FOOD CONTACT GUIDELINES
FOR THE COMPLIANCE OF PAPER & BOARD MATERIALS AND ARTICLES

FOREWORD

Paper and board has a successful history of safe use in a wide range of food contact applications: these are, for example, tea bags, baking papers, filters, beverage cartons, sacks, packaging for dry and frozen foods, including transport and distribution packaging, and tissue products.

The paper and board supply chain has a longstanding commitment to the protection of human health and the interests of consumers through the provision of safe and functionally effective materials.

To this end, the paper and board supply chain has cooperated over the past decades with government, both at national and supra-national level, and with other regulators to ensure necessary measures for consumer protection. The cooperation was also developed with other actors along the chain, namely the food producers, the suppliers of those materials that are used in the operations to convert paper and board materials into finished articles such as inks, varnishes, adhesives, as well as with consumers.

So far, no specific Union measure has been introduced for paper and board. It is for this reason that the paper and board supply chain considered appropriate to update the existing Food Contact Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact whose first publication dates back to 2010, under the aegis of CEPI and CITPA, and first revision to 2012.

The Food Contact Guideline was well received by organisations and authorities at both European and national level. It has become a reference for the paper and board food packaging value chain. Its history makes it a consolidated document and a solid background for this and future developments.

As was the case for the former versions, this Food Contact Guideline is aimed at all those with an interest in ensuring the safety of paper and board intended for food contact: manufacturers and suppliers require a harmonised approach and support for compliance with the legislative requirements and value chain communications; national authorities require background material against which to base their inspection regimes; business operators in the food supply chain need guidance on the special properties of paper and board; consumers need assurance that appropriate food contact safety rules are in place.

Whilst this Food Contact Guideline provides a methodology for the demonstration of the suitability of materials and articles for a variety of food contact applications, it has no legal weight. Its use is voluntary and it should be noted that other compliance mechanisms exist which may be used separately or in conjunction with it.

The present revision has been possible thanks to more than two years' work by the value chain to which many sectors' professional associations provided their active contribution.

It is important to note that the number of associations that worked on this revision and endorse it are greater than before, which makes this version of the Food Contact Guideline more widely representative of the paper and board for food contact applications supply chain and hence even more solid.

The key elements of the present revised version of the Food Contact Guideline have been transposed into a document that was prepared in the frame of a process to finalise a CEN Workshop Agreement which was launched in 2018. This process aims at developing, at a later stage, harmonised standards on the same subject of the Food Contact Guideline, i.e. providing manufacturers of the paper and board supply chain with a tool that will give them the presumption of conformity with the requirements of EU Food Contact Materials legislation. This approach is in line with the recent commitment of the European Commission on developing standards as part of the legal framework*.

That document was circulated by UNI/CEN for a two month period of public consultation (mid September - mid November 2018) and some of the comments that were received in that frame have been used to amend the present Food Contact Guideline, which has been improved thanks to this consultation. Associations participating in the revision of this Food Contact Guideline agreed to consider that consultation as being "de facto" a wide, transparent and value-adding peer review of the final version of the Food Contact Guideline as the aforementioned key elements were not substantially questioned by those who sent in comments.

The English digital version of the present guideline is the original version and the one to be referenced to in case of uncertainties with the translated versions.

* Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - Brussels, 22.11.2018 COM(2018) 764 - https://ec.europa.eu/docsroom/documents/32615

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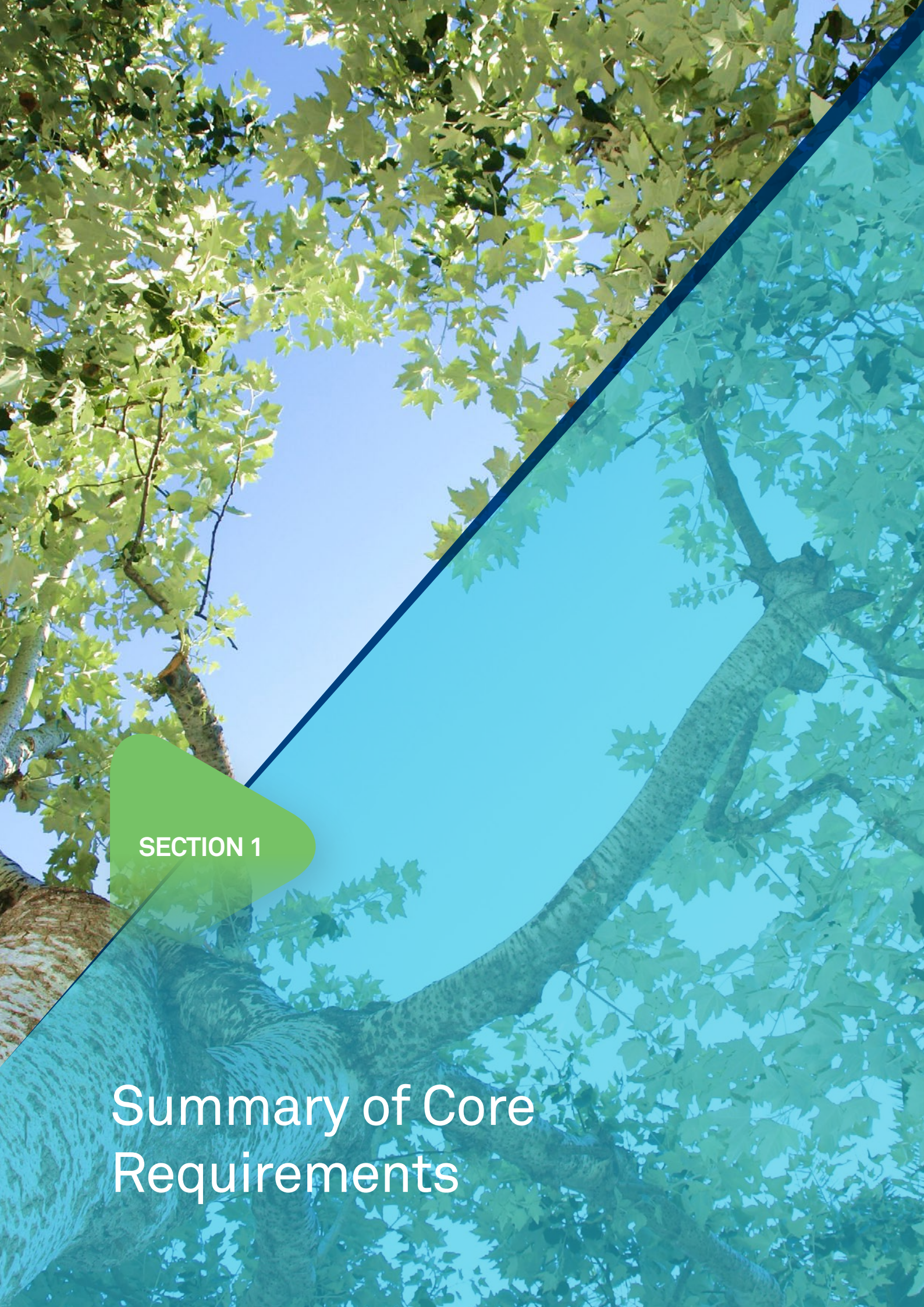


