.

21. Satisfying the first need for good manufacturing practice requires the business to examine its raw material requirements, its processes and its procedures. This will ensure that it establishes the means for achieving and maintaining appropriate and acceptable standards of quality and quality control for its products and its customers. To establish and document the processes requires a step-by-step, systematic approach to identify the minimum acceptable standards for each stage of the business operation.

22. In **manufacturing and converting** the materials**,** this involves examination and documentation of the process from establishing the standards for raw materials, the time and temperature and other technical requirements of the processes, the means of assuring the quality of the finished product and the means for reviewing, identifying and correcting variations from the standards. In some cases where ingredients for the material are bought against established industry standards that ensure the quality of the final material, day-to-day controls may well establish good factory quality assurance procedures such as accurate measuring of raw materials to maintain material composition. In some processes, temperature and time play important roles in the manufacturing process.

23. In **importing** businesses, it involves examination and documentation of the controls necessary to establish the provenance and quality of the import, including knowledge of the supplier's ability to consistently meet the standards necessary to produce goods that comply with the EU laws applicable to them.

24. Satisfying the second need to attest a product's legal compliance requires the business to establish the behavioural characteristics of its product and the quality and/or performance requirements of its customers. In particular, material converters, that is those businesses that convert a material into a food contact article, need to take account of the legal requirements that apply to each of the components of the article. This could include, for example, different plastic layers (possibly including recycled material) and components of the final material such as adhesives, coatings, colourants, printing inks, functional barriers and possibly non-plastic layers where they are used in a product containing different materials. This not only helps to ensure that the product is fit for the intended purpose, but also that any legal restrictions on or conditions for the product's proper and safe use are established and explained. The business has to provide information on the performance of

the whole product in relation to the requirements laid down in European law to ensure the operating margins are understood by the customer in case it affects the customers operation.

25. An important consideration is whether or not so-called 'dual use' additives have been used in the material. That is to say a substance used for its technical effect in the material that is also an authorised food ingredient. The end user who puts food into the article has to take account of the presence of the additive/ingredient in case it migrates to the extent that too much of the ingredient could be present in the final food causing the foodstuff to breach a limit laid down in the legislation controlling food ingredients.

26. Businesses wanting to ensure adequate protection of their proprietary information may establish procedures with their customers for the exchange of information deemed confidential and commercially sensitive. Measures to ensure the preservation of confidentiality may include confidentiality agreements (sometimes called 'non-disclosure agreements') and the limiting of the exchange of information to make sure it takes place only between named parties within the businesses. Variations around this practice include two part declarations consisting of a general declaration that is not confidential, and a confidential section containing any proprietary information it is necessary to disclose. Businesses may also agree to disclose confidential details to an independent third party – such as a respected laboratory or law firm – for review. In entering into arrangements to protect confidential information, business operators must make sure that they can still provide adequate information to enforcement officers to demonstrate that their goods and their business operations comply with the legal rules applicable to them.

27. Businesses importing goods from companies located outside the EU must be particularly careful to ensure that their suppliers are aware of the EU legislation and other rules and standards with which goods must comply. They should have defined procedures in place to ensure this.

28. From this, it is clear that each business in the production chain, with the exception of the manufacturers of the starting substances for materials, should have these controls in place and documented. This applies to the producers of the materials that will be used for food contact, to those who convert the materials to products and those who combine these products with other goods (such as those that bring inner bags together with outer boxes to

form complete packaging – as for, say, many breakfast cereals), importers and so on through to the seller of the product to the fillers and the retailers.

29. Business operators may prepare different types of documents about their products to serve various commercial, legal or other purposes. Some of those documents may include references to food contact legislation – for example, a technical specification or marketing datasheet might state that a product complies with the requirements of 2002/72/EC. It is possible that the presence of references to food contact legislation in those documents could cause ambiguity about which document constitutes the declaration of compliance (as defined in Article 16(1) of the Framework Regulation). This may be especially likely to occur in cases where the document contains some (or much) of the information that is required content for the declaration of compliance, as laid down in the applicable specific measures.

Good practice

For the avoidance of doubt, it would be good practice for business operators explicitly to state on their declaration of compliance that 'for the product named [above/below] this document is the declaration of compliance within the meaning of Article 16(1) of Regulation (EC) No. 1935/2004' (or some other words to this effect).

