FoodContact

BEST PRACTICE

Paper & Board for Food Contact Compliance Documentation

cepi

TABLE OF CONTENTS

1 BACKGROUND

All materials and articles intended for food contact manufactured within the EU must comply with the requirements of Regulation 1935/2004[1], the so-called "Framework Regulation". In Article 16, "Declaration of Compliance", it is stated that specific measures for individual packaging materials (as foreseen elsewhere within the framework regulation) shall require that materials and articles be accompanied by a written declaration stating that they comply with the rules applicable to them and that appropriate documentation shall be available to demonstrate such compliance. The documentation to prove compliance shall be made available to competent authorities on demand. So far, no such specific measure for paper and board materials and articles has been developed so the legal requirement to produce documentation does not yet exist.

However, many customers in the food supply chain as well as authorities believe it is good business practice to provide compliance declaration voluntarily. So, even in the absence of a specific paper and board measure, requests for a declaration of compliance (DoC) are becoming more frequent and the supply of DoCs is becoming a routine procedure for paper and board suppliers.

This document aims to provide advice to manufacturers of paper and board materials and articles about the best practice to be used when providing DoCs and supporting information. It is designed to be informative only and its use is voluntary.

2 DOCUMENTATION

2.1 Types of Documents

There are two main types of documentation involved when claiming compliance. These are as follows.

- **Declaration of Compliance (DoC)**

  The DoC is the core document which the manufacturer passes to the downstream user when the material or article is placed on the market. Although, as stated above, a DoC is not currently a legal requirement for paper and board, an example of the information which is required is given in Annex 1[2]. The manufacturer uses it to declare that all relevant rules have been met. In principle, the DoC is the only compliance document which needs to be passed to the downstream user.

- **Supporting Documentation**

  This can consist of a number of documents which could include, for instance, analysis reports, calculations, certificates from suppliers of raw materials and chemical additives, testing certificates from third party laboratories and institutes and/or other evidence of safety which demonstrates the correctness of the declaration of compliance. It is not necessary to pass this material to the downstream user but must be retained for inspection by the "competent authorities".

1. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food
2. Extract from the Industry Guideline for the compliance of paper and board for food contact http://www.cepi.org/content/default.asp?PageID=558&DocID=52810

2.2 Function of the Documents

It is most important that the specific uses of these two types of documents are fully understood.

If compliance is being requested or claimed, then it will be in accordance with one or more of the paper and board measures currently in existence e.g. the Industry Guideline, the Council of Europe Resolution ResAP (2002) 1, BfR Recommendation 36, national legislation, etc. These measures all contain a number of safety requirements although each one differs in the detail and the number of those requirements. These latter include, for instance, lists of approved chemicals, end product specifications, contaminant limits, testing protocols, guidelines for the use of recycled fibres, Good Manufacturing Practice guidelines, etc.

In order to claim compliance with one of these measures, it is essential that all the elements contained within that particular measure are fulfilled. Thus, a DoC must cover all the stated requirements of the measure. In addition, internal, supporting information must be compiled which demonstrates such compliance.

2.3 Avoidance of Misuse

From the above, it is clear that supporting information must be complete and able to demonstrate the fulfilment of all elements within the measure which is being used. A particular area where attention is needed is the use of independent institutes to provide third-party certificates of compliance. In general, such certificates should be used as part of the collection of internal supporting documentation as they may contain incomplete data. A difficulty will arise where such certificates are used as the sole means of demonstrating compliance because, often, not all requirements in the particular measure will have been examined. Typically, a third party certificate will examine and approve some aspects of the final product but will do so without giving the necessary, related details of the manufacturer's internal processes. Such a certificate has very doubtful regulatory status and is not a substitute for a full DoC. It can give the dangerous and incorrect impression that all regulatory requirements have been satisfied.

It is acceptable for a manufacturer to use an independent institute to provide a DoC on its behalf but, if it is intended as the only means of demonstrating compliance, it must cover all the requirements within the relevant measure. This is the only circumstance in which a third party certificate can replace a DoC.

3 BEST PRACTICE

Downstream users will not always have the skill and experience of paper and board manufacture which is necessary for correctly evaluating compliance documentation. Therefore, the procedure required for supplying the documentation must be clear, unambiguous and transparent.

3.1 Primary Method

In general, the best overall practice is for a manufacturer to provide the downstream user with a DoC covering all elements in the regulatory measure being used (e.g. Industry Guideline, BfR Recommendation 36, etc.). It will be necessary for the manufacturer to collect and retain supporting data for all elements mentioned in the DoC. The format of the DoC should reflect the example shown in Appendix 1 although the precise content will depend upon the measure against which compliance is being claimed. Optionally, a manufacturer can provide voluntarily, in addition to the full DoC (not as a substitute), a third-part certificate to illustrate compliance with a certain element within the relevant measure.

3.2 Alternative Method

As an alternative, the responsibility for providing the full DoC, and any supporting data, can be delegated to an independent institute provided that it can truly claim to have verified, on behalf of the manufacturer, compliance with all elements within the relevant measure. In order to assist those wishing to follow this route, guidance is provided in Annex 2.

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ANNEX 1

EXAMPLE OF REGULATORY DECLARATION OF COMPLIANCE [3]

The declaration of compliance shall contain the information listed below. The declaration shall be renewed when substantial changes in the production occur, when new scientific data are available or when there is a change in applicable regulations.

1 Date of Declaration of Compliance

2 Manufacturer

2.1 Identity and address of the organization which manufactures the materials or articles.

2.2 Where appropriate and if different from 2.1, the address of the manufacturing site.

3 Identity of the materials and articles

3.1 Generic product description.

3.2 Trade name or grade description, including other relevant identifying information.

3.3 If appropriate, special instructions to be observed for safe and appropriate use.

4 Confirmation of Compliance with this Guideline and Regulation 1935/2004

4.1 Statement that the product complies with Article 3 of Regulation 1935/2004.

4.2 Statement that all raw materials are in compliance with Annex 1 and, if appropriate, Annex 2 of this Guideline.

4.3 Statement that the product has been manufactured in accordance with Regulation 2023/2006 on Good Manufacturing Practice.

4.4 Statement, if appropriate, that the product has been manufactured in accordance with a specific GMP, hygiene standard or management system described in Section 5 of this Guideline.

4.5 Statement of the conditions of use for the product including type or types of food envisaged for the intended end-use and any special package storage conditions.

4.6 When the product is required for lamination to food contact plastics where the Paper and Board is not in contact with food, a quantitative statement is required of all intentionally added substances having quantitative restrictions in Directive 2002/72/EC and subsequent amendments. This may be covered by a confidentiality agreement between user and supplier when appropriate.

4.7 When relevant, include a statement on the presence of any “dual use” [4] additives which have been used in the manufacture of and are present in the Paper and Board

3. The content will vary according to the measure being used.
4. Dual use additives are substances which are approved for food use and hence may be in the food being packed, and also used in paper and board manufacture.

ANNEX 2

PROVISION OF COMPLIANCE DOCUMENTATION [5] BY INDEPENDENT INSTITUTES

GUIDANCE ON CONTENT

Product name

- Trade name(s) of the product(s) and other details necessary to clearly identify for which product(s) the certificate is issued (i.e. a specific grammage or all grammages)

Identity of the manufacturer

- Name and address of the manufacturer

Date of issue

Identity of the certificate

- A certificate No/Ref. to ensure traceability to underlying documentation and to be able to clearly distinguish between different certificates for the same product

Legal reference

- The measures (regulations, recommendations, standards, etc.) used for the assessment must be clearly identified and the latest available texts should be used.

Scope of the assessment

- It must be clearly stated which type of assessment has been made i.e. does it cover all the elements in the relevant measure including formulation of the product and testing end-product requirements or only an incomplete assessment.
- If the certificate is only based on testing it should be clearly written that other elements are needed (approval of raw materials and chemical additives) to ensure full compliance with the actual regulation/guideline. It should be indicated in the certificate that the responsibility lies with the manufacturer to assess and provide information on these additional elements. It should also be stated how the results of the limited testing affect the suitability of the actual product for various food contact applications.
- It is recommended to clearly state that the testing is performed on a sample(s) of the actual product(s) e.g. *"a sample of the above product has been tested according to … (the measure in use) and has been found to comply with the end product requirements specified in that measure."*
- It is not appropriate to state legal compliance for various end use applications only based on testing as full compliance depends upon a complete assessment.

5. Sometimes known as a third-party certificate of compliance

Specification of Intended use or limitations for use (only possible for complete assessments)

- The suitability for different end uses should be clearly indicated taking into account the different requirements for different food types.

Validity date

- If a validity date is given, it must be clearly indicated that this is only valid for the actual product as it was manufactured at the date of issue and the actual regulations in force at that time.
- It should be indicated that it is the responsibility of the manufacturer to update the certificate if there have been significant changes in the manufacturing that can affect the validity of the certificate and the suitability for its end use as well as any changes in the legislation that will affect the correctness of the certificate.

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