Guidance on Legal Compliance and Best Practice for Business Documentation

MATERIALS AND ARTICLES IN CONTACT WITH FOOD

September 2008

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CONTACT TELEPHONE 0207 276 8553 or 8594
## Summary

<table>
<thead>
<tr>
<th>Intended audience:</th>
<th>This guidance is relevant to businesses that, in the course of their business, use materials and articles intended to come into contact with food, or those that could be brought into contact with food or those that could be the source of chemical migration into food. These businesses will range from large to small in size and scale of operation and will include material and article manufacturers, converters, fillers, importers and sellers on the market. It is also relevant to environmental health and trading standards officers involved in the enforcement of the law governing these materials and articles.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional coverage:</td>
<td>This guidance is specifically for those businesses and enforcement officers that operate in England, but it is also relevant to those that operate in Northern Ireland, Scotland and Wales where parallel legislation is in place.</td>
</tr>
</tbody>
</table>
| Legal status:     | This guidance is intended to:  
|                   | • be used in conjunction with the regulations it names; and,  
|                   | • address issues of best practice as highlighted in the following pages. |
| Purpose:          | This guidance 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; plus particular requirements in specific EU measures enacted in legislation in England dealing with declarations of compliance as they apply to the materials that are the subject of those measures; and  
|                   | • best practice in this area. |

These guidance notes should be read in conjunction with the legislation itself. The guidance on legal requirements should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power. It is ultimately the responsibility of individual businesses to ensure their compliance with the law. Compliance with the advice on best practice is **not** required by law. **To distinguish between the two types of information, all advice on best practice is in shaded boxes, with a heading of Best Practice.**

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.
1. INTRODUCTION

1.1 This guidance is based around the legal requirement for producing safe food contact materials and articles. The area of the law with which this guidance concerns itself lays down requirements that ensure that any migration of chemicals from food contact materials and articles into food is at levels that will not harm human health nor detrimentally affect the nature and quality of the food. It focuses on the requirements to document good manufacturing practice procedures and the legal compliance of goods down the manufacturing chain. This is a principle means of control for both the business operator and for the enforcement authorities.

1.2 Foods come into contact with many different materials during preparation, processing, packing and transportation. These materials will be used in the machinery used to prepare and process the food, package the food and to serve the food to the final consumer. Much of the equipment used in food preparation and processing will consist of many materials, while modern packaging will often consist of multiple layers of different materials.

1.3 Within the European Union there is detailed legislation that controls the migration of chemicals into food from food contact materials and articles. The legislation develops continuously as scientific understanding and laboratory techniques improve and develop. These controls exist to ensure that the final consumer is protected from any damaging effects to their health arising from ingesting food contaminated with harmful levels of chemicals from these materials and articles. These health effects would not be immediately 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 controls also exist to ensure that the consumer can buy food that has not been adversely affected by such migration, even if the levels of migration are insufficient to harm health. Finally, the controls ensure 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. It is essential that the rules governing 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.

1.4 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 production and commercial use of food
contact materials and articles establish their own in-house controls to ensure the compliance of the goods they produce and that they attest that compliance to their customers in relation to the specific rules that apply to the product. As well as ensuring the freedom to trade in safe, legally compliant products, in-house controls and documentation will 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 equally to material and article manufacturers, converters, fillers, sellers and importers.

2. FOOD CONTACT MATERIALS

2.1 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, films and containers. There is also a wide range of paper and board products, laminates and metal and wooden containers. Many modern forms of packaging will make use of all these in a single packaging product and will also contain adhesives to bond layers together and coatings and lacquers that allow the packaging to protect the foodstuff under often very harsh conditions during processing and transportation.

2.2 As well as materials used for packaging the food, others will be used in the equipment that prepares or processes the food. This equipment will bring 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.

2.3 In addition to these materials and articles, printing inks will 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. All materials and articles in contact with food directly or indirectly will be made from and probably treated with chemicals to help them perform their role safely and reliably.

3. LEGISLATION

3.1 Throughout the EU the core legislation controlling all food contact materials and articles is European Regulation (EC) number 1935/2004. This Regulation came into force on 3 December 2004 and replaced the previous ‘framework’ Directive that
had been in place for fifteen years, Council Directive 89/109/EEC. The European Regulation is directly and fully applicable in all EU Member States. National regulations in each of the countries of the United Kingdom, such as The Materials and Articles in Contact with Food (England) Regulations 2005, were put in place to establish the means for enforcing the EU Regulation. They also create offences for failing to comply with that Regulation and defences against some alleged offences, along with the penalties that may be imposed by the Courts upon conviction for an offence.