GOOD MANUFACTURING PRACTICE (GMP)

30. Since 1 August 2008, Regulation (EC) No. 2023/2006 has required that businesses establish and document good practices and procedures. The Regulation elaborates the general requirement from the 2004 Regulation in relation to GMP. In so doing it lays down the rules for the groups of materials and articles intended to come into contact with food that are listed in the annexes and combinations of those materials and articles or recycled materials and articles. The regulation applies to all sectors and to all stages of manufacture, processing and distribution of food contact materials and articles. It does not apply to the production of the starting substances used in the manufacture of food contact materials and articles, such as those given in Annex II of Commission Directive 2002/72/EC in relation to food contact plastics. The detail of the Regulation defines GMP and ties it securely into the general requirement of Article 3, of the 2004 Regulation. It's definitions include the terms:

(a) '*good manufacturing practice*'. These are those aspects of quality assurance that ensure that materials and articles are consistently produced and controlled, to ensure they comply with the law and with the quality standards appropriate to their intended use, so that any migration of chemicals does not endanger human health or cause unacceptable changes in the composition of the food or a deterioration in its sensory characteristics;

(b) '*quality assurance system'*. This is the total sum of the organised and documented arrangements made to ensure that materials and articles are of the quality required to comply with the law and the quality standards necessary for their intended use;

(c) '*quality control system.'* This means the systematic application of the quality assurance system to ensure that starting, intermediate and finished materials and articles comply with the specification determined in the quality assurance system.

31. In elaborating the first two of these terms, the GMP Regulation requires that business operators document their systems and apply them proportionately to the size of the business to avoid excessive burden on the business. The documented system put in place in the business has to be made available to the Authorities for inspection on demand. Annex 1 provides an outline of some common issues to take account of in developing the use and documentation of good manufacturing practices.

DECLARATIONS OF COMPLIANCE

32. The European Regulation, 1935/2004, requires that specific measures, that is measures laying down controls on specific food contact materials such as plastic, also lay down specific requirements that the materials and articles they cover are accompanied by a written declaration attesting their compliance with the **rules** that apply to them. It is important to note the use of the plural term in the Regulations and Directives. The requirement is therefore that wherever a rule, such as a migration limit, is laid down, it must be addressed in the Compliance Declaration if that declaration is to attest the compliance of the material or article with the rules applicable to it. This will apply to all substances in the material subject to a rule governing their use, such as a migration limit. This compliance has to be supported by documented evidence that must be made available to the authorities on demand. The rules on regenerated cellulose film, ceramics and food contact

plastics already contain detailed provisions concerning compliance declarations. Other materials not subject to these legal requirements yet, may be accompanied by compliance declarations voluntarily and it would be good business practice to do so.

Good Practice

Generally, it would be good business practice for declarations accompanying food contact materials and articles and provided to the business customer to contain information about:

i. who manufactured or imported the materials or articles or the substances intended for their manufacture;
ii. what they are;
iii. when the declaration was made;
iv. confirmation that the materials or articles meet relevant requirements laid down in Regulation (EC) No 1935/2004 and in any other legislation;
v. information about the compliance of substances used that are subject to any restrictions and/or specifications to allow the downstream businesses to ensure compliance with those restrictions;
vi. information about the compliance of substances subject to a restriction in food, about the level of their specific migration and, where appropriate, purity criteria to enable the user of these materials or articles to comply with the law;
vii. specifications on the use of the material or article, such as:
    - type or types of food with which it is intended to be put in contact;
    - time and temperature of treatment and storage in contact with the food;
    - ratio of food contact surface area to volume used to establish the compliance of the material or article;
viii. confirmation that the material or article complies with any rules on functional barriers when one is incorporated into the material or article.

33. This is clearly based on the requirements laid down in the rules governing food contact plastics. However, those rules establish a useful marker on the information that should flow through the manufacturing and supply chain for other materials. This is not the case though, where products are subject to material specific legislation. It is most likely that guidance is available from

representative associations tailored to the requirements and the needs of the businesses in their sector(s).

Good practice

The written declaration must make it easy to identify the materials, articles or substances it relates to. It should be renewed whenever a change in production or materials supply affects changes in the behaviour of the product, migration of substances from it or when new scientific data are available in the published literature that affects the conditions under which the declaration is issued. The new data could, for example, concern progressive improvements in the measurement techniques that could have implications for compliance testing. A senior member of the business providing the declaration should be designated the person responsible for the declaration, its documentation and its provenance.

Declarations and the documentary evidence on which they are based, should be renewed any time there is a substantive change in the production of the material or article in question, whether the change is in the process or the ingredients used in the material or article. Where no such change arises, it would be good practice to review supporting documentation annually.

34. Two generic formats for written declarations are provided at Annex 2. Business operators are not compelled to use them but may choose to do so, or they may use them as a basis for their own document design for a declaration. These formats deal with the minimum requirements of the legislation.

ISSUES FOR DECLARATIONS OF COMPLIANCE

35. *Frequency:* A declaration of compliance should accompany each shipment of the product to a customer. The information on the declaration will identify the shipment to which it relates. Where such shipments are constant and regular between the same supplier and customer there may be an agreement that declarations are provided at a given frequency rather than continuously. However, they should always be provided when the documentary evidence on which the declaration is based is reviewed, renewed or changed in any way. Where production of the goods is constant and quality parameters are

unchanging, sampling and testing for compliance should be done at intervals consistent with maintaining the quality and compliance of the product.

