FoodContact

Industry Guideline

for the Compliance of

Paper & Board Materials and Articles for Food Contact

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Developed by the European paper and board food packaging chain:

CEFIC (suppliers of chemicals)
CEPI (paper and board manufacturers)
CITPA (paper and board converters)
FPE (paper and board multilayer manufacturers)

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FOREWORD

Paper and board has a long and successful history of safe use in the food industry in a wide range of applications. These include applications where intimate contact is involved, such as tea bags, baking papers, and filters, and direct contact packaging such as butter wrapping, sugar bags, and cartons for dry and frozen foods. In addition it has a very wide range of uses in transport and distribution packaging.

Although there is a wide range of applications, the proportion of packaging made from uncoated and untreated paper and board and coming into direct contact with food bought by the end-consumer was estimated to be less than 3.5% (3.39% is the actual value quoted) of all direct contact food packaging in the EU-15 in 2000 (Ref. 1). Compared to other direct contact food packaging materials, for example plastics (estimated proportion around 70%), this estimate of 3.5%, less than 0.9 kg paper per person per year, is relatively low and thus consumer exposure is similarly low. In addition direct contact is primarily with dry food (approximately 50%) and with food that is to be peeled or washed (approximately 30%) so only the remaining 20% is for contact with moist and/or fatty food.

Uncoated and untreated paper and board is not suitable to pack food with very high moisture content (for example liquid food or wet chilled products), since exposure to high moisture will cause disintegration of the material. For these food types coated paper and board is commonly used, and in the great majority of applications direct food contact is with a plastic layer. The proportion of packaging made from coated paper and board was estimated to be 17% (equivalent to 4.4 kg per person per year) of all direct contact food packaging in the EU-15 in 2003 (Ref. 2). Between 70-80% of all coated paper and board that is in direct contact with food is liquid packaging board (used for instance in cartons for milk and beverages) and 75% of this has aluminium foil as a barrier layer in the laminate structure that will prevent migration from the paper and board. If liquid packaging board containing an aluminium layer is excluded, the proportion of coated paper and board packaging used for food contact is 7.6% (equivalent to 1.93 kg per person per year).

The paper and board sector has a long-standing commitment to the protection of human health and the interests of consumers through the provision of safe and functionally effective materials. The sector has cooperated over a long period of time with government, both at national and supra-national level, and with other regulators to ensure necessary measures for consumer protection. Over the past thirty years the basis for this measure at the European level has been Directives and most recently a Regulation concerning materials and articles intended to come into contact with food (Directives 76/893/EEC, 89/109/EEC and Regulation No (EC) 1935/2004).

These Directives and the Regulation have all made provision for the adoption of specific directives or measures relating to particular groups of materials or articles. However so far no specific measure at the level of the European Union has been introduced for paper and board and, although national and other provisions exist, the European paper and board sector considers that it is now appropriate to publish this Guideline. As well as providing a methodology for establishing the suitability of paper and board for particular food contact applications, it is envisaged that this Guideline could form the basis of a specific legislative measure in the future, a development that the paper-based packaging industry would welcome.

This Guideline considers the specific nature of food contact paper and board with regard to the following aspects:

1. Paper and board consists predominantly (around 99%) of cellulose fibres, naturally occurring minerals such as calcium carbonate, and natural polymers such as starch. Cellulose itself is a natural polymer based mainly on glucose units. The properties required of specific paper grades are obtained by adding chemicals that are in most cases used in amounts significantly less than 1% by weight of the paper and board. There are two categories of chemicals added:
   - Functional additives that are intended to stay in the paper and board in order to achieve a technical effect.
   - Process chemicals or processing aids that are used to improve the efficiency of the papermaking process. These chemicals are not intended to stay in the paper and board and are usually washed out during the papermaking process.
2. Paper and board for food contact is different from plastics where most legislative provisions have so far been concentrated. For instance:
   - It has low consumer exposure due to the low proportion of all direct contact food packaging, where the main application is contact with dry food.
   - It has a completely different manufacturing process compared to plastics.
   - Its predominant base polymer is cellulose whose monomer, ß-glucose, has no known adverse health issues.
   - Standard migration test methods used for plastics are not easily applicable or not appropriate for control.

For these reasons regulation and control of paper and board for food contact using the "plastics" approach with control of numerous specific migration limits does not appear to be the most suitable. The already existing and widely used Recommendation XXXVI (plus parts I, 2 and 3) of the German BfR (Bundesinstitut für Risikobewertung, see Annex 1) sets compositional limits and seems to be a more appropriate basis for regulation and control. This Recommendation is also referred to in other national requirements, e.g. the French "Guide de Bonnes Pratiques". The methodology in this Guideline is based on this BfR Recommendation, although substances which are the subject of other approvals may also be permitted (see Annex 1). Also introduced is a larger element of final product testing and specific requirements for the control of recovered paper.

This Guideline has been the subject of an independent peer review, carried out by Pira International.
The entire peer review can be downloaded at
http://www.cepi.org >Publications >Food Contact

1 INTRODUCTION

1.1 Objective

This document is aimed at manufacturers of paper and board materials and articles intended for food contact and is designed to provide guidance for establishing compliance with Regulation (EC) No 1935/2004. Whilst it provides a methodology for the demonstration of the suitability of materials and articles for a variety of food contact applications, in itself it has no legal force. Its use is voluntary and it should be noted that other compliance mechanisms exist which may be used separately or in conjunction with this Guideline.

It is the intention that the contents of this document are not fixed and will be updated in accordance with evolving best practice and knowledge of food safety. See Annex 5 for details of two developments currently in progress within the paper and board industry.

1.2 Field of Application

Paper and board materials and articles are manufactured from cellulose-based natural fibres both bleached and unbleached, from primary and recycled sources. In addition paper and board may contain functional additives and synthetic fibres and also other treatment agents and polymeric binders for organic and inorganic pigments.

This Guideline applies to materials and articles constituted of paper and board (excluding non-wovens as defined by ISO 9092) which may comprise one or more layers of fibre and which in their finished state:

- are intended to be brought into contact with food, or
- are already in contact with food and were intended for that purpose, or
- 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 two principal operations in the manufacture of paper and board materials and articles for food contact are normally papermaking and conversion. Most of the specific requirements given in this Guideline will apply at the papermaking stage and will be applicable to paper and board at the completion of that operation. Some requirements are relevant to the converting operation.

Paper and board includes mineral coated papers, and the components including polymeric binders in the coating formula are covered by the requirements of this Guideline.

This Guideline may also be applied to paper and board as it is used in other coated and laminated materials, including combinations with plastics, aluminium, and waxes. Specific sections of this Guideline deal with multi-material multilayer materials involving combinations of paper and board and plastics, filtering and baking applications, and secondary packaging applications.

Tissue paper, kitchen towels and napkins are covered by specific guidelines (Ref. 3) and are excluded from the scope of this Guideline.

In providing requirements and a methodology to establish compliance with Regulation 1935/2004, it is expected that this Guideline would become widely used by companies operating in markets potentially covering all member states of the European Union. Certain European countries have specific national legislation covering food contact applications which will take precedence over this Guideline and compliance with that legislation may be required.