SECTION 1

Summary of Core Requirements

SUMMARY OF CORE REQUIREMENTS

1.1 BACKGROUND

This document has been initially developed as guidance for a future paper & board regulation based on the belief, within the industry that produces paper and board materials and articles for food contact, that there is a need for EU legislation which specifically covers its products. The continued absence of such legislation is having a progressive, negative impact on the business. The industry has concluded that the best method of achieving this aim would be for the European Commission to develop a specific measure for paper and board as envisaged within Regulation (EC) No 1935/2004, hereafter referred to as the *Framework Regulation.*

It has been understood that this specific measure on paper & board will not be drafted in the foreseeable future. Even if the industry still believes in its potential benefits, it has been necessary to redirect its efforts to create a guidance document. This will help industry, in the absence of such a specific measure, and could be used as a starting point whenever the European Commission decides to choose paper & board as their next priority for regulation[1].

The contents of the document recognise the increasing regulatory emphasis towards the use of a compliance framework which includes risk management, product design, material selection, Good Manufacturing Practice (GMP) and process monitoring and control, in addition to end-product testing.

Where special conditions apply only to certain parts of the manufacturing chain, the details are made clear in the text. Otherwise, the contents of this document cover all paper & board materials and articles and, as such, apply to paper & board manufacture, tissue manufacture, converting operations right through to final food contact materials and articles.

1.1.1 Target Audience

This document is aimed at all those with an interest in ensuring the safety of paper and board intended for food contact, because:

- manufacturers and suppliers along the paper and board supply chain require a harmonised approach, explanations of the legislative requirements of the Framework Regulation and the various ways in which compliance with it can be achieved in order to support the demand of the market and customers for product safety;
- national authorities require background material against which to base their inspection regimes and their interpretation of the necessary legal requirements covering manufacturing, documentation, quality management, etc.;
- business operators in the food supply chain need guidance on the special properties of paper and board intended for food contact so that relevant products, appropriate to final use, can be chosen;
- consumers need assurance that appropriate food contact safety rules are in place and adherence to them is a transparent process that can be independently assessed.

Whilst this Guideline 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 it.

1.1.2 Scope

A schematic diagram, showing the operations and products covered by the scope of this Guideline, appears in Section 2.

Paper and board materials and articles are manufactured from cellulose-based natural fibres both bleached and unbleached, from both primary and recycled sources. In addition, paper and board materials may contain man-made fibres (regenerated and/or synthetic cellulose), functional additives and other treatment agents, polymeric binders for organic and inorganic pigments and plastic films. Paper and board articles may contain, in addition, inks, varnishes, coatings, adhesives and plastic films used during the conversion process.

This Guideline applies to materials and articles constituted mainly of paper and board (excluding non-wovens as defined by *ISO 9092:2011*[3]) 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 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.

It covers:

- untreated paper and board (dyed and undyed);
- coated papers including those coated with polymeric dispersions (without mineral fillers) as well as mineral coated (dyed and undyed) paper and board and the components of the coating formula, including polymeric binders and waxed papers;
- tissue products, non-printed, printed and dyed, mainly intended for wiping and absorption e.g. kitchen towels and napkins with only occasional and short time contact;
- multi-material-multi-layer materials formed by extrusion or lamination of paper and board (dyed and undyed) with other materials;
- paper and board for filtering and baking applications;
- easy release papers, siliconised or treated with wax;
- converted articles made of paper and board, i.e. printed, unprinted and glued bags, boxes, wrappings etc.;

- secondary and tertiary packaging applications and transport packaging (when the risk assessment for these applications indicates possible transfer of constituents to the packaged foodstuff).

1.2 SUPPLY CHAIN COMMUNICATION

The existence of a flow of relevant information and documents between the business operators in the whole supply chain, from raw materials to final food packaging or food contact article, is a prerequisite to ensure effective compliance with the Framework Regulation. Converters are encouraged to request information from packer/fillers and, when available, to pass them along the supply chain. The compliance of the final food contact material and article with EU provisions can only be ensured if, along the supply chain, relevant information exchange takes place between the supplier and the customer and *vice versa*. The information must be clear and distinct. The aim must always be to avoid misunderstandings about the match between product properties, testing regimes and foreseeable conditions of food contact use.

A very important part of the communication is dialogue on the compliance status of substances used during the manufacture of the material or article. Compliance of these substances with the requirements of the *Framework Regulation* must be assured and relevant documentation must be exchanged which covers the outcome of the risk assessment (this could possibly be the Declaration of Compliance), including the assessment of the substances added, formed or present in the material; see also sections 1.4.3 and 1.4.4 of this Guideline. Additionally, information on dual use substances with a quantitative restriction in food legislation must be exchanged when a risk assessment indicates that there is a risk of transfer to food. Also required is the maximum interchange of information from end users and downstream business operators about the intended conditions of food contact use, relevant supply chain conditions (e.g. storage time, temperature, barrier layers, etc.) and from upstream business operators about any restrictions on the final food contact application. The compliance work that can be performed is dependent on the position of the business operator in the supply chain and the information that is available to that business operator.

Two-way communication in the supply chain can help to identify relevant information that allows suppliers and customers to adequately perform their own compliance work. It also helps to build trust, which is essential, as the Declaration of Compliance (DoC) does not include all of the information contained in the supplier's supporting documentation.

Some general principles of the communication process are:

- a business operator introducing or knowingly forming a substance in a product (raw material, intermediate or finished material or article) is responsible for implementing controls in order to check compliance of this substance;
- the compliance of the finished article can only be ensured if all business operators in the chain, from the manufacturer of raw materials, substrates and substances to the food packer, assume the necessary responsibility for their manufacturing step, with a view to the compliance of the finished article;
- for food contact paper and board, the compliance information that is communicated to the customer must be specific and allow that customer to perform its compliance work. 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.

Because of the large and diverse range of operations in the supply chain for paper and board food contact materials and articles, it is not possible to make firm recommendations about additional, non-mandatory communications. However, it is possible to produce a 'best practice' list of supply chain communication tools and this is shown in Section 7.