36. *Language:* The declaration of compliance and its supporting documentation shall be written in a language understood by the business to which it is provided and the enforcement authority that requires to see it. The Legal requirement laid down by Directive 2002/72/EC is that "The written declaration shall permit an easy identification of the materials, articles or substances for which it is issued …" It is clear that such identification cannot take place if the business receiving the declaration cannot understand the language in which it is written.

Good practice

Business operators should bear in mind that they are obliged to make available their declarations of compliance and supporting documentation to enforcement officers upon request. Businesses based in England may therefore wish to ensure that they receive from their suppliers – whether based in the UK, in another EU Member State, or outside of the EU – and provide to their own customers, declarations of compliance that have been prepared in the English language.

37. Model *calculations:* Modelling to enable migration from food contact plastics to be calculated must follow recognised, validated methods.

38. '*Own brand'* food product retailers are regarded as producers of food and should have the same documentation as 'branded' food producers and processors. Similarly, retailers who import pre-packed food or food contact materials directly should have the same documentation as the mainstream importers of such goods.

39. *Delegating Compliance Assurance*: Some business sectors argue that it is not always possible to provide a comprehensive compliance declaration to all customers. They argue that this is because, in some cases, the precise use to which the customer might put the material or article cannot be ascertained at their point in the production chain. In such cases, it is argued, the compliance of the material is delegated to the purchaser. In the legislation on food contact plastics, Directive 2007/19/EC inserted a new Article 9 into Directive 2002/72/EC. This laid down the explicit requirement that, at the marketing stages other than the retail stage, plastic materials and articles as well as the substances intended for their manufacture, shall be accompanied

by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004. No exception from this requirement is provided for.

40. However, in providing a declaration in accordance with this requirement, the business supplying the material or article makes it clear what necessary conditions of use apply and what the product is intended for. The necessary conditions for use may restrict the temperatures to which the article or material may be exposed, or, for example, the types of foodstuff with which it has been tested. The intended use of a product may not include use with some types of foodstuffs. Under these circumstances, it becomes the responsibility of the purchasing business to understand the use parameters of the product they are buying. They must test the product under the intended conditions of use should they depart from those laid down in the compliance declaration (or other documentation where use with food under specific conditions was not intended) that was provided by the supplier.

Good practice

Knowledge of suppliers and customers: It is good business practice to know enough of the requirements of your customers to be able to supply their demands. This knowledge of the customer's requirements should be sufficient to enable the supplier to determine the suitability of the product for the customer's needs in relation to its technical and performance specification. Where the customer's detailed requirements cannot be ascertained, they should be made fully aware of the technical performance characteristics designed into the product they are buying, particularly if there are restrictions that have to apply to the product's use if it is to be used within its designed specification. These restrictions may relate to storage or process temperatures, food types that may be used with the product and so on.

Product Analysis: There are two general points:

- Sampling for analysis should be done at critical points in the manufacturing process. These are likely to be points in the process at which critical action takes place, possibly in terms of a temperature or time-critical event or some other event whose success is critical to the finished product;
- Sample analysis should follow a standardised or at least a documented method for which the laboratory has accreditation.

41. This has implications for enforcement officers. They need to be aware of the requirement as it exists in the Plastic Materials and Articles in Contact with Food Regulations for food contact plastics in particular as they are enacted in the territories of the United Kingdom.

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May 2009

ANNEX 1: COMMON ISSUES TO TAKE INTO ACCOUNT IN DEVELOPING THE USE AND DOCUMENTATION OF GOOD MANUFACTURING PRACTICES

ACKNOWLEDGEMENT

This annex draws on the guide to good manufacturing practice prepared by many European and national representative associations. The Agency is happy to acknowledge the significant contribution the work that all these associations have made to this more generalised guide for all businesses to apply as appropriate and proportionately within their businesses.

Good practice

In relation to the manufacture of food contact materials and articles, Good Manufacturing Practice (GMP) is a legal requirement. It applies to the procedures for their formulation, production and control. The elements of GMP described here help to ensure that products comply with the law or other generally accepted requirements, are fit for the purpose intended and meet customer's needs of the product.

Controls

Manuals

Detailed operational manuals cover orders receipt, formulation, manufacture and product delivery to agreed standards. Recording systems ensure that the correct action for each stage can be verified.

Production Instruction Documents

An instruction document (sometimes called a 'batch card') is issued for each batch of products manufactured. This details the materials, quantities and equipment to be used and highlights any process critical operations and any specific precautions to be followed. Each stage is recorded.