2 CORE REQUIREMENTS

2.1 Regulation (EC) No 1935/2004

In accordance with Article 3 of Regulation 1935/2004:

"Materials and articles, made of paper and board, 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:

- **endanger human health, or**
- **bring about an unacceptable change in the composition of the food, or**
- **bring about a deterioration in the organoleptic characteristics of the food."**

This is the core EU legislative requirement for all materials and articles intended for food contact and which has been essentially unchanged since 1976. Further sections of this Guideline deal with specific test and performance requirements and the methodology for their application, that provide the practical demonstration of conformance with this legislative requirement.
In particular:

- Clause 5 of this Guideline gives the requirements which shall be followed to provide the assurance of good manufacturing practice. Paper and board shall be of a suitable microbiological quality taking into consideration the potential end-use applications and control of this aspect is a part of the GMP requirements in Clause 5.
- Annex 1 of this Guideline lists the substances permitted for use in the manufacture of paper and board intended for food contact and conditions for their use. The restrictions provided in Annex 1 shall apply.
- Recovered paper is used in the manufacture of many grades of food contact paper and board. This Guideline has in place a number of requirements and ensures that there is a structured and controlled framework for operations involving the use of recovered paper. Annex 2 lists the details of these controls and gives the requirements which shall apply.

2.2 Demonstration of Compliance

In order to provide evidence of compliance with this Guideline and Regulation 1935/2004, two mechanisms shall be in place. Firstly, a formal declaration of compliance shall be prepared for each grade or type of food contact material or article. This shall be issued and available for immediate inspection both by enforcement authorities and customers. Annex 4 gives the requirements for the content of the declaration of compliance.

Second, business operators shall maintain appropriate documentation and records which serve as evidence of the statements made in the declaration of compliance. It is expected that these latter records will consist largely of a continuously updated database of internal information and, as such, cannot be made available in a single dossier for immediate inspection. Business operators shall however produce on demand and within a reasonable timeframe for the competent authorities adequate summaries of this information to demonstrate such compliance. This documentation shall include the conditions and results of testing, calculations, other analysis, and evidence of the safety or reasoning demonstrating compliance.

The documentation shall be made available to the competent authorities on demand. The operator may indicate which information is to be treated as confidential on the ground that its disclosure might significantly harm its competitive position.

Substances which are subject to a restriction in food, and which are present in paper and board shall not transfer to food in quantities which might cause the level in the food to exceed the required limits, even though the level in the paper and board is within the limits required by this Guideline. This might happen, for instance, if a particular substance occurred in the food through the presence of an approved food additive or by migration from another part of a multilayer. When relevant, the presence of any “dual use” additives which have been used in the manufacture of and are present in the paper and board shall be included in the Declaration of Compliance (Annex 4)[1].

The requirements of Article 15 of Regulation 1935/2004 with regard to labelling shall be applied. It should be noted that paragraph 2 of Article 15 states that labelling shall not be obligatory for articles which, because of their characteristics, are clearly intended to come into contact with food.

1. A list of potential “dual use” substances can be found at http://www.cepi.org/content/default.asp?pageid=617

3 METHODOLOGY

3.1 Assessing Compliance

Figure 1 provides a schematic representation of the method for assessing compliance for papermaking operations, working through the processes in a logical sequence.
It covers:

1. control of raw materials as required by Annexes 1 & 2
2. control of the process as required by Clause 5 (GMP)
3. product requirements covered by:
    - chemical testing required by Clause 4
    - traceability as required by Clause 9

In fulfilling the sequence described in Figure 1, the assessments for the papermaking operations are complete. The subsequent stage covers conversion operations and the controls required for these operations are summarised in Figure 2.

3.2 General Principles relating to Frequency of Testing

The purpose of the restrictions and the relevant chemical tests, detailed in this Guideline, is to ensure that the material or article is fit for its intended purpose. Testing shall therefore be performed at a frequency which relates to the likelihood of a particular restriction being exceeded[2]. In the special case where conclusive evidence demonstrates that a substance could never exceed its restriction in the material or article then testing is not required[3].

3.3 Risk Assessment Frequency

A documented risk assessment shall be performed when significant changes have taken place in the equipment or process used to manufacture the material or article or in the supply of its raw materials. The purpose of this would be to establish if product characteristics were likely to be altered sufficiently to necessitate short or long-term changes in the testing regime.

2. Guidance on this matter is given in the CEPI Good Manufacturing Practice for papermaking due to be published in 2010.
3. This exception does not replace the responsibility of the operator to ensure compliance, at all times, with Regulation 1935/2004, particularly Article 3.

4 CHEMICAL TESTING

The restriction limits given in Table 1 shall apply to all paper and board covered by this Guideline. As described in the following paragraphs and Note 3 to Table 1, testing requirements will depend on the paper and board used and the type of contact.

The substances identified in the "Remark" column of Table 1 with * are generally found only in recovered paper and board and will not need, in normal circumstances, to be subject to tests for paper and board manufactured solely from virgin fibre. See *General Principles relating to Frequency of Testing* in Clause 3 for further guidance in cases where testing is not required.

The substances identified in the "Remark" column of Table 1 with # will need to be subject to tests only if, in normal circumstances, the end use of the paper and board is known to be for contact with moist and/or fatty food[4].

Table 1 – Purity Requirements

SUBSTANCE	LIMIT IN FOOD	TESTED IN PAPER & BOARD	REMARK
	SML (mg/kg food)	Limit	
Cadmium	-	0.5 mg/kg	#
Lead	-	3.0 mg/kg	#
Mercury	-	0.3 mg/kg	#
Pentachlorophenol	-	0.15 mg/kg	
Antimicrobial Substances	-	No release of substances in quantities which have an antimicrobial effect.	
Michler's ketone	0.01 mg/kg (non-detectable)	0.0016 mg/dm^2	*
4,4-bis (diethylamine) benzophenone (DEAB)	0.01 mg/kg (non-detectable)	0.0016 mg/dm^2	# *
Azo colourants	-	0.1 mg/kg as aromatic amine[5] (non-detectable)	# *
Dyes and colourants	-	no bleeding	#
Fluorescent Whitening Agents (FWAs)	-	no bleeding	#
Polycyclic Aromatic Hydrocarbons (PAHs)	0.01 mg/kg (non-detectable)	0.0016 mg/dm^2 [6]	*
Dibutylphthalate (DBP)	0.3 mg/kg	0.05 mg/dm^2	*
Di(2-ethylhexyl)phthalate (DEHP)	1.5 mg/kg	0.25 mg/dm^2	*
Diisobutylphthalate (DiBP)	0.5 mg/kg (baby food)	0.08 mg/dm^2	*
	1.0 mg/kg (other food)	0.17 mg/dm^2	*

4. This is from the BfR Recommendation (see Annex 1) and this exception does not replace the responsibility of the operator to ensure compliance, at all times, with Regulation 1935/2004, particularly Article 3.
5. Sum of listed amines
6. Sum of listed PAH's