1.3 THE MANUFACTURING PROCESS

From a regulatory point of view, it is important to understand that the manufacturing process for paper and board differs significantly from that of most other food contact materials. The main raw materials for paper and board are cellulose fibres, starch and mineral filler, all naturally occuring materials. Functional chemicals are added in only very small quantities. The papermaking process itself is predominantly mechanical rather than chemical, involving the suspension of fibres in large volumes of water, their subsequent recovery and drying at high temperature. Converting processes are partially mechanical in nature and involve, for instance, combining layers of paper and board with other substrates, changing the physical shape of the product, printing and gluing.

Thus, the traditional regulatory regimes, based largely on chemical formulation and migration testing, have less relevance when applied to paper and board materials and articles. To achieve the required level of product safety, the emphasis must be more on assuring the quality of the raw materials and the manufacturing process through risk management and Good Manufacturing Practice. Product testing still has relevance and is dealt with in Section 3 of this document. Although such testing is only representative of a limited quantity of the production, it will, nevertheless, have validity as an indicator of the quality of total production output. This is because of the increased emphasis on GMP and risk assessment as well as process and quality control.

1.4 COMPLIANCE REQUIREMENTS

Before placing paper and board materials and articles on the market they must meet the requirements of the *Framework Regulation*. The following parts of Section 1.4

describe the various requirements which apply to manufacturers of those materials and articles in order for them to ensure compliance with that Regulation.

It should be noted that this Guideline gives industry best practice interpretations of the regulatory requirements for all paper and board materials and articles. The method of achieving these requirements may be tailored according to factors such as the scale of foreseeable risks and the size and nature of a particular manufacturing process. More details are given elswhere in this Guideline.

1.4.1 Good Manufacturing Practice

It is a requirement of the *Framework Regulation* that all materials and articles intended for food contact shall be manufactured in accordance with Good Manufacturing Practice (GMP). The components and principles of such a GMP are described in *Regulation EU 2023/2006*[3] (hereafter refered to as the *GMP Regulation*). Because the *GMP Regulation* applies to all types of food contact materials and articles, there is a need for specific guidance on its implementation in each material manufacturing sector. In the case of the paper and board sector, GMP guidance must be further sub-divided to suit each major part of the supply chain. Sector-specific GMPs appear in sectors' specific GMPs.

1.4.2 Risk Management

The mechanism of risk management has not, in the past, been described in detail within European food contact legislation. Recently, however, risk management has come to be regarded as an essential tool for achieving food safety. Although an integral component of GMP, risk management is not described in the GMP Regulation but guidance on how to implement this essential product safety tool can be found in sectors' specific GMPs.

The adverse elements likely to affect food contact materials and articles which might cause organoleptic or other unacceptable foodstuff deterioration can be classified, for example, as chemical, physical or microbiological in nature. To fulfil the *GMP Regulation,* it is essential to know how the composition of the paper or board and/or any subsequent treatments is controlled and how process variables affect that composition. It is also necessary to understand the possibility that contaminants might be present, how and where they might occur, what risk they pose and how that risk can be controlled. When implementing GMP, a risk analysis, i.e. a hazard inventory followed by a risk assessment, through the whole process in question, should be carried out. This is to control product safety aspects along the whole supply chain up to the point of sale of a product, which includes the risk for the end consumer.

General principles

Risk management has a number of core elements and these are described in more detail in sectors' specific GMPs.

Product specific requirements

Those parts of risk management, which are relevant only to specific parts of the manufacturing chain for paper and board materials and articles, are written within the sector's specific GMPs.

1.4.3 Compositional Requirements - Intentionally Added Raw Materials and Substances (IAS)

General

Only substances that are risk assessed or included in positive lists in national regulations and recommendations may be intentionally added, during the production process, to paper and board food contact materials and articles. Complementary information on this subject can be found in Section 3.

Paper and board manufacturing

Fresh fibre pulp and recycled fibre pulp

Fibres originating from wood or from paper for recycling can be used in the manufacturing of pulp for food contact paper and board. A risk assessment for food contact suitability shall be carried out for all grades of pulp, irrespective of whether the fibres are originating from wood or from paper for recycling, to ensure that the final material or article satisfies the requirements of Article 3 and where it applies, Article 4, of the *Framework Regulation.*

When using paper for recycling as a raw material, a risk assessment of the grades (according to *EN 643*[4]) shall be carried out in relation to the actual food contact applications. The supplier of the paper for recycling raw material will be requested to provide statements of compliance with the *CEPI Responsible Sourcing Guidelines*[6]. In addition, reference should be made to *EN 643,* to exclude those grades that are clearly unsuitable for the manufacturing of food contact paper and board. See Section 4 for more details regarding the use of paper for recycling as a raw material.

Chemical additives - papermaking chemicals

A risk assessment for food contact suitability shall be performed for supplies of applied materials used in the papermaking and coating processes. The suppliers of those chemicals must provide a DoC, or equivalent, confirming their suitability and possible usage limitations for food contact applications. This declaration shall state the suitability for food contact applications including any restrictions for use, potential migrants (deliberately added substances only), and information on purity requirements (including known NIAS, when relevant). In addition, reference to food contact positive lists, with which the chemical complies, shall be given.

Currently, no unified EU-wide list of substances exists for paper and board and, until one is developed, the requirements of Article 5 of the *Framework Regulation* shall apply. This requires that only substances that are "in a list of substances authorised for use in the manufacturing of materials and articles" can be used as specified in the list.

In practice, this means substances existing in recognised national legislation and best practice recommendations for paper and board, examples of which include:

- Germany: BfR Recommendation XXXVI[7 8 9 10]
- The Netherlands: Warenwet Hoofstuk[11]
- USA: FDA Regulation[12]
- Italy: Decreto ministeriale[13]
- Belgium: Decree Arrete Royal[14]
- France: DGCCRF Regulation[15]

When the substances listed differ between these documents and/or there are variations in their limits and restrictions, it is the responsibility of the paper and board manufacturer to decide which limits to apply and then to assess the product in relation to those limits. Such decisions should be transparent and are normally defined and agreed with customers.

Substances not appearing on the above lists may be used provided that they are not excluded under any relevant paper and board industry commitment and:

a) there is no detectable migration into food or food simulants with a detection limit of at least 10 µg/kg food and the substance is not classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Section I of *Regulation (EC) No 1272/2008*[16] and the substance is not engineered as a nanomaterial

or

b) the substance is a direct food additive and/or is included in the positive list of other food contact materials and any restrictions are complied with

or

c) a risk assessment (based, for example, on the threshold of Toxicological Concern approach) has been carried out.