Product Test Specifications

Product test specifications should exist for each product. They list the tests that are

required during and following manufacture to ensure the batch meets the required specification and is fit for intended use according to agreed tests. The specifications should contain the appropriate tolerances for each test.

Quality Review Procedure

In the event of non-compliance at any stage of the process or of a complaint, a procedure should exist to take preventative or corrective action to find the cause, rectify the problem, and if necessary make the appropriate improvement(s) to the manuals or other controls to prevent a repetition. A person should be appointed to accept responsibility for the rectification processes.

Personnel and Training
Commitment

The entire workforce, involving all levels of management should be committed to the objectives of GMP to make it work. The benefits to the business should be obvious.

Training

Training programmes and facilities should be established to ensure that all personnel are fully aware of their functions and responsibilities and are competent to carry them out.

Raw Material Controls
Objective

GMP requires complete co-operation with the suppliers of raw materials and knowledge of the needs of the customer. Raw materials should be carefully selected to ensure that the components of the food contact material or article comply with the requirements of appropriate EU or national legislation, are suitable for the necessary quality standard and are within agreed tolerances.

Suitability

Raw materials should be selected and used so that, when the product is correctly used, it should not:

- endanger human health;
- cause a deterioration in the sensory nature of the foodstuff;
- cause an unacceptable change in the foodstuff's composition or quality.

Any industry-wide agreement or practice concerning substances, their purity or quality criteria that mean they should not be used on safety grounds should be observed and noted.

Specifications

Each raw material should have a specification agreed between the supplier and the manufacturing customer. The specification should include physical and chemical properties, including purity criteria, to maintain agreed manufacturing quality and end use technical requirements.

Compliance

Raw materials should be tested in house or, alternatively, be supported by a declaration of compliance from the raw material supplier that relates to the agreed specification and any legal requirements. In some instances, pre-delivery samples representing the batch may be submitted to the manufacturing customer for special tests prior to the delivery being accepted.

Identification and Traceability

A name, reference number and batch or delivery number should identify each raw material, so that it can be traced, if necessary. The traceability of raw materials is achieved throughout the production chain and in-house by the delivery and/or batch reference numbers. It is a legal requirement that traceability exists at least to the level of one stage back and one stage forward.

Storage and Use

Raw materials should be stored under conditions that prevent contamination or deterioration. Rejected materials should be clearly marked as such and kept apart from those to be used. Raw material stocks should be rotated and used on a first-in first-out basis.

Material or Article Technical Requirements

The following parameters should be considered and any effect on the material understood when formulating food contact materials and articles:

- type of material and/or component combinations;
- type of foodstuffs being brought into contact;
- type of processes and equipment involved;
- package-forming and filling processes;

- end-user specifications;
- compliance to health, safety and consumer protection regulations;
- compliance with environmental policies manufacturing processes and end-use.

Food contact material products should be formulated in such a way as to:

- have the necessary resistance to physical and chemical stress,
- be suitable for the method of use/processing and for subsequent converting processes,
- have the substance combination to meet product resistance specifications such as ISO standards or other agreed end use specifications,
- ideally have no measurable transfer or migration of substances into the foodstuff when appropriately used, or migration only within limits in law.

Production
Objective

To convert raw materials into products specified to meet the customers' requirement.

Manufacturing Instruction Document

Manufacturing instructions should be issued and followed for each batch, giving details of the raw materials, the quantities and the equipment to be used. Critical parts of the process should be recorded and checked by the operator.

Manufacturing Formulation

Only raw materials that have passed the prescribed quality control procedures are used in quantities and proportions necessary to ensure the quality of the product.

Equipment

The equipment used should be suitable to manufacture the products required and be maintained in good repair; clean and, where necessary, calibrated. Maintenance documentation should be established and monitored.

Quality Control
Objective

To carry out laboratory and manufacturing tests on manufactured food contact materials and articles to ensure they are supplied to the customer fit for end use,

conforming to customer's specifications and the law relating to them.

Production Quality Control

Testing of product samples at selected stages of the process should be carried out in order to monitor the required quality standard. A procedure should be established for process operators to adjust the process or product within specified limits when necessary.

Testing

Products should be sample tested to ensure they meet established specifications at each critical stage. Test methods may be agreed with customers.

Test Equipment

All measuring equipment must be maintained and tested and/or calibrated where appropriate to a schedule to ensure that the test results are accurate.

Product Information
Identification

A descriptive title or a trade name, reference number and specific batch number, should identify each product.

Compliance

Each delivery of the product must be supported by a declaration of compliance, confirming that it meets the agreed specification, with direct reference to any restriction or criteria laid down in EU law.

Data Sheets and Documentation

Each product has supporting product data sheets detailing relevant chemical, physical and safety data, and suitable end uses and methods of application. Testing on the product during manufacture should be recorded and retained. Data on the legal compliance of the product should also be retained and updated whenever there has been change in production process, raw material or specification.

Packaging
Specification

Packaging for the product should be selected to protect it during shipment and

storage and to ensure it conforms to the appropriate national, European and UN requirements for the nature of the product packed and the means of transport.

Cleanliness

New containers should be inspected for cleanliness. Returned containers should be inspected and cleaned, if necessary, to avoid any contamination with other products or foreign materials.

Accurate Filling

Filling controls must be accurate within legal measuring limits. All weighing equipment must be examined for accuracy, re-calibrated if necessary and frequently inspected.

Labelling

Each container should have the minimum following information on labels:

- identification of the producer
- reference number and description of product
- batch number
- net weight
- health, safety and transport information as required.

Storage

All products (including raw materials) should be stored in conditions that prevent, as far as possible, any deterioration of the material. Where appropriate a procedure exists to test stock that may have been held for some time to ensure it continues to conform to specification. Rejected stock should be clearly marked as such and isolated to avoid accidental use.

Delivery

All products should be delivered in clean and clearly labelled suitable containers.

ANNEX 2, PART A: A FORMAT FOR A DECLARATION OF COMPLIANCE BASED ON REGULATION (EC) NO.1935/2004 ARTICLE 3

Good practice

Name of Manufacturer/Importer/Supplier					
Batch/Consignment/Shipment Contents					
Date of Declaration					
Points of note (important product usage, storage, handling etc. information)					
Identification of approved food ingredients used as technical additives in the material.	Name and CAS number:		Restriction in food:		
Declaration of compliance with Article 3 of Regulation (EC) No 1935/2004					
Substance and CAS Number		Detected Migration Level (from analytical tests)	Estimated Daily Intake (Evidence of calculations should be maintained in supporting documentation for further reference and examination)	**A**. Formally pronounced Acceptable Daily Intake or Tolerable Daily Intake or Tolerable Weekly Intake ADI/TDI/TWI	Compliance/Non-compliance (add any conditional comments)
				B. Company's own calculated safe level of daily intake	
				A.	
				B.	

ANNEX 2, PART B: A FORMAT FOR A DECLARATION OF COMPLIANCE BASED ON A SPECIFIC MEASURE E.G. DIRECTIVE 2002/72/EC:

Good practice

Manufacturer/Converter/Importer/Supplier		
Product covered by this declaration.		
Date of Declaration		
Declaration of compliance with [Title of specific EU measure/National instrument]		
Information about the compliance of substances used that are subject to any restrictions and/or specifications.		
All substances - compliance with any overall migration limit [e.g. 10 mg/dm2of the surface area of the material or article] [60 mg/kg foodstuff]		
Individual substances	Restrictions in law	Test results (or estimated level of migration from calculations – method(s) of calculation should be maintained in supporting documentation and retained for inspection by the Authorities)
1.		
Etc.		
Information about the compliance of substances subject to a purity criteria (where applicable)		
Substance	Restrictions in law	Established migration
1		
Etc.		
Information about the use of 'dual-use' additives in the material that are subject to restriction in food law.		

Food additive	Restriction in food law.	Established migration
1.		
Etc.		

Parameters or specifications on the use of the material or article (these reflect the designed and tested limitations of the product):

type or types of food with which it is intended to be put in contact;

time and temperature of treatment and storage while in contact with the food;

ratio of food contact surface area to volume used to establish the compliance of the material or article;

Other specifications:

Functional barrier (if part of the material or article) – declaration of compliance

Signed _____ Position _____-

Date _____

ANNEX 3 - REGULATORY TEXT RELEVANT TO LEGAL COMPLIANCE GUIDE

Issue	EC Reference	Extract	UK Reference	Extract	Comment
Defining food contact materials and articles	Regulation (EC) No. 1935/2004 Article 1	*Article 1* **Purpose and subject matter** 1. The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers. 2. This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state: (a) are intended to be brought into contact with food; or (b) are already in contact with food and were intended for that purpose; or (c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.	The Materials and Articles in Contact with Food (England) Regulations 2007. The Materials and Articles in Contact with Food (Scotland) Regulations 2007. The Materials and Articles in Contact with Food (Wales) Regulations 2007. The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007.	PART 1 Preliminary **Interpretation** 2. (3) Expressions used in these Regulations and in Regulation 1935/2004 have the same meaning in these Regulations as in that Regulation	Paragraphs 7, 8 and 9 of the Guide. In the 1987 regulations, a Directive was transposed and terms used in that Directive were defined and used in the regulations. In the 2007 regulations, a European regulation is given full effect by the national regulations and it is as a point of clarity that this reference appears.