SUBSTANCE	LIMIT IN FOOD	TESTED IN PAPER & BOARD	REMARK
	SML (mg/kg food)	Limit	
SUM DBP + DiBP	0.5 mg/kg (baby food)	0.08 mg/dm^2	*
	1.0 mg/kg (other food)	0.17 mg/dm^2	*
Benzylbutylphthalate (BBP)	30 mg/kg	5 mg/dm^2	*
Diisononylphthalate (DINP)	9 mg/kg	1.5 mg/dm^2	*
Diisodecylphthalate (DIDP)	9 mg/kg	1.5 mg/dm^2	*
Benzophenone	0.6 mg/kg	0.1 mg/dm^2	*
SUM benzophenone+ hydroxy-benzophenone+ 4-methylbenzophenone	0.6 mg/kg	0.1 mg/dm^2	
Diisopropylnapthalenes (DIPN)	-	As low as technically possible	*
Bisphenol A	0.6 mg/kg	0.1 mg/dm^2	# *

NOTE 1: *Testing for compliance with the limits in Table 1 should be carried out according to the testing methods and principles set out in Annex 3. Figure 3 provides a schematic representation of some elements of the determination of compliance.*

NOTE 2: *The limits quoted in Table 1 are from published sources, principally the BfR Recommendation XXXVI and the Council of Europe Resolution ResAP (2002)1 and its Technical Document No. 3. The limits for phthalates are taken from Directive 2007/19/EC from March 30, 2007 (DBP, DEHP, BBP, DINP, DIDP) and for DiBP from BfR Recommendation XXXVI. (see Annex 1)*

NOTE 3: *There is a wide range of end use applications for paper and board food packaging which vary greatly in their potential for substances to migrate to food. Thus testing for compliance with the limits in Table 1 need not be performed if it can be shown that the requirements of Regulation 1935/2004 are met. This requires that, under normal and foreseeable conditions of use, materials and articles 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 food: or

c) bring about a deterioration in the organoleptic characteristics thereof.

Where testing is needed to demonstrate compliance with the requirements of Table 1 and Annex 1, the general principles in Clause 3 and the CEPI GMP document shall apply.

NOTE 4: *The reason for some limits being quoted in units of weight/weight and some in weight/area is the different sources for the limits. The limits expressed as mg/dm^2 are derived from specific migration limits (SMLs) and are expressed as maximum permitted residual amount (QMA) of a substance in paper and board assuming total transfer.*
In practice, an analytical measurement will give a weight/weight result and a conversion to weight/area considering the actual grammage of the paper and board will be required for comparison with limits expressed as weight/area. (See Note, Figure 3)

NOTE 5: *If it is assumed that complete migration of a substance occurs from the paper and board to the food it is possible convert limits in food (SMLs) to a total quantity of the substance in paper and board. The "standard" packaging /food ratio in EU risk assessments of migration is 6 dm^2 packaging material in direct contact with 1 kg food. Using this "standard" ratio the SML should be multiplied by 0.167 (or divided by 6) to obtain a maximum permitted content in 1 dm^2 of paper and board (QMA).*

If the packaging to food ratio differs from the standard ratio of 0.167 and the value of the ratio is known, it is permitted to use this value to obtain the QMA.

5 GOOD MANUFACTURING PRACTICE

Good Manufacturing Practice (GMP), in relation to food contact materials is defined as: “those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof”

GMP shall apply to all aspects of the processes involved, starting from the selection and usage of chemicals, wood-pulp and recovered paper, through the operation of paper machines and finishing with converting operations and transport. It is recommended that GMP is implemented through formal management systems. Where this is not the case it shall be demonstrated that the arrangements provide the same level of assurance as a formal management system.

NOTE: *A Commission Regulation on GMP (EC) No 2023/2006 became applicable in August 2008 and contains a requirement for a formal quality assurance system.*

Conformance with the requirements of the ISO 9000 series will cover much of what is required to fulfil GMP requirements which will include conformance to specification and use of appropriate substances and preparations. The balance could be provided by conformance with formal hygiene management systems (which include aspects such as control of contamination). The following are examples of schemes which include some or all of the above aspects.

Aspects of the special safety controls required for the use of recovered paper in paper and board for food contact will be included in the management systems set up under the GMP requirements. These controls relating to GMP are included in Annex 2.

Papermaking operations

- Industry GMP Standard (under development)

NOTE 1: *This GMP will include requirements covered by the CEPI Guidelines for Responsible Sourcing and Supply of Recovered Paper (Ref. 4)*

NOTE 2: *This GMP is a development of the CEPI GMP (Ref. 5)*

NOTE 3: *The relevant standards listed for converting operations may be applied to papermaking operations. This may be on the initiative of the manufacturer or as a result of a customer request. Such standards will normally be applied in mills manufacturing grades of paper and board for the most critical food contact applications.*

Converting operations

- CEN Standard EN 15593:2008
- other appropriate standards include the FEFCO/ESBO GMP, the FPE/CITPA GMP and the BRC/IOP Standard. (Ref. 6, 7, 8).

6 BEST PRACTICE FOR TREATMENTS APPLIED DURING CONVERTING OPERATIONS

Best practices for converting operations should result from a hazard analysis and a risk assessment. For packaging, the risk analysis shall be extended to the whole packaging system.

Inks, varnishes and adhesives used for printing and converting should be selected to ensure the lowest possible levels of migration into food by following the requirements of the Regulation 2023/2006. This process should be facilitated by consultation with the suppliers of those materials and the use of their guidance on the use of low migration and low odour products.

A special case is the use of UV cured inks. In view of the history of the use of these products and the photoinitiators that they contain, it is recommended that they are not used in any packaging application. However, it is known that certain manufacturers have begun to produce new and safer photoinitiators and operators could use such products following assurances from those manufacturers about their suitability for food contact in the application envisaged.

See also Section 3.1 of Annex 2.

REQUIREMENTS FOR USE WITHIN MULTILAYERS

7.1 General

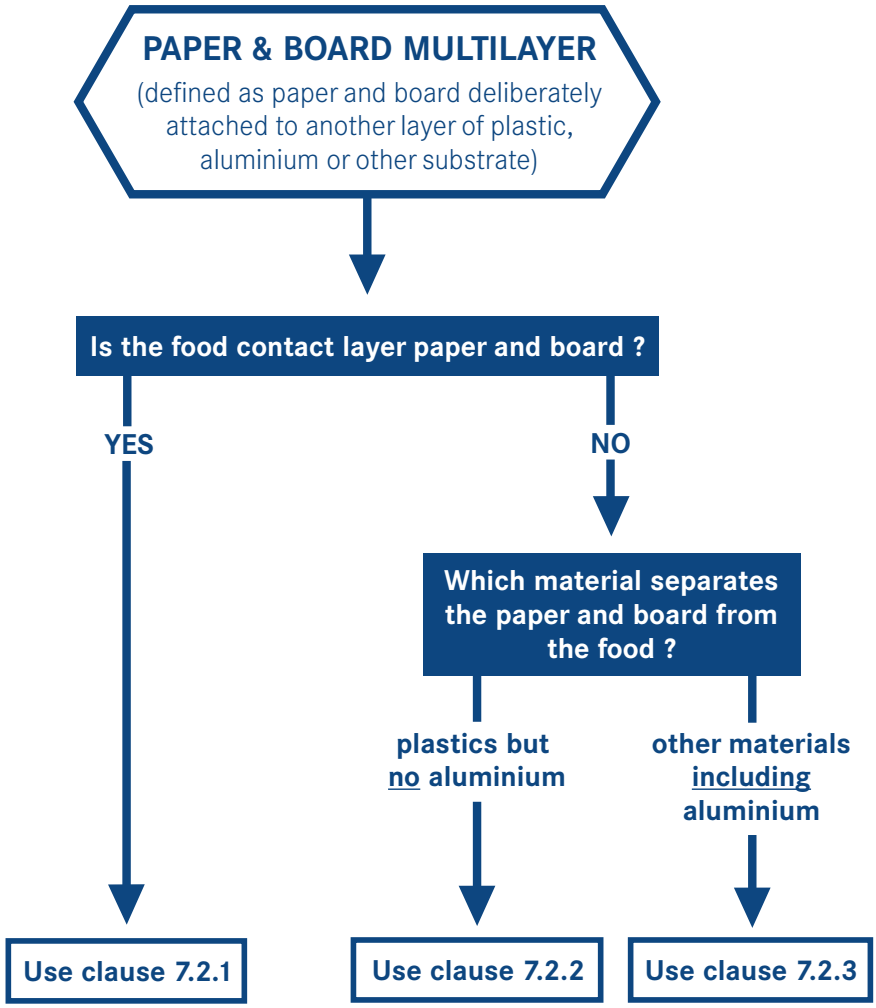
This clause provides the requirements for materials and articles intended for direct food contact and which are composed of two or more layers of different types of materials which are intentionally bound together. Such materials can be termed multi-material multilayers. The commonly used materials for such multilayer constructions in combination with paper and board are various types of plastic film and aluminium foil as well as coatings and printing inks.