Suppliers of substances covered by points a) to c) above should provide a declaration confirming compliance with those points. This declaration should also include, where known, details of the purity of the substances and recommended usage rates.

Multi-material multi-layers (MMMLs)

A risk assessment for food contact suitability shall be performed for supplies of all layers and any additives incorporated into the construction of MMMLs. The risk assessment will take into account the nature of the intended food end use, the layer in contact with the food and the presence of functional barriers in the matrix. The manufacturer of MMMLs shall receive a DoC from the suppliers of all the components of the MMMLs. In general, any layer which may contact the food or may transfer its constituents to the food must comply with the EU legislation covering the material which the layer consists of as if it were being used on its own. For example, paper and board must comply with the *Framework Regulation* and plastic must comply with the requirements of *Commission Regulation (EU) no 10/2011 on plastic materials and articles intended to come into contact with food*[17], (hereafter referred to as the *Plastics Regulation*).

Testing of the MMMLs for compliance with overall and specific migration limits and other restrictions (abbreviated to OML and SML respectively) as defined in the *Plastics Regulation*, is not mandatory. However, an assessment by the manufacturer of the final MMML construction in relation to relevant requirements may be required. Such assessment is normally based on information from up-stream suppliers of the various materials and it is the responsibility of the manufacturer of the MMML to decide and apply a relevant assessment methodology, based on the construction of the MMML, known end use applications, customer requirements, etc.

Paper and board converting operations

Paper and board substrates

A risk assessment for food contact suitability shall be carried out for all grades of paper and board used for converting into food contact materials and articles. The risk assessment shall take into account the actual end use application and supply chain conditions. A DoC shall be supplied with the paper and board stating the suitability for food contact applications including any restrictions for use, potential migrants (deliberately added substances only), and information on purity requirements (including known NIAS, when relevant).

Applied materials – Inks, adhesives, varnishes and other coatings

A risk assessment for food contact suitability shall be performed for supplies of applied materials used in converting processes. In the absence of a harmonised Union List of authorised substances in inks, varnishes and adhesives, those that are listed in national regulations and recommendations are permitted for use. The limits prescribed for the use of permitted substances in these national measures shall be applied. If no applicable national regulations or recommendations exist, best practice documents and guidelines from the relevant industry sectors shall be used and adhered to. Printing ink for food contact materials/ low migration inks, adhesives and varnishes shall be used when required by the risk assessment.

Suppliers of inks and adhesives shall provide written statements including adequate information on recommended usage rate, potential migrants, any purity requirements, (including known NIAS, when relevant), for the final converted article linked to the use of the substance and any food contact positive lists or industry sector guidelines which the ink or adhesive is known to comply with. These statements should also include, where relevant, details of the purity of the substance and recommended usage rates if there are restrictions related to impurities and usage rates.

Non-authorised substances may be used provided that they are not excluded under any relevant paper and board industry commitment and:

a) there is no detectable migration into food or food simulants with a detection limit of at least 10 µg/kg food and the substance is not classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in Reference15 and the substance is not engineered as a nanomaterial

or

b) the substance is a direct food additive and/or is included in the positive list of other food contact materials and any restrictions are complied with

or

c) a risk assessment based on the Threshold of Toxicological Concern approach has been carried out.

Suppliers of substances covered by points a) to c) above should provide a declaration confirming compliance with those points. This declaration should also include, where known, details of the purity of the substances and recommended usage rates.

Coating materials applied to paper and board must comply with the relevant specific legislation.

Tissue paper manufacturing and converting operations

Fresh fibre pulp and recycled fibre pulp

Fibres originating from wood or from paper for recycling can be used in the manufacturing of pulp for tissue paper products. A risk assessment for food contact suitability shall be carried out for all grades of pulp, irrespective of whether the fibres are originating from wood or from paper for recycling, to ensure that the final material or article satisfies the requirements of article 3 and where it applies, article 4, of the *Framework Regulation*

When using paper for recycling as a raw material, a risk assessment of the grades, according to EN 643, shall be carried out in relation to the actual food contact applications. The supplier of the paper for recycling raw material will be requested to provide statements of compliance with the *CEPI Guidelines for Responsible Sourcing and Supply of Recovered Paper*. In addition, reference should be made to *EN 643,* to exclude those grades that are clearly unsuitable for the manufacturing of food contact paper and board. See Section 4 for more details regarding the use of paper for recycling as a raw material.

Applied materials – papermaking chemicals, dyes, inks, adhesives

A risk assessment for food contact suitability shall be performed for supplies of applied materials used in the papermaking and converting processes. The risk assessment may take account of its specific properties such as short contact time, absorption capacity, etc. The suppliers of those chemicals, including dyes, inks and adhesives, must provide a compliance statement confirming their suitability for food contact applications or sufficient information to enable risk assessment of such uses. This statement should include details of the purity of the chemicals, the recommended usage rate, any restrictions related to usage such as maximum level, finished product purity and/or testing requirements, etc. In addition, all food contact positive lists with which the chemical is known to comply shall be given.

To date there are no lists which specifically refer to approved substances for tissue papermaking and converting. In the absence of a harmonised Union List of authorised substances used in applied materials, inks and adhesives, those that are listed in national regulations and recommendations are permitted for use. The list of approved substances in the BfR Recommendation XXXVI can be seen as important guidance. The limits prescribed for the use of permitted substances in these national measures shall be applied. If no applicable national regulations or recommendations exist, best practice documents and guidelines from the relevant industrial sectors shall be used and adhered to. Printing ink for food contact materials/ low migration inks and adhesives shall be used when required by the risk assessment.

Suppliers of inks and adhesives shall provide written statements including, when relevant, adequate information on recommended usage rate of the substances, potential migrants and any purity requirements, including known NIAS, related to the final converted article. Information must also be provided on any food contact positive lists or industry sector guidelines which the ink or adhesive is known to comply with.

Non-authorised substances may be used provided that they are not excluded under any relevant paper and board industry commitment and:

a) there is no detectable migration into food or food simulants with a detection limit of at least 10 µg/kg food and the substance is not classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in Reference 15 and the substance is not engineered as a nanomaterial

or

b) the substance is a direct food additive and/or is included in the positive list of other food contact materials and any restrictions are complied with

or

c) a risk assessment based on the Threshold of Toxicological Concern approach has been carried out.

Suppliers of substances covered by points a) to c) above should provide a declaration confirming compliance with those points. This declaration should also include, where known, details of the purity of the substances and recommended usage rates.