Issue	EC Reference	Extract	UK Reference	Extract	Comment
Excluding particular materials and articles from the Regulation.	Regulation (EC) No. 1935/2004 Article 1	*Article 1* **Purpose and subject matter** 3. This Regulation shall not apply to: (a) materials and articles which are supplied as antiques; (b) covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food; (c) fixed public or private water supply equipment.	The Materials and Articles in Contact with Food (England) Regulations 2007. The Materials and Articles in Contact with Food (Scotland) Regulations 2007. The Materials and Articles in Contact with Food (Wales) Regulations 2007. The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007.	Part 1 Preliminary ***Scope*** Regulation 3. The provisions of these Regulations do not apply to those materials and articles specified in sub-paragraphs (a), (b) and (c) of Article 1(3).	Paragraph 13 of the Guide.
The general requirement.	Regulation (EC) No. 1935/2004 Article 3	*Article 3* **General requirements** 1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of	The Materials and Articles in Contact with Food (England) Regulations 2007. The Materials and Articles in Contact with Food (Scotland) Regulations 2007. The Materials and Articles in Contact with Food (Wales) Regulations 2007.	PART 2 General Requirements for Materials and Articles **Enforcement of Regulation 1935/2004** Regulation 4 Subject to the provisions of Article 27 (transitional arrangements), any person who contravenes any of the following provisions of Regulation 1935/2004 is guilty of an offence — Article 3 (general requirements);	Paragraphs 3 and 14 and, for GMP, paragraphs 14

Issue	EC Reference	Extract	UK Reference	Extract	Comment
		the food; or (c) bring about deterioration in the organoleptic characteristics thereof. 2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.	The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007.		
Business documentation: ***GMP***	Regulation 2023/2006 on GMP	*Article 4* **Conformity with good manufacturing practice** The business operator shall ensure that manufacturing operations are carried out in accordance with: (a) the general rules on GMP as provided for in Article 5, 6, and 7, (b) the detailed rules on GMP as set out in the Annex.	The Materials and Articles in Contact with Food (England) Regulations 2007. The Materials and Articles in Contact with Food (Scotland) Regulations 2007. The Materials and Articles in Contact with Food (Wales) Regulations 2007. The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007.	PART 2 General Requirements for Materials and Articles **Enforcement of Regulation 2023/2006** Regulation 5 (Regulation 4 in the Northern Ireland regulations) Any person who fails to comply with the requirements of Article 4 (conformity with good manufacturing practice) of Regulation 2023/2006 is guilty of an offence.	Paragraph 14 and 16, 19, 21 to 23, 30 and 31.

Issue	EC Reference	Extract	UK Reference	Extract	Comment
Declarations of compliance	Regulation 1935/2004	*Article 16* Declaration of compliance 1. The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them. Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand. 2. In the absence of specific measures, this Regulation shall not prevent Member States from retaining or adopting national provisions for	The Materials and Articles in Contact with Food (England) Regulations 2007 The Materials and Articles in Contact with Food (Scotland) Regulations 2007. The Materials and Articles in Contact with Food (Wales) Regulations 2007. The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007.	PART 2 General Requirements for Materials and Articles **Enforcement of Regulation 1935/2004** Regulation 4 Subject to the provisions of Article 27 (transitional arrangements), any person who contravenes any of the following provisions of Regulation 1935/2004 is guilty of an offence — (e) Article 16(1) (declaration of compliance);	Paragraphs 3, 6, 19 and 20, 24 to 29. Additional requirements relating to declarations of compliance are given in the specific measures, namely **Directives: 2002/72/EC** on plastic materials and articles in contact with food; **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; and, **2007/42/EC** relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. Directive 2002/72/EC is enacted in England by The Plastic Materials and Articles in Contact with Food (England) Regulations 2009, in Scotland by The Plastic Materials and

Issue	EC Reference	Extract	UK Reference	Extract	Comment
		declarations of compliance for materials and articles.			Articles in Contact with Food (Scotland) Regulations 2009, in Northern Ireland) by The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2009, the other Directives are enacted in England by The Materials and Articles in Contact with Food (England) Regulations 2007, in Northern Ireland by The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007, in Scotland by The Materials and Articles in Contact with Food (Scotland) Regulations 2007.
Good manufacturing Practice (detail)	Regulation 2023/2006 on GMP	*Article 5* **Quality assurance system** 1. The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system. That system shall: (a) take account of the adequacy of personnel, their knowledge and skills, and the organisation of the premises and equipment such as is necessary to ensure	The Materials and Articles in Contact with Food (England) Regulations 2007 The Materials and Articles in Contact with Food (Scotland) Regulations 2007. The Materials and Articles in Contact with	PART 2 General Requirements for Materials and Articles **Enforcement of Regulation 2023/2006** Regulation 5 Any person who fails to comply with the requirements of Article 4 (conformity with good manufacturing practice) of Regulation 2023/2006 is guilty of an offence.	Paragraphs 30 and 31 Although the European regulation gives detailed provisions regarding GMP in Articles 5, 6 and 7, these all elaborate the basic provision established under Article 4. Our national regulations therefore need only refer to the need to comply with Article 4.

Issue	EC Reference	Extract	UK Reference	Extract	Comment
		that finished materials and articles comply with the rules applicable to them; (b) be applied taking into account the size of the business run by the operator, so as not to be an excessive burden on the business. 2. Starting materials shall be selected and comply with pre-established specifications that shall ensure compliance of the material or article with the rules applicable to it. 3. The different operations shall be carried out in accordance with pre-established instructions and procedures. *Article 6* **Quality control system** 1. The business operator shall establish and maintain an effective quality control system. 2. The quality control system shall include monitoring of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.	Food (Wales) Regulations 2007 The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007.		

Issue	EC Reference	Extract	UK Reference	Extract	Comment
		Article 7 **Documentation** 1. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article. 2. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to records covering the various manufacturing operations performed which are relevant to compliance and safety of the finished material or article and with respect to the results of the quality control system. 3. The documentation shall be made available by the business operator to the competent authorities at their request.			
Declarations of Compliance (detail)	Regulation 2023/2006 on GMP	*Article 16 (as above)*	The Materials and Articles in Contact with Food (England) Regulations 2007 The Materials and Articles in Contact with Food (Scotland)	PART 2 General Requirements for Materials and Articles (as above). **Labelling and Documentation (and documentation in the Northern Ireland Regulations)**	Paragraphs 32 to 41 The generic requirement is in Regulation (EC) No. 1935/2004. However, the most developed expression of

Issue	EC Reference	Extract	UK Reference	Extract	Comment
	Detail is taken from Directive 2002/72/EC Annex	**ANNEX VIa** **DECLARATION OF COMPLIANCE** The written declaration referred to in Article 9 shall contain the following information: (1) the identity and address of the business operator which manufactures or imports the plastic materials or articles or the substances intended for the manufacturing of those materials and articles; (2) the identity of the materials, the articles or the substances intended for the manufacturing of those materials and articles; (3) the date of the declaration; (4) confirmation that the plastic materials or articles meet relevant requirements laid down in this Directive and Regulation (EC) No 1935/2004; (5) adequate information relative to the substances used for which restrictions and/or specifications are in place under this Directive to allow the downstream	Regulations 2009 The Materials and Articles in Contact with Food (Wales) Regulations 2007. **The Plastic Materials and Articles in Contact with Food (England) Regulations 2009** The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 **The Plastic Materials and Articles in Contact with Food (**Wales**) Regulations 2009** The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2009	14—(1) At marketing stages other than the retail stage a person who places on the market any plastic material or article or any substance intended for the manufacture of a plastic material or article must ensure that the plastic material or article or substance is accompanied by a written declaration which — a) accords with Article 16(1) of Regulation (EC) No. 1935/2004; b) contains the information specified in Schedule 4.; and c) complies with paragraph (2). (2) A written declaration made under paragraph (1) must be revised when substantial changes in the production of a plastic material or article for which the declaration is issued bring about changes in the migration or when new scientific information is available.	the generic requirement is given in the rules on food contact plastics, Directive 2002/72/EC as amended. It is these requirements that are used here as the basis for guidance and good practice.

Issue	EC Reference	Extract	UK Reference	Extract	Comment
		business operators to ensure compliance with those restrictions; (6) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 95/31/EC, 95/45/EC and 96/77/EC to enable the user of these materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food; (7) specifications on the use of the material or article, such as: (i) type or types of food with which it is intended to be put in contact; (ii) time and temperature of treatment and storage in contact with the food; (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;			

Issue	EC Reference	Extract	UK Reference	Extract	Comment
		(8) when a plastic functional barrier is used in a plastic multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 7a(2), (3) and 4 of this Directive. The written declaration shall permit an easy identification of the materials, articles or substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.			
Language issues	Directive 2002/72/EC, as amended by Directive 2007/19/EC	**ANNEX VIa** **DECLARATION OF COMPLIANCE** The written declaration shall permit an easy identification of the materials, articles or substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.	The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009 The Plastic Materials and Articles in Contact with Food (Northern Ireland) 2009	SCHEDULE 4 Information to be contained in a declaration of compliance	Paragraph 36 Schedule 4 brings into effect the main specific provisions of Annex Via of the Directive, but there is no specific reference to language. However, under the due diligence provisions in the legislation the business buying-in the material or article must ensure that it understands any declaration provided to it so that it is able to meet it's responsibilities to its