In general, multilayers in which paper or board is present, can be subdivided into three categories:

1. multilayers in which the paper or board layer is in direct contact with the food
2. multilayers in which there is at least one plastic film between the paper or board and the food, but no aluminium foil;
3. multilayers in which there is aluminium foil and optionally plastic film between the paper or board and the food.

A plastic layer extrusion-coated on to the paper web, is considered a plastic film in the context of the three classes of multilayers defined above. It has to be noted that such products are often referred to as “coated paper” within the industry although strictly a distinction should be made between the plastic coated papers covered by this Clause and papers coated with minerals such as calcium carbonate.

The following diagram provides guidance on the use of this Clause



7.2 Requirements

7.2.1 Category 1- Multilayers in which the paper or board layer is in direct contact with the food

Requirements for materials other than paper and board

Materials other than paper and board used in multilayer constructions shall conform to the relevant European or national legislation and requirements applicable to them. In the case of plastics the relevant European legislation is Directive 2002/72/EC, as amended.

Requirements for paper and board as direct food contact layer

Paper and board in multilayers, where there is no plastic film or aluminium foil between the paper or board and the food, shall comply with this Guideline as if it was used by itself.

7.2.2 Category 2 – Multilayers with at least one plastic layer between paper or board and the food

Requirements for materials other than paper and board

Materials other than paper and board used in multilayer constructions shall conform to the relevant European or national legislation and requirements applicable to them. In the case of plastics the relevant European legislation is Directive 2002/72/EC, as amended.

Requirements for paper and board behind a plastic layer

Paper and board in multilayers, where there is a plastic layer (but no aluminium foil) between the paper or board and the food, shall comply with this Guideline. Testing required by this Guideline, may be carried out either on the paper and board, or, when appropriate for the specific test, on the finished multilayer.

Assessment of the multilayer

In addition, the multilayer has to be assessed for compliance with overall and specific migration limits and other restrictions (abbreviated as OML and SML respectively) defined by Directive 2002/72/EC, as amended, for substances used in plastics. The SML of any restricted substance present in the multilayer shall apply to the entire multilayer. Only substances intentionally added to the paper and board or to the plastic shall be considered.

The identity of substances with SML, and adequate information for their compliance assessment, shall be obtained from the suppliers of additives to paper and board manufacturers and from the plastic raw materials suppliers, respectively.

In case the substance is used in the paper or board but not in the plastic, the migration can be determined by testing or calculation at the plastic food contact layer or at the paper and board layer. The correction factors PBCF and EXCF (see below) apply to the migration determined at the paper and board layer. The correction factors PLRF and EXCF (see below) apply to the migration determined at the plastic layer.

In case the substance is used in both the paper or board and in the plastic food contact layer, the migration can be determined by testing at the food contact layer, or by calculation i.e. addition of the migration from the plastic and from the paper and board determined separately. The correction factor PBCF applies to the migration determined at the paper and board layer. The correction factor PLRF applies to the migration determined at the plastic layer.

Similarly, the total multilayer material shall comply with the OML, adjusted by the Correction Factor PLRF, and compliance shall be determined at its intended food contact surface.

The following correction factors may apply to the compliance assessment with SML:

- PBCF = the correction factor applicable to paper and board is 1[7];
- PLRF = the reduction factors defined for plastics by Directives 85/572/EEC and 2002/72/EC;
- EXCF = a correction factor defined as 6 dm^2 divided by X dm^2 where X is the area of paper/plastic multilayers to which the consumer is daily exposed. 6 dm^2 is the area conventionally considered for exposure to plastics. Based on current information (unpublished Exposure Matrix data) X equals 0.8 dm^2 so that EXCF = 7.8.

For migration testing at the plastic food contact surface, simulants shall be selected according to Directive 85/572/EEC, as amended, and test conditions shall follow Directive 82/711/EEC, as amended. Due consideration shall be given to the fact that certain test simulants and/or test conditions applicable to plastics, may give rise to physical changes (e.g. swelling) in the multilayer which do not happen in contact with the food. In such cases a less severe simulant or test condition, more appropriately representing the actual conditions of use may be selected.

7.2.3 Category 3 – Multilayers with aluminium foil between paper or board and the food

Requirements for materials other than paper and board

Materials other than paper and board used in multilayer constructions shall conform to the relevant European or national legislation and requirements applicable to them. In the case of plastics the relevant European legislation is Directive 2002/72/EC, as amended.

Requirements for paper and board behind aluminium foil

The paper or board shall comply with this Guideline.

7. See Annex 5 for further information relating to correction factors for paper and board.

8 REQUIREMENTS FOR USE AS SECONDARY AND TERTIARY PACKAGING

NOTE: *the term "secondary and tertiary packaging" is used in this Guideline to cover all packaging not in direct contact with the product (normally with the exception of multi-material multilayers). The term is thus used in a rather wider context than as it is defined in the Packaging and Packaging Waste Directive (94/62/EC).*

Regulation No 1935/2004 requires a judgement to be made on whether packaging not in direct contact still falls within the scope of the Regulation because of a transfer of constituents. With regard to transport and distribution packaging used for food already contained in a primary packaging, a decision has to be made on whether or not such packaging, "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" (Article 1 (c)). In many applications the primary packaging very obviously provides a complete barrier (examples of such primary packaging include glass bottles and metal cans) and the paper and board packaging does not fall within the scope of this Regulation.

In other applications, for instance when the primary packaging is a thin film which may allow transfer or the food being packed is particularly susceptible to organoleptic changes, the Regulation may apply. The packaging manufacturer is not normally in a position to assess the interactions which may occur given the diversity of food packed in similar containers and the complexity of the interactions particularly relating to taint and odour. Thus, while the manufacturer will be in a position to give assurances on the constituents of the final packaging, the user of the packaging, (commonly the packer/filler) should conduct a hazard analysis and risk assessment of the ultimate suitability of the entire packaging system for the food being packed, if necessary in conjunction with the primary packaging manufacturer. If it is decided that the packaging is within the scope of the Regulation then this Guideline shall apply.