3.2 The 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. It also brings two other types of materials or articles 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 adhesive labels that may be used on packaging. However, it specifically excludes covering or coating substances that are part of the food and that may be eaten with it, such as sausage skin 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 consumer water supply systems are also excluded from this Regulation.

3.3 The Regulation requires that all food contact materials and articles should be manufactured using good manufacturing practice (see paragraph 4.2 below). 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 to its taste, texture, aroma and appearance. Whilst this encompasses the traditional provision dealing with the adventitious migration of substances for 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. It also requires that the labelling, advertising and presentation of a material or article shall not mislead the consumer.

4. BUSINESS DOCUMENTATION

4.1 The legal requirement for business documentation is based on two sets of needs and they are both rooted in legal requirements laid down in EU legislation.
These are: Regulation (EC) No. 2023/2006 on good manufacturing practice and Regulation (EC) No. 1935/2004 on materials and articles in contact with food. This latter Regulation is given further elaboration in 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 2008, the other Directives are enacted in England by The Materials and Articles in Contact with Food (England) Regulations 2007. The devolved administrations in Northern Ireland, Scotland and Wales have parallel legislation in force. The first of these needs is for the business to ensure the standards of its own processes and procedures to ensure 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).

4.2 Satisfying the first need will require the business to examine its processes and procedures to ensure that it establishes the means for achieving and maintaining 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. In manufacturing this will involve 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 importing businesses it will involve examination and documentation of the controls necessary to establish the provenance and quality of the import, including knowledge of the supplier’s ability to meet the standards necessary to produce goods that will comply with the EU laws applicable to them.

4.3 Satisfying the second need will require the business to establish the behavioural characteristics of its product and the quality and/or performance requirements of its customers. This will ensure the product is fit for the intended purpose and that any restrictions or conditions for the product’s use within the legislative requirements are established and explained. The business will have to provide information on the performance of the product in relation to the requirements
laid down in EU law to ensure the operating margins are understood by the customer in case it affects the customers operation.

4.4 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 used for food contact, to those who convert the materials to products and those who combine these products with other goods, importers and so on through to the seller of the product to the fillers and the retailers.

5. GOOD MANUFACTURING PRACTICE (GMP)

5.1 Regulation (EC) No. 2023/2006, from 1 August 2008, requires 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, but not the production of the starting substances used in the manufacture of food contact materials and articles. The detail of the Regulation defines GMP as those aspects of quality assurance that ensure that materials and articles are consistently produced and controlled to ensure compliance with the rules applicable to them and with the quality standards appropriate to their intended use. It ties this definition securely into the general requirement, of Article 3, of the 2004 Regulation. It also defines what it means by the terms:

(a) ‘good manufacturing practice (GMP)’. 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 that 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 materials, intermediate and finished
materials and articles comply with the specification determined in the quality
assurance system;

5.2 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 practice and documentation of good manufacturing
practices.

6. DECLARATIONS OF COMPLIANCE

6.1 The European Regulation requires that specific measures for particular
materials and articles provide for them to be accompanied by a written declaration
attesting their compliance with the rules that apply to them. This compliance has to
be documented and made available to the authorities on demand. The rules on
regenerated cellulose film, ceramics and food contact plastics already contain more
detailed provisions concerning compliance declarations.

6.2 Generally, declarations accompanying food contact materials and articles
must 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 specific measures;

v. information about the compliance of substances used that are subject to
any restrictions and/or specifications that will allow the downstream
businesses 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
6.3 The written declaration must make it easy to identify the materials, articles or substances it relates to. It has to be renewed whenever a change in production affects changes in the behaviour of the product, migration of substances from it or when new scientific data are available.

6.4 Two formats for written declarations are provided at Annex 2 that may inform businesses own document design for such a declaration. These formats deal with the minimum requirements of the legislation.

7. ISSUES FOR COMPLIANCE DECLARATIONS

7.1 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 demands to see it.

7.2 Knowledge of suppliers and customers: It is common business good 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.

7.3 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 method for which the laboratory has accreditation.

7.4 Model calculations: Modelling to enable migration from food contact plastics to be calculated must follow recognized methods.
7.5 Retailers of ‘own brand’ goods 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.

7.6 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 detailed 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. This means that any business buying a product that is not accompanied by a declaration of compliance must carry out the compliance testing itself. It has to assume the responsibility for ensuring that the product is safe for the intended purpose and remains within the law on food contact materials and articles while it is used in the way the business intends.

7.7 This has implications for enforcement officers. They need to be aware that where a supplier has no declarations of compliance intended for customers of the business, those customers will have had to assess and attest the product’s compliance themselves for the use to which they put the product. This may therefore require liaison with authorities in whose area the customer business is situated.

The Food Standards Agency,

Incident Prevention and Chemical Risk Management Unit,

The Food Contact Materials Team.

London.

September 2008
ACKNOWLEDGEMENT

This annex draws on the guide to good manufacturing practice prepared by the European Council of Paint, Printing Ink and Artists’ Colours Industry (CEPE), it does so in conjunction with guides by other European and national representative associations. The Agency is happy to acknowledge the significant contribution their work has made to this more generalised guidance for all businesses to apply as appropriate and proportionately within their businesses.

1. COMMON ISSUES TO TAKE INTO ACCOUNT IN DEVELOPING THE PRACTICE AND DOCUMENTATION OF GOOD MANUFACTURING PRACTICES

<table>
<thead>
<tr>
<th>Best Practice</th>
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<tbody>
<tr>
<td>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 will help to ensure that products comply with the law or other generally accepted requirements, are fit for the purpose intended and meet customers needs of the product.</td>
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<table>
<thead>
<tr>
<th>Controls</th>
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<tbody>
<tr>
<td>Manuals</td>
</tr>
<tr>
<td>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.</td>
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<table>
<thead>
<tr>
<th>Production Instruction Documents</th>
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<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Test Specifications</th>
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<tbody>
<tr>
<td>Product test specifications should exist for each product. They list the tests which</td>
</tr>
</tbody>
</table>
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;
- bring about an unacceptable change in the composition or quality of the foodstuff.

Any industry-wide agreement or practice concerning substances, their purity or quality criteria that means 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.
A format for a declaration of compliance based on Regulation (EC) No.1935/2004 Article 3:

<table>
<thead>
<tr>
<th>Best Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Manufacturer/Importer/Supplier</td>
</tr>
<tr>
<td>Batch/Consignment Contents</td>
</tr>
<tr>
<td>Date of Declaration</td>
</tr>
<tr>
<td>Points of note (product usage, storage, handling etc.)</td>
</tr>
</tbody>
</table>

### Declaration of compliance with Article 3 of Regulation (EC) No 1935/2004

<table>
<thead>
<tr>
<th>Substance</th>
<th>Detected Migration Level</th>
<th>Estimated Daily Intake</th>
<th>A. Formally pronounced Acceptable Daily Intake or Tolerable Daily Intake ADI/TDI</th>
<th>Compliance/Non-compliance (add any conditional comments)</th>
</tr>
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Annex 2
Part B

A format for a declaration of compliance based on a specific measure e.g. Directive 2002/72/EC:

<table>
<thead>
<tr>
<th>Best Practice</th>
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</thead>
<tbody>
<tr>
<td>Manufacturer/Importer/Supplier</td>
</tr>
<tr>
<td>Contents</td>
</tr>
<tr>
<td>Date of Declaration</td>
</tr>
<tr>
<td>Declaration of compliance with [Title of specific EU measure/National instrument]</td>
</tr>
</tbody>
</table>

Information about the compliance of substances used that are subject to any restrictions and/or specifications.

<table>
<thead>
<tr>
<th>All substances - compliance with the overall migration limit</th>
<th>Restrictions in law</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>[10 mg/dm² of the surface area of the material or article] [60 mg/kg foodstuff]</td>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>Individual substances</th>
<th>Restrictions in law</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
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<td>2.</td>
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<tr>
<td>Etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Information about the compliance of substances subject to a purity criteria (where applicable)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Restrictions in law</th>
<th>Established migration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Etc.</td>
<td></td>
<td></td>
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</tbody>
</table>

Specifications on the use of the material or article:

| 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