Issue	EC Reference	Extract	UK Reference	Extract	Comment
					downstream customers. It should therefore be a matter of contractual obligation that the declarations it receives are in a language it understands, can us and show to an enforcement officer to establish the compliance of its products.
Mathematical modelling of migration.	Directive 2002/72/EC, as amended by Directive 2007/19/EC	**ANNEX VIa** **DECLARATION OF COMPLIANCE** 6) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 95/31/EC, 95/45/EC and 96/77/EC to enable the user of these materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food;	The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009 The Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2009	SCHEDULE 4 **Information to be contained in a declaration of compliance** 6 Adequate information relating to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with the purity Directives to enable the user of the materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.	Paragraph 37 The Directive, and reflected in the regulations, deals with using calculations to establish migration in the context of the compliance declaration. However, as with the issue of language, the business would be failing in its due diligence behaviour if it did not use a recognised, validated method of calculation to establish substance migration levels by theoretical means.

ANNEX 4 - UK STATUTORY INSTRUMENTS

Regulations	*Statutory Instrument(SI) No.*	*ISBN No.*
• **The Materials and Articles in Contact with Food (England) Regulations 2007**	**2007 No. 2790**	**978-0-11-078794-7**
The Materials and Articles in Contact with Food (Scotland) Regulations 2007	2007 No. 471	978-0-11-078473-1
The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007	Statutory Rule 2007 No. 434	978-0337-97163-1
The Materials and Articles in Contact with Food (Wales) Regulations 2007	2007 No. 3252	(W.287) 978 0110 916729
The Ceramic Articles in Contact with Food (England) Regulations 2006	**2006 No. 1179**	**0-11-074531-0**
The Ceramic Articles in Contact with Food (Scotland) Regulations 2006	2006 No. 230	0-11-070393-6
The Ceramic Articles in Contact with Food (Wales) Regulations 2006	2006 No. 1704	(W.166) 0110913 868
The Ceramic Articles in Contact with Food Regulations (Northern Ireland) 2006	Statutory Rule 2006 No. 217	0337965 056
Food Safety Act 1990 (Consequential Modifications) (No.2) (Great Britain) Order 1990	1990 No. 2487	0-11-005487-3
Food Safety (Exports) Regulations 1991	1991 No. 1476	0-11-014476-7
The Plastic Materials and Articles in Contact with Food (Lid Gasket) (England) Regulations 2007	**2007 No. 2786**	**978-0-11-078793-0**
The Plastic Materials and Articles in Contact with Food (Lid Gasket) (Scotland) Regulations 2007	2007 No. 433	978-011-078437-3
The Plastic Materials and Articles in Contact with Food (Lid Gasket) (Wales) Regulations 2008	(W.11) 2008 No. 56	978-0-11-091734-4
The Plastic Materials and Articles in contact with Food (Lid Gasket) Regulations (Northern Ireland) 2007	Statutory Rule 2007 No. 419	978-0-337-97153-2
The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2008	**2008 No. 1642**	**978-0-11-081902-0**
The Plastic Materials and Articles in Contact with Food (Scotland) (Amendment) Regulations 2008	2008 No. 261	978-0-11-082007-1
The Plastic Materials and Articles in Contact with Food (Wales) (No.2) Regulations 2008	2008 No. 1628 (W 162)	978 0110 918228

Regulations	*Statutory Instrument(SI) No.*	*ISBN No.*
The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2008	Statutory Rule 2008 No. 271	978-0-337-97436-6
The Plastic Materials and Articles in Contact with Food (England) Regulations 2009	**2009 No. 205**	**978-0-11147363-4**
The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009	2009 No. 30	978-0-11-100228-5
The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009	2009 No. 481 (W. 49).	978-0-11-091963-8
The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2009	Statutory Rule 2009 No. 56	978-0-337-28 97654-4
Cooking Utensils (Safety) Regulations 1972	**1972 No. 1957**	**0-11-021957-0**
N-Nitrosamines and N-Nitrosable Substances in Elastomer or Rubber Teats and Dummies (Safety) Regulations 1995	**1995 No. 1012**	**0-11-052962-6**

The *Materials and Articles in Contact with Food Regulations, The Plastic Materials and Articles in Contact with Food Regulations* and *The Ceramic Articles in Contact with Food Regulations* have been made under powers given in Chapter 16 of the *Food Safety Act 1990*. The Regulations on cooking utensils and babies' dummies have been made under the provisions of the *Consumer Protection Act 1987* (1961 for the cooking utensils regulations).

All regulations on food contact materials and articles in Great Britain can be purchased from Stationery Office book shops or the Stationery Office PO Box 29, Norwich, NR3 1GN □: 0870 600 5522, fax: 0870 600 5533. Statutory Instruments issued since 1997 are also published, free-of-charge, on the website of the Office of Public Sector Information (previously Her Majesty's Stationery Office (HMSO)), address http://www.opsi.gov.uk. Copies can also be purchased from this website address.