9 TRACEABILITY GUIDELINES

Business operators shall use systems designed to meet the requirements of Regulation 1935/2004: "the traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility".

Industry has at the request of the European Commission produced guidelines intended to assist business operators in implementing traceability. These can be found on the website of the EU's Joint Research Centre[8].

The following points, which add clarification, should be noted when designing and operating traceability systems[9]:

1. there is no single set of rules. The systems will differ from operation to operation and will consist of those elements within the traceability guidelines (or possibly additional ones) which are necessary to achieve the requirement in the Regulation;
2. business operators are free to use whichever tools they feel are appropriate to facilitate the operation of traceability; these could include, for instance, supplier invoices with batch numbers, storage vessel and machine logs (manual or computer generated), weight lists, paper and board samples, quality control records and bar code systems ;
3. the guidelines cover the traceability of the food contact material or article itself (see 4, below) and not its raw materials or additives. However, it is recommended that all operators should have systems in place to establish the origin and, thus, the liability for defective incoming materials; otherwise, they will have to accept that liability themselves;
4. the traceability chain for paper and board packaging for food is taken to start from the paper reel at the dry end of the paper machine and the key element of information transferred to the food packer/filler is the job or batch number of the converted packaging;
5. retention of batch samples at the papermaking stage is recommended wherever possible. In cases of suspected chemical or physical contamination, testing of such samples can rapidly locate the exact time and source of an event and help to reduce the amount of material liable to recall. The need for retention of samples in conversion operations will be determined by the nature of the operation;
6. traceability systems should be included in the relevant procedures forming part of a business operator's quality management system, based on the ISO 9000 series or an equivalent;
7. rules should be made to cover the retention time for documents and samples within the traceability framework. These should be in line with the shelf-life of the product. In the absence of reliable data, a minimum period of five[10] years for documents is recommended.

The correct functioning of the traceability system should be demonstrated for instance by testing periodically using a simulated alert. A product, previously supplied to a customer, should be identified by its reel/job/batch number and assigned as being defective. Then, the business operator should test the ability to successfully and rapidly track its progress during production, identify its source from another business operator (if appropriate) and identify any other material likely to share the same characteristics, so as to facilitate a total recall.

The details required under Clauses 2.1 and 2.2 of the declaration of compliance (see Annex 4) form essential elements of the traceability system.

8. http://crl-fcm.jrc.it/index.php?option=com_docman&task=cat_view&gid=41&Itemid=57
9. Two common systems already in use in the paper industry are the CEPI Unit Identifier and the FEFCO Bar Code Standard for Corrugating Materials.
10. DG SANCO – Standing Committee on the food chain law and animal health – Guidance on the implementation of articles 11, 12, 16, 17, 18, 19 and 20 of regulation (EC) N° 178/2002 on general food law.

10 REFERENCES

1. Consumer Exposure Project Final Report. Prepared for *CEFIC FCA Additives in paper & board Industry Group (APBIG)* and *Confederation of European Paper Industries (CEPI)*. Pira International November 2002.
2. Consumption of Coated Paper & Board in Contact with Food in the EU. Final Report for CEFIC FCA Additives in Paper and Board Industry Group (APBIG). Pira International, April 2005.
3. Council Of Europe; Policy statement concerning tissue paper kitchen towels and napkins. Version 1 – 22.09.2004 .
4. CEPI: "Guidelines for Responsible Sourcing and Supply of Recovered Paper". January 2006.
5. CEPI GMP: Council of Europe Resolution ResAP (2002) 1, Technical Document No. 4
6. FEFCO/ESBO: "International Good Manufacturing Practice Standard for Corrugated and Solid Board". October 2003.
7. Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food. A Flexible Packaging Europe Initiative, realised in close co-operation with CITPA. February 2006.
8. BRC/IoP: "Global Standard for Packaging and Packaging Materials". January 2008.

ANNEXES

ANNEX 1

LIST OF SUBSTANCES (including lists for filtration, baking and other specific applications)

The substances permitted for use in paper and board conforming to this Guideline are given in BfR Recommendation XXXVI. Paper and board for food contact *.

The web link for this document is: http://bfr.zadi.de/kse/faces/resources/pdf/360-english.pdf
The limits prescribed for the use of permitted substances in these Recommendations shall be applied.

Substances listed in the national legislation of the Netherlands (commonly known as the "Warenwet")** are also permitted for use.

Substances which have been the subject of approvals other than BfR shall be permitted for use if evidence is provided which demonstrates compliance with Article 3 of Regulation 1935/2004. In particular FDA*** approvals made under 176.170(a)5 and 176.180 will provide such evidence of compliance.

If there is a conflict between the limits given for a specific substance in the above lists, then the limit for that substance given in BfR Recommendation XXXVI shall apply.

The substances permitted for use in paper and board for specific applications defined in the following list are given in the BfR Recommendations listed below:

Cooking Papers, Hot Filter Papers and Filter Layers: Recommendation XXXVI/1
Web link: http://bfr.zadi.de/kse/faces/resources/pdf/361-english.pdf

Paper and Paperboard for Baking Purposes: Recommendation XXXVI/2
Web link: http://bfr.zadi.de/kse/faces/resources/pdf/362-english.pdf

Absorber pads based on cellulosic fibres for food packaging: Recommendation XXXVI/3
Web link: http://bfr.zadi.de/kse/faces/resources/pdf/363-english.pdf

Alternatives to Compliance Testing for Substances in this Annex

If it can be shown, by documented calculation from a knowledge of the contents of the paper and board or other sources, that a limit or restriction given in the lists referred to in this Annex cannot be exceeded, then testing for that particular substance is not required.

Testing with real food is permitted and migration test results obtained with the type of food or foods envisaged for the intended end-use prevail.

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* Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment)

** Packaging and Food Utensils Regulation (Commodity Act) of The Netherlands of 20 Nov. 1979 and its amendments up to and including VGB/P&2535892 of 22 Nov. 2004.

*** Food and Drug Administration (USA)

ANNEX 2

REQUIREMENTS FOR RECOVERED PAPER

1. General

In the absence of fully recognised tools to assess non-intentionally added substances (e.g. biological tests, exposure assessment tools, threshold of toxicological concern) and to further ensure the safety of paper and board manufactured from recovered paper, the following aspects shall be considered when assessing the suitability of recovered paper as a raw material for food packaging paper and board:

- the intended use of the material (food type, contact time and temperature etc.) and the likelihood of transfer of constituents during that use;
- the quality and source of the recovered paper;
- the processing technologies applied within the paper mill to remove unwanted substances and materials.

Requirements and guidelines related to these three aspects are given in the following sections.

2. The Intended Use of the Material

The type of food to be packed and the conditions of storage, contact time and temperature determine whether or not recovered paper is suitable for a particular application. If recovered paper is judged to be suitable, then the grades which are appropriate need to be determined and the following sections include the requirement for a risk assessment[11].

The current best practice would be through the following steps:

a) identify the source of any contaminants;

b) establish a methodology for reducing those contaminants to a safe level in the final product;

c) state any restrictions on food type which might result from a risk analysis of the above steps.

To ensure that these steps are followed in the case of recovered paper, the requirements of sections 3 to 5 of this Annex shall be applied and shall be incorporated into the management system used to ensure compliance with the GMP.

11. Normally, this risk assessment should apply only on a “once-only” basis in order to approve continuing bulk supplies of a particular grade of recovered paper. It is not the intention that it should be applied on a regular basis, for instance on each delivery of that grade.

3. Quality of Recovered Paper

3.1. High Quality of Original Paper and Board

The paper industry, both manufacturers and converters, have control over the contents of the paper and board which is later recovered. The industry maintains a dialogue with its suppliers to make them aware that most grades of paper and board can eventually become part of the recycling stream and thus find their way into food contact grades. These suppliers are expected to maintain vigilance about the safety of their raw materials and communicate any concerns to the paper industry. In particular, converting operators are responsible for applying a range of substances to paper and board, e.g. inks and adhesives. These substances shall have well documented safety properties, known to the operator, as the converted product may either be used as a food packaging material or article or eventually returned to paper mills for recycling into food contact grades. Knowledge about the safety of substances is changing continuously and, in cases where new toxicological evidence is confirmed about substances previously considered safe, joint action will be taken rapidly to ensure that food contact grades remain in compliance with all legislation. Currently, this action is formalised within the Eco-design project being run by the Technical Committee which is part of the European Recovered Paper Council which represents all industrial stakeholders with an interest in the paper and board value chain and has the European Commission as an official observer.

3.2. Exclusion of Certain Sources

Certain grades of recovered paper are unsuitable for use in food contact material as the normal high standards of purity cannot be guaranteed. This is because of the way they have been treated during use or subsequent collection and sorting. The following sections give details of such grades. It is essential that paper mills have in place appropriate arrangements to secure and demonstrate their exclusion.

3.3. Use of European Standard EN643

The basis for commercial trading in recovered paper is European Standard EN643[12] and the standard is intended to facilitate the necessary collection and sorting operations, within a structured framework. However, the grading system used in the standard is not based on toxicological criteria. Such criteria are related mainly to the hygienic standards employed during handling of the material and not to the types of paper described. There are exceptions to this rule where certain grades may be known to contain substances as a result of treatment operations e.g. coating or printing.

However, the standard contains two general requirements which are relevant to food contact applications. These are given below.

a) It is stated that collected paper from refuse sorting stations is not suitable for use in the paper industry.

b) It is a requirement that recovered paper originating from multi-material collection systems cannot be mixed with other grades and shall be specially marked. (See also section 3.4.)

12. CEN Standard EN643:2001, Paper and board - European list of standard grades of recovered paper

3.4. Unusable Fractions

The following fractions of recovered paper are considered unsuitable for inclusion in food contact paper and board[13]:

- Contaminated waste paper and board from hospitals;
- Recovered paper and board which has been mixed with garbage and subsequently sorted out;
- Used stained sacks which have contained for example chemicals and foodstuffs;
- Covering materials, such as paper used for covering furniture during repair and painting work;
- Batches mainly consisting of carbonless copy paper;
- Waste paper from households containing used hygienic paper, such as used kitchen towels, handkerchiefs and facial tissue;
- Old archives from libraries, offices etc., if they contain PCBs.

In addition, it is considered in BfR Recommendation XXXVI and the Responsible Sourcing Guidelines that recovered paper originating from multi-material collection systems is unsuitable for use in food contact materials.

3.5. Identification of Recovered Paper

The recovered paper and manufacturing sectors of the paper industry have agreed a system for identifying supplies of recovered paper sent to paper mills. The system uses data combining information about the recovered paper supplier and the EN643 grade reference. Thus, a paper mill using the system can organise stocks of recovered paper in an ordered fashion and knows, at all times, the identity of the supplier of any given batch of material. Thus, a two-way communications channel is available to ensure the rapid tracing and removal from the system of any supplies of non-standard material at paper mills and their suppliers.

4. Sourcing of Recovered Paper

4.1. Responsible Sourcing

Recovered paper for use in food contact grades shall be collected and used in accordance with CEPI guidelines on responsible sourcing. (See Ref. 4) This document lays out a number of requirements to ensure consistent and clean supplies of recovered paper. These requirements cover:

- the need for quality management systems by recovered paper suppliers;
- necessary information for those involved in the business;
- best practice for collection;
- standards of hygiene for sorting stations and transportation;
- mutual notification of food contact requirements.

13. The list of grades is extracted from: Council of Europe Resolution ResAP (2002) 1, Technical Document No. 3.

4.2. Incoming Quality Control

It is essential that all incoming recovered paper is inspected by paper mills to ensure only clean and correctly identified material is used. To do this, paper mills shall operate in accordance with industry standards on quality control and the elimination of unsuitable materials[14]. These standards specify requirements for items such as:

- visual inspection of bales of recovered paper;
- internal inspection using extracted “cores”;
- information relevant to personnel involved in supply and inspection;
- the need for agreed quality specifications.

5. Processing Technologies applied within the Paper Mill

The processes used for the treatment of recovered paper are possibly the most important single element in ensuring that the appropriate level of quality and hygiene is achieved. The Council of Europe Resolution provided some requirements for processing although even these were to be applied at the discretion of the manufacturer. This Guideline does not provide any specific requirements for processing technologies which is considered to be in line with current thinking, but the following requirement in relation to the application of the GMP shall apply:

As part of the management system set up to ensure compliance with the GMP, a risk assessment shall be made to demonstrate that the processing technologies used can provide the required level of quality and hygienic appropriate to the intended use of the materials.

14. CEPI Recovered Paper Quality Control Guidelines and CEPI Guidelines on the control of the content of unusable materials in recovered paper.

ANNEX 3

TESTING METHODS

As a general principle internationally recognised and validated methods should be used (e.g. EN, ISO or equivalent) if such methods are available.
If such standardised methods are not available, analytical methods with appropriate accuracy and precision may be used.

For testing to ensure compliance with limits given in Table 1 the test methods listed below are recommended. If other methods are used it shall be ensured that they give comparable results to those specified below. For substances where standardised methods do not currently exist, literature references are given as guidance on methodology that can be applied until validated standards have been developed.

EN 645	Preparation of a cold water extract
EN 647	Preparation of a hot water extract
prEN 15519	Preparation of an organic solvent extract
EN 14338	Conditions for determination of migration from paper and board using modified polyphenylene oxide (MPPO) as simulant
EN 12498	Determination of cadmium, lead and chromium in an aqueous extract
EN 12497	Determination of mercury in an aqueous extract
EN ISO 15320	Determination of pentachlorophenol in an aqueous extract
EN 1104	Determination of transfer of antimicrobic constituents
Primary Aromatic Amines	- Amtliche sammlung von untersuchungsverfahren nach §35 LFBG, Methode L 00-00-6; Bestimmung von primären aromatische aminen in wässrigen lebensmittelsimulanzien or prEN Determination of primary aromatic amines in an aqueous extract
EN 648	Determination of colour fastness of fluorescent whitened paper and board
prEN	Determination of the migration of PAH-TEQ into food simulants
prEN	Determination of phthalates in extract from paper and board
Michler's ketone & DEAB	Castle, L. et.al Food Additives and Contaminants, 1997, Vol.14, No.1, 45-52 Migration studies from paper and board packaging materials. Part 2; Survey for residues of dialkylamino benzophenone U-cure ink photoinitiators.
Benzophenone	Castle, L. et.al Deutsche Lebensmittel.Rundschau, 91 Jahrg., Heft 3, 1995 Studies on functional barriers to migration. 1. Transfer of benzophenone from printed paperboard to microwaved food.
prCEN/TS 13130-13	Materials and articles in contact with foodstuffs – Plastics substances subject to limitation - Part 13: Determination of 2,2-bis (4-hydroxyphenyl) propane (Bisphenol A) in food simulants.

ANNEX 4

DECLARATION OF COMPLIANCE

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 (EC) No 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 Commission Regulation (EC) No 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” additives which have been used in the manufacture of and are present in the paper and board

NOTE: *“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 5

FUTURE DEVELOPMENTS

Clause 1.1 "Objective" of this document makes clear that future developments would be included in the requirements of the Guideline as knowledge evolves. In the paper and board industry, there are two areas where knowledge is currently being developed and which may eventually form part of this Guideline. At the moment, neither are sufficiently refined to use as risk management measures and details are given purely for information. They are biological tests and correction factors.

1. Biological Tests

Draft methodology for biological testing of food contact paper and board is in existence. This methodology is the outcome of the joint European Commission/Industry project known as *Biosafepaper* which concluded in 2005[15]. The concept of biological testing in this context is new and, consequently, development work is still in progress in order to convert the results into a scheme suitable for industrial use. Developments include standardization of the test methods and validation of testing institutes. Also, it is planned to add endocrine-disruption and neurotoxicity end-points to those of human genotoxicity and cytotoxicity which are already included. Ultimately the application of the methodology will need the approval of the appropriate authorities.

It is believed that biological tests will be particularly suitable for the safety assessment of additives not having current EFSA approvals and for the validation of paper and board recycling processes. The ultimate intention is to move towards an integrated testing regime where validated biological tests replace most, but not all, chemical tests.

2. Correction Factors

Another development is the use of Correction Factors which extends the "Fat Reduction Factor" concept, recently introduced into EU legislation, to make a link between quantitative limits for potential migrants and the nature of the food being packed, for instance if it is dry, moist, fatty or frozen.

A central feature of current EU legislation on food contact materials and articles is the restriction of the migration of chemical substances from the material or article into food.
The restrictions are based on experiments and calculations involving, firstly, toxicological data of the substances and, second, the amounts of these substances which are likely to transfer to food. The second of these two factors is derived from an EU benchmark which states that 1 kg of food is wrapped in 6 dm^2 of packaging.

This benchmark was set during the early days of the writing of food contact legislation and was determined as a result of experience with plastic packaging. Whilst this benchmark might be appropriate for a minority of uses of paper and board where direct and intimate contact with food occurs, it would be inaccurate and misleading to apply it to the remainder of its uses.

15. Biosafepaper Final Report available at http://www.cepi.org/content/default.asp?pageid=617

In these latter cases paper and board is used for much less aggressive applications than plastic, for instance to pack dry food, for applications where the contact is brief or with the surface of food which is subsequently removed or washed before consumption. In these cases migration of substances will be much below those expected using the benchmark.

Therefore, there is a need to apply Correction Factors to the results arising from quantitative substance tests for the material or article before comparing them with restrictions and composition limits so that they accurately reflect the actual contact conditions. In many cases, the use of correction factors would remove the need for testing for a particular substance as calculation would show that transfer from paper and board to food could not occur at levels which would exceed permitted levels in food in a particular application.

A further advantage of the Correction Factor concept is that it may no longer be necessary for a manufacturer of a paper or board material or article to know the intended end use of the product. Using the results of the test methodology, a reverse calculation could be made giving the paper or board a Correction Factor threshold value. Thus, the paper or board could be sold for a range of food contact applications having an equivalent or larger Correction Factor. This will also be of value to converters in selecting the appropriate grade of paper or board for a specific application. This mechanism would allow compliance with the requirement in Regulation 1935/2004 for a declaration of special conditions of use.

FIGURES

FIGURE 1

COMPLIANCE ASSESSMENT SCHEME FOR PAPERMAKING OPERATIONS

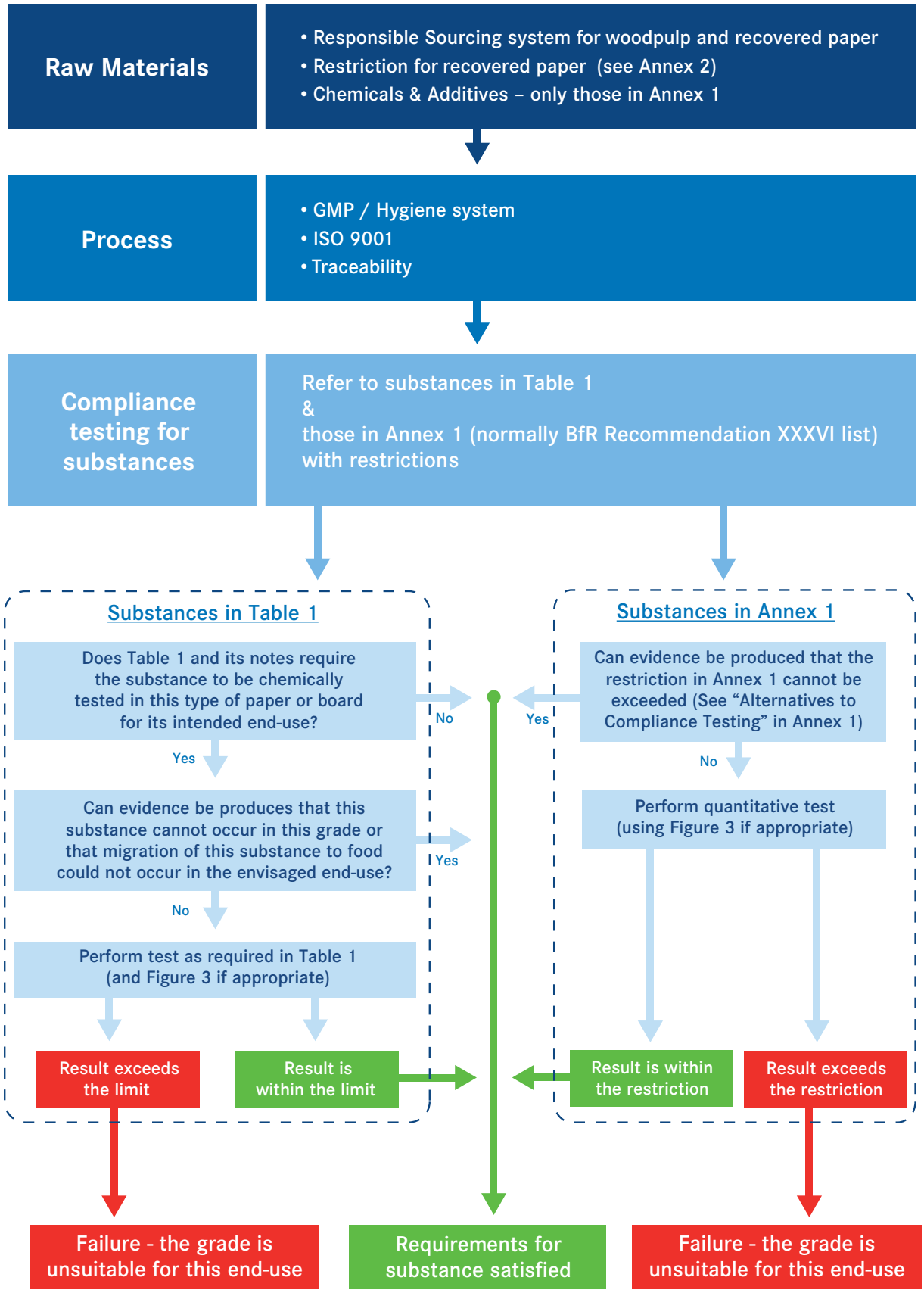


FIGURE 2

COMPLIANCE ASSESSMENT SCHEME FOR CONVERTING OPERATIONS

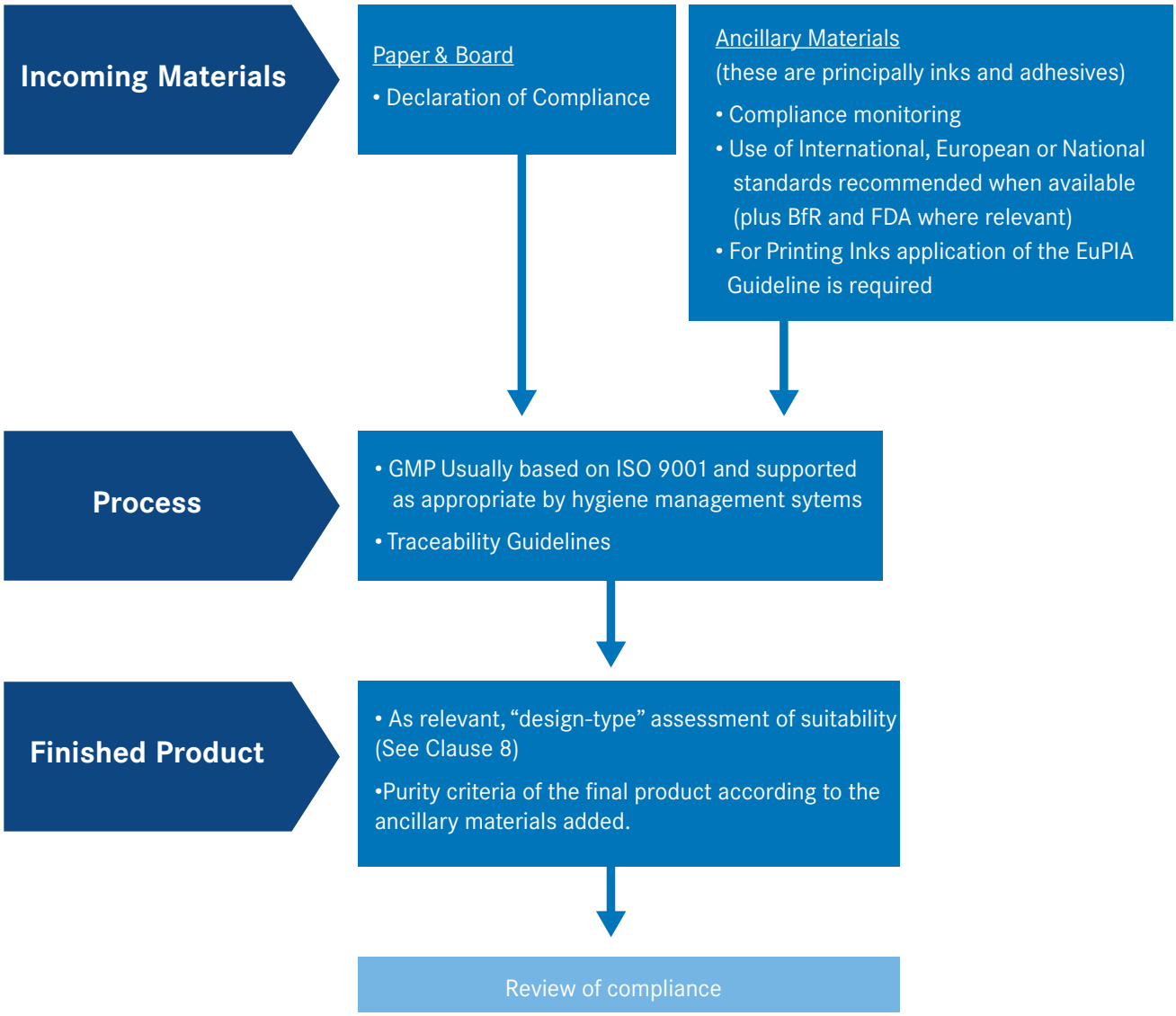
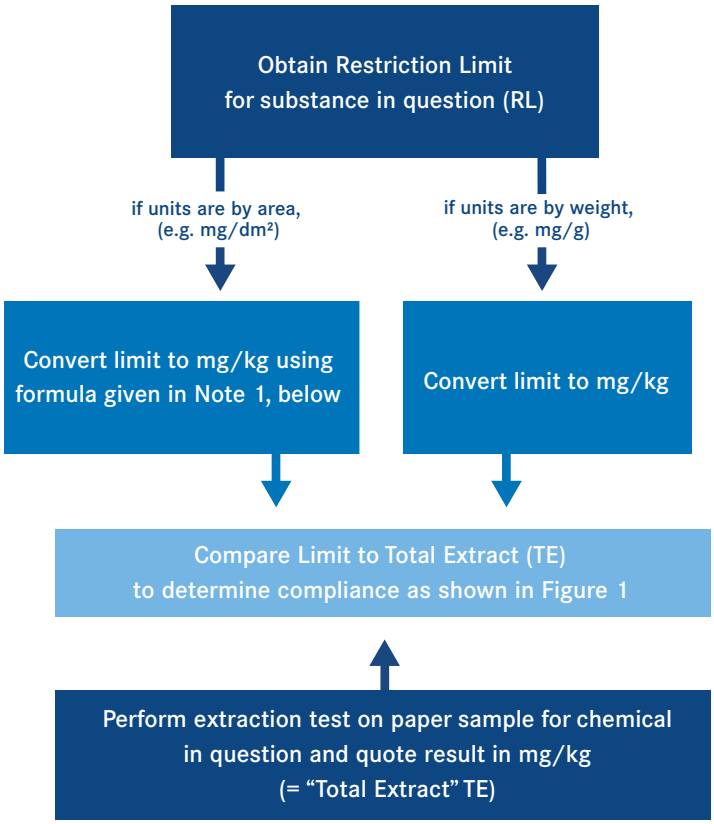


FIGURE 3

ELEMENTS OF THE DETERMINATION OF COMPLIANCE



Note

$$Qm = \frac{Qa \times 100000}{G}$$

Qm = concentration of substance in paper as mg/kg
Qa = concentration of substance in paper as mg/dm²
G = grammage of paper as g/m²

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CEPI aisbl
Confederation of European Paper Industries
250 Avenue Louise, Box 80
B-1050 Brussels
Tel: +32 2 627 49 11 Fax: +32 2 646 81 37
mail@cepi.org - www.cepi.org

CITPA
International Confederation of Paper and Board Converters in Europe
250 Avenue Louise, Box 108
B-1050 Brussels
Tel: +32 2 646 40 70 Fax: +32 2 646 64 60
www.citpa-europe.org

Design by Ben Timmers (CEPI)