1.4.4 Compositional Requirements - Non intentionally added substances (NIAS)

General

The paper and board industry continuously evaluates and engages in relevant research projects aimed at

examining NIAS in food contact paper and board materials and articles. The objective is to assess and control any relevant risks related to NIAS. Until that work is complete, the following two sub-sections covering GMP and Supply Chain Communications should be used to ensure non-authorised substances, whilst not being fully eliminated, will not present a significant safety risk.

It is known that the use of paper for recycling may cause the occurrence of NIAS in the finished paper and board materials and articles. As an interim measure, before the aforementioned work on NIAS results in a control framework, a set of testing rules using a list of known impurities is described in Section 3 of this Guideline. Section 3 also contains more details on purity requirements and NIAS.

Good Manufacturing Practice

GMP is dealt with in detail in sector-specific GMPs but is mentioned here as its Risk Assessment component has a major role to play in the control of NIAS.

With regard to compliance with the *Framework Regulation*, the selection of raw materials implies that impurities, by-products and contaminants are taken into consideration, at least as far as they have the potential to migrate. As NIAS are unavoidable, this aspect must be considered when performing the risk assessment on raw materials as noted in section 1.4.3 above, on intentionally added materials and substances. In addition, more attention has to be given to production operations, where further creation of NIAS in each processing step from the starting material to the final article has to be considered. However, contamination during the production process can be managed and minimised with the appropriate application of GMP. Also, raw materials may have varying impurity profiles which might not be fully characterised and which may have an impact on the final product.

Supply Chain Communication

Supply chain communication has a very important part to play in reducing the risk from NIAS. A key problem of complex manufacturing processes is that usually no single stage can perform the complete compliance work. Information on composition, presence of NIAS as raw materials' impurities, product processing conditions, composition of the food, storage and contact conditions, among others, is not known at every step of the supply chain. Therefore, sufficient exchange of information is essential to ensure the compliance of the final material or article.

Best practice for supply chain communication is provided in Section 7.

1.4.5 Traceability

Business operators throughout the supply chain shall use systems designed to meet the traceability requirements of the *Framework Regulation*. The following guidelines should be noted when designing and operating traceability systems.

- 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 *Framework Regulation*.
- Business operators are free to use those tools which they feel are appropriate to facilitate the operation of traceability; these could include, for instance, supplier invoices with batch numbers, storage vessels and machine logs (manual or computer generated), weight lists, paper and board samples, quality control records and bar code systems. (Two common systems already in use in the paper industry are the CEPI Unit Identifier and the FEFCO Bar Code Standard for Corrugating Materials.) The chosen system must be open to external audit.
- Certain documents needed to demonstrate traceability may already be generated for other purposes and need not be duplicated.
- The *Framework Regulation* requires the traceability of materials and articles. It also requires the facilitation of defective product recall and the ability to attribute responsibility. Therefore, business operators must have in place systems which allow full traceability of materials and articles. They must also adopt procedures which allow them to connect output of materials and articles to incoming raw materials and additives. The identification of the origins of individual batches of paper for recycling and bales of pulp may prove very difficult for papermaking operators. Also, the tracing to individual batches of chemicals or other additives will be almost impossible for papermakers and converters alike where batch deliveries are often involved. In these cases, the concept of technological feasibility, as detailed in the *Framework Regulation*, can be introduced. This concept does not mean traceability can be abandoned but instead allows business operators to use less detailed systems which nevertheless continue to allow the recall of defined quantities of production.
- The main traceability chain for paper and board for food contact is taken to start from the paper reel at the dry end of the paper machine and the key element of information transferred onwards is that reel number and/or the number of a smaller reel or batch of sheets to which it may be cut before leaving the paper mill. Later in the supply chain, the identification may become the job or batch number of the converted packaging or another recognisable identification.
- Retention of batch samples at the papermaking stage is recommended wherever possible. In cases of suspected chemical, physical or microbiological 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.

- Traceability systems should be included in the relevant procedures forming part of a business operator's quality management system, based on the ISO 9000 Quality Management System or an equivalent.

Relevant documents shall be kept for the minimum period requested by national legislation, where applicable; if not applicable, the period is defined within the existing management system of the business operator. Samples shall be kept for a period agreed with the customer. If there is no such agreement then they must be kept as defined and stated by the business operator.

Detailed guidance about traceability is provided in Section 5.

1.4.6 Labelling

The *Framework Regulation* requires materials and articles destined for food contact uses to be accompanied along the supply chain by labelling and/or documentation which indicates its suitability for that use. The main elements of that labelling are:

- the words "For Food Contact" or a specific use, e.g. "Filters for coffee machines" or the symbol shown in Section 6;
- if necessary, special instructions for safe and appropriate usage;
- name of the supplier (could be a manufacturer, processor or seller);
- information ensuring traceability.

Where operations within the supply chain for paper and board food contact materials and articles are remote from the retail stage, the principle method of indicating suitability for food use will be on documents (paper or electronic) that accompany the goods along the supply chain. The requirement to label the product itself, at that stage, is optional. Where the goods are being supplied to the retail market, the labelling must appear on the goods themselves or their immediate packaging unless their appearance makes it very clear that they are intended for food use. In this latter case, no labelling is needed.

It should be noted from Section 1.4.5 that there is a requirement to provide information ensuring traceability so the labelling and traceability guidance should be considered together to prevent duplication.

Detailed guidance about labelling is provided in Section 6.

1.4.7 Declaration of Compliance (DoC)

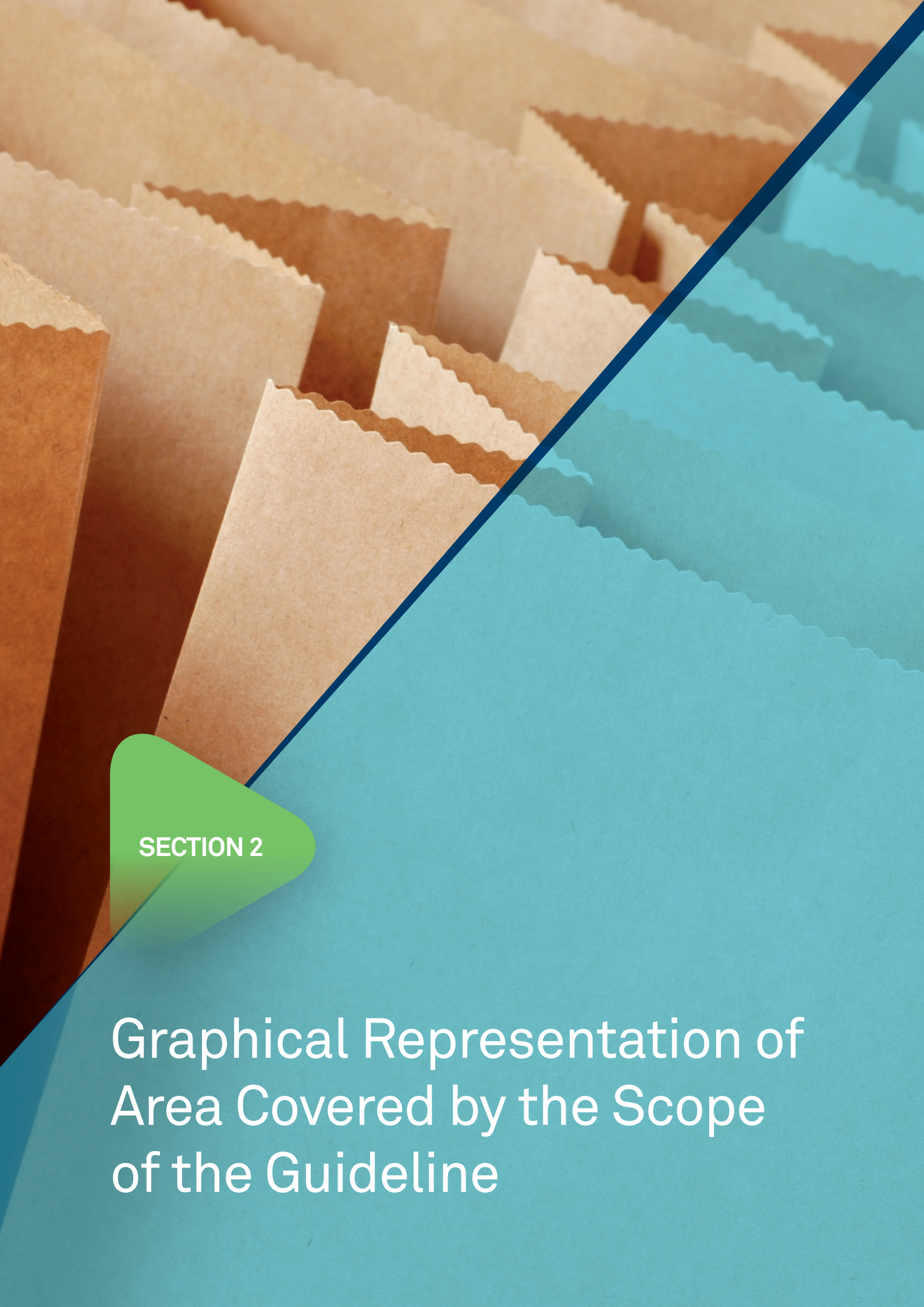
The *Framework Regulation* requires that food contact materials and articles which are subject to a specific measure must be accompanied by a written declaration stating that they comply with the rules which apply to them. In the case of paper and board, for which no specific measure exists currently, these rules are contained in the *Framework Regulation* and in this Guideline. Although not strictly legally required until a specific measure is in place, the paper and board manufacturing chain believes that it is the most appropriate tool for communication in the supply chain and represents current best practice. Therefore, a DoC requirement is included in this Guideline. The *Framework Regulation* also requires that appropriate (supporting) documentation "shall be made available to the authorities on demand".

The DoC must be supplied to the downstream business operator who takes delivery of the goods. Its function is to state to the customer which relevant requirements have been met and to provide the customer with the necessary information to check compliance of the supplied material or article. When the food contact material or article is further processed and/or modified in a downstream process, the downstream business operator must obtain adequate information from the supplier allowing the business operator to perform further compliance work and to issue a further DoC. This means that each business operator has to declare compliance for the manufacturing steps under its responsibility. (As an exception, a DoC is not normally supplied in cases where a business operator supplies directly to consumers.)

It should be emphasised that the DoC is the sole responsibility of the manufacturer of the material or article and its production cannot be subcontracted to third parties who, typically, examine and approve only the properties of the final product. Such a document is not valid as a DoC within the meaning of the *Framework Regulation*.

In case of import (from non-EU countries) of food contact materials and articles, the importer is legally equal to the manufacturer and thus the one who first places the materials on the EU market and therefore is also responsible for the DoC.

Detailed guidance about the construction of DoCs is provided in Section 8.



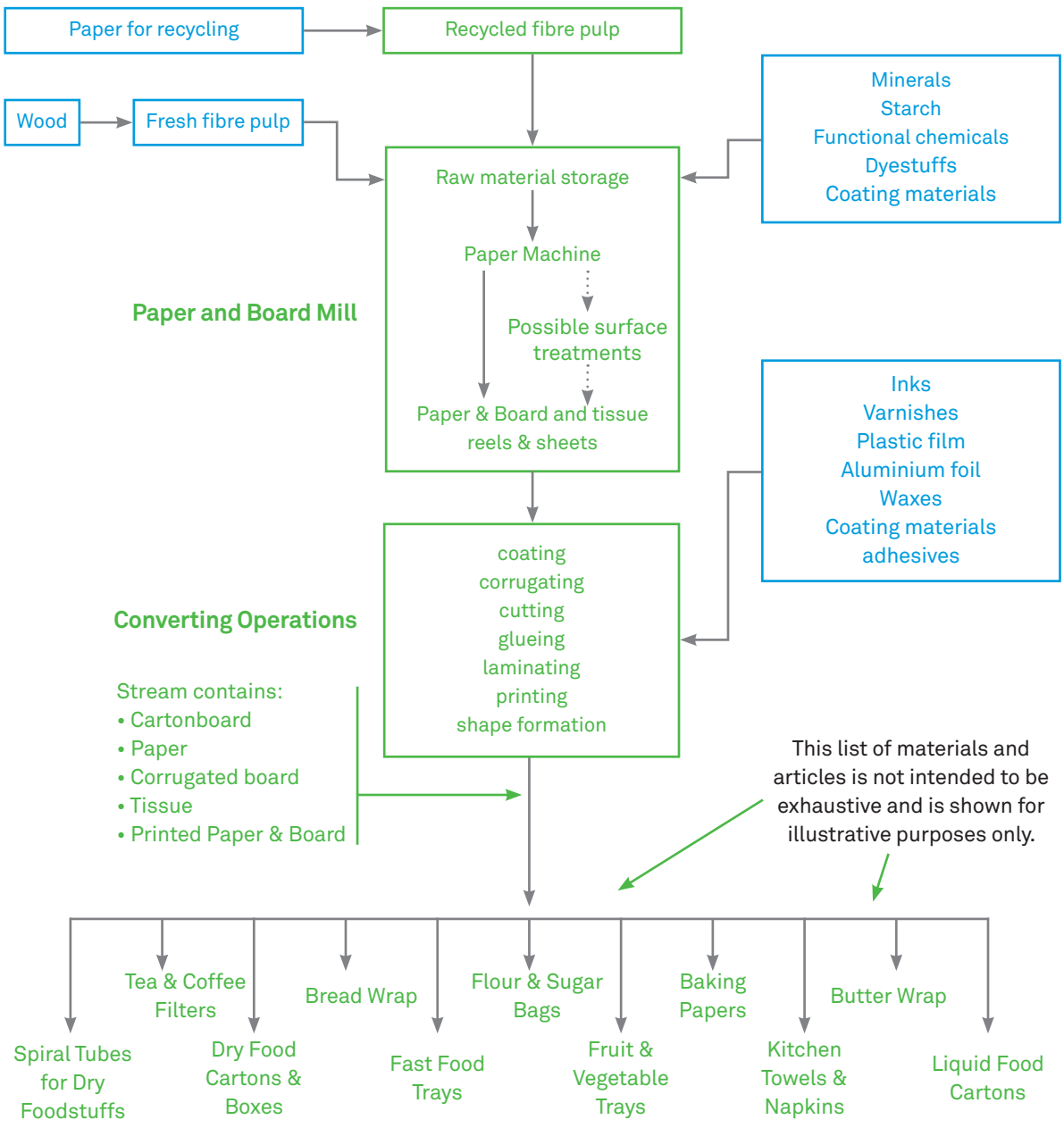
SECTION 2

Graphical Representation of Area Covered by the Scope of the Guideline

GRAPHICAL REPRESENTATION OF AREA COVERED BY THE SCOPE OF THE GUIDELINE

This diagram is intended only to give a general idea of the 'shape' of the operations covered by this Guideline and is not intended to give a fully accurate representation of the flow-lines or products.

Figure 1



Green = included in scope

Blue = the **use** of these materials in paper and board is within the scope of this Guideline but their **manufacture** is not and is mostly covered by national legislation and/or industry recommendatios/best practice.

SECTION 3

Testing for Compliance

TESTING FOR COMPLIANCE

3.1 GENERAL CONSIDERATIONS FOR ALL PAPER AND BOARD MATERIALS AND ARTICLES

3.1.1 Testing methodology and scope

Due to the porous properties of paper and board materials and articles, contact with liquid food does not intentionally take place unless the paper and board have been specifically treated to be used in such applications. Such applications would include materials and articles where, for instance, a plastic layer is extrusion coated or laminated on to the paper, see Section 3.3, below, on Multi-material multi-layers (MMMLs). Therefore, migration testing with liquid simulants, as required for plastic materials and articles, has little relevance and is not appropriate for paper and board material and articles as this will lead to an absorption and penetration of those simulants into the paper and board matrix.

Testing with liquid simulants will be an extraction rather than a one-sided migration test from the food contact side of the material or article, which can lead to a significant overestimation of migration for most applications. Such testing is often an assessment of the total content of extractable substances rather than migration from the food contact side. Modified Polyphenylene Oxide, MPPO, is the only known simulant that can be applied to paper and board for the purpose of performing a one-sided migration test simulating a real food contact situation for typical uses.[18 19 20]

There is one group of paper products which is an exception to the above conditions and that is filter papers and tea bags. These are manufactured specifically to allow the passage of liquid foodstuffs. For these materials, extraction testing represents a close copy of intended final use.

In addition to this significant, technical limitation, the regulatory and testing regime for paper and board food contact materials and articles will be different from existing systems for other materials which rely on the control of numerous specific migration limits.

There are two main types of constituents for which compliance testing may be required. These are, firstly, Intentionally Added Substances (IAS) including raw materials and applied materials. A brief explanation and the lists of such materials were set out in Section 1.4.3.

Secondly, there are Non Intentionally Added Substances (NIAS) (see Section 1.4.4) including trace quantities of impurities which enter the manufacturing chain as minor constituents of approved raw materials and applied materials including reaction and degradation products. Further details on compliance testing for both classes of constituents are given later in this Section.

Limits and other restrictions referred to in this Section (NIAS and IAS) may be subject to revision by national authorities in the future. It is foreseen that this Section will be updated when such changes are implemented but as this process will take some time it has to be emphasised that it is the responsibility of the individual manufacturers carrying out the tests to check the limits and other restrictions to ensure that up-to-date information is used in the compliance assessment.

3.1.2 Supply chain conditions

A number of factors need to be considered to be able to decide on appropriate testing protocols for paper and board materials and articles such as food type, storage time, filling and storage temperature, packaging/food ratio, etc. Appropriate testing protocols can only be established if sufficient details about this are available.

Testing for microbiological quality might be needed, depending on the raw materials which have been used and the intended end use application of the paper and board materials and articles. There are no general specifications or limits set in national or European legislation for such tests. The need for such tests is normally decided on a case-by-case basis between supplier and customer as part of commercial agreements. [21 22]

Article 3(c) of the *Framework Regulation* requires that food contact materials and articles should not cause a deterioration in the organoleptic properties of the food. Therefore, sensory testing should be considered to verify compliance with this requirement. However, in a similar way to microbiological quality, there are no general specifications or limits set in national or European legislation for such tests and it has to be recognised that there are applications that are more sensitive than others and any requirements for such tests and limits for acceptance are also normally communicated by customers on a case-by-case basis.[23 24 25]

As a general principle, it is not necessary to test for all foreseen conditions of use if the worst foreseeable conditions have been considered in the testing set-up.

3.1.3 Alternatives to compliance testing

If it can be shown, by documented calculation, from knowledge of the contents of the paper and board or other sources, that a limit or restriction given in the lists referred to in Section 1.4.3 of this document and in Table 1 of this Section, cannot be exceeded, 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 have the highest validity although food matrices are, in many cases, very complex which makes such tests more difficult and potentially less reliable.

Testing can be made in-house or by third-party laboratories as appropriate, taking into consideration feasibility, time constraints, etc. and by using internationally recognised and validated methods (e.g. EN, ISO or equivalent) if such methods are available.

Modern evaluation techniques can also be used to support the verification of compliance with the *Framework Regulation*.

3.2 RECOMMENDED TESTING FOR PAPER AND BOARD MATERIALS

3.2.1 General

Included here are untreated paper and board, dispersion and mineral coated paper and board including greaseproof coating, siliconised paper and waxed paper and board and tissue paper, i.e. paper and board which will be submitted to further converting operations such as printing, gluing, etc. but excluding paper and board extrusion coated or laminated with plastic films and/or metal foil which are covered in Section 3.3 below.

Uncoated and mineral/dispersion coated paper and board materials and tissue paper (direct contact) are not typically used for the packaging of liquid food so liquid simulants are less relevant for assessing migration of substances from such papers. However, extraction testing[26 27 28] is the most commonly used testing method when testing for compliance with limits set for various substances in food contact paper and board materials. As described above, it needs to be taken into account that this is not a migration test but rather reflects the composition and purity of paper and board. If migration limits are exceeded when using extraction tests a more realistic testing protocol should be considered or correction factors could be applied. For purity restrictions, i.e. restriction is set as maximum residual content in paper and board (QM limit), extraction testing using an appropriate solvent is relevant.

It is worth noticing that polar solvents such as acetone and ethanol are very efficient extraction solvents for materials made from cellulose fibres as they have the ability to swell the fibres and dissolve/release substances which are normally tightly bound to the fibre surface and therefore have a low potential for migration. Non-polar solvents such as iso-octane are the most relevant solvents especially for applications involving contact with fatty food and consequently water extraction could be a viable alternative for applications involving contact with moist/aqueous food.

Migration testing using MPPO[29] is recommended to test uncoated mineral/dispersion coated paper and board materials as this is the only method that mimics a real food contact situation where transfer of substances from the food contact side of the paper and board can be assessed.

Greaseproof paper and silicone coated paper and board can also be tested by using MPPO. Greaseproof paper is either mechanically or chemically (e.g. vegetable parchment) treated to give very low air permeability or dispersion coated with special coatings to give grease resistance. For some of the dispersion coated greaseproof papers, ethanol is not suitable as a simulant/solvent due to its possible interaction with the coatings used for such papers. For greaseproof papers which are non-coated, all solvents can be used for extraction, as appropriate. For greaseproof paper to be used in baking applications, relevant conditions (time and temperature and using MPPO as a simulant) should be used.

For high temperature applications, except tissue paper[a], migration to MPPO according to EN 14338 can be used and is, in most cases, the only viable method. This is similar to the approach for testing of other food contact materials where migration to MPPO is stipulated for high temperature applications.

3.2.2 Testing related to Intentionally Added Substances (IAS)

For certain IAS there are quantitative restrictions (e.g. maximum usage rate, residual content in paper, maximum concentration of known impurities, SMLs, etc.). Such restrictions are included in various national and European regulations and recommendations. Examples of IAS with quantitative restrictions are fluorescent whitening agents, certain dry and wet strength agents, sizing agents, etc.

It is essential that suppliers of applied materials are required to communicate any restrictions related to the use of IAS (including information on known NIAS) to enable the paper and board manufacturer to assess, and where necessary test their products to ensure compliance with the restrictions.

In most cases, it is possible to verify compliance with IAS restrictions through calculation if sufficient information is available from the chemical supplier. If it is not possible to verify compliance through calculation, testing is needed using suitable test protocols as described above.

3.2.3 Testing for Non Intentionally Added Substances (NIAS)

NIAS could originate both from the raw materials used and from intentionally added applied materials (impurities, reaction/degradation products).

Some NIAS are normally found only in paper and board manufactured from recycled fibre pulp and testing for them will not be needed when examining paper and board manufactured solely from fresh fibre pulp. However, a risk assessment of potential NIAS should be carried out also for fresh fibre grades (in principle chemicals used in a pulping and bleaching process). In addition, some of the restrictions are only applicable if the paper and board are to be used in contact with certain food types, i.e. moist and/or fatty food and consequently such

[a] Migration testing with MPPO is not suitable for tissue paper testing as it does not correspond to real exposure conditions and gives overestimated results

restrictions do not apply if the papers are not going to be used or are not approved for such applications.

A table of general purity requirements, representative of current state-of-the-art knowledge on NIAS in paper and board materials, is shown in Table 1, below.-

Limitations related to food type are indicated in the "food type" column. It should be noted that for some of the substances in Table 1 where testing is indicated only for recycled grades, testing might be needed also for fresh fibre based papers if they are intentionally added during manufacturing, for example the addition of fluorescent whitening agents.

NIAS present in intentionally added applied materials are not specified in Table 1 for practical reasons due to the large variety and number of substances. Such NIAS should be communicated by the supplier of the additives and any restrictions applicable to them to enable appropriate testing, if necessary. Examples of such NIAS are residual monomers in wet strength resin and retention aids, dialkylketones in AKD sizing, etc.

See Sections 3.1.3 and 3.8 for further guidance on cases where testing is not required and Section 3.6 for information on testing frequency.

Testing for compliance with the requirements in Table 1 should be carried out according to the testing methods and principles set out in this section. Figure 1 provides a schematic representation of some elements of the determination of compliance.

There is a wide range of end use applications for paper and board food packaging. These applications 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 the *Framework Regulation* are met.

The requirements quoted in Table 1 are from published sources, principally national recommendations and regulations.

TABLE 1: TESTING RECOMMENDATIONS FOR KNOWN NIAS

NIAS REQUIREMENTS FOR ALL PAPER/BOARD GRADES IRRESPECTIVE OF FIBRE SOURCE					
Substance	**Requirement**		**Source**	**Method**	**Food type**
	QMA[a]	**SML[b]**			
NIAS in intentionally added chemicals according to information from suppliers	According to communication from suppliers	According to communication from suppliers	According to communication from suppliers		According to communication from suppliers
Cadmium (Cd)	5 ug/l cold water extract 0.5 mg/kg paper or board	–	DE:BfR XXXVI[7] FR: DGCCRF[30]	EN 12498[30] EN 12498	Moist and/or Fatty Moist and Fatty
Lead (Pb)	10 ug/l cold water extract 3 ug/dm2 paper or board 3 mg/kg paper or board	–	DE:BfR XXXVI IT: DM 21.03.73[32] FR: DGCCRF	EN 12498 Allegato IV Sez VI.5.2 EN 12498	Moist and/or Fatty All Moist and/or Fatty
Mercury (Hg)	0.3 mg/kg paper or board	–	FR: DGCCRF	EN 12497[33]	Moist and/or Fatty
Chromium (CrVI)	0.25 mg/kg paper or board	–	FR: DGCCRF	EN 12498	Moist and/or Fatty
Pentachlorophenol (PCP)	0.1 mg/kg paper or board	–	FR: DGCCRF	EN-ISO 15320[34]	All
Antimicrobial substances	The finished paper or paperboard must have no preserving effect on the foodstuffs with which they come into contact.	–	DE:BfR XXXVI FR: DGCCRF	EN 1104[35] EN 1104	All All

[a] Maximum permitted content in paper or board expressed as mg/kg paper or board or as mg/dm^2 paper or board

[b] Maximum permitted transfer to food expressed as mg/kg food

NIAS REQUIREMENTS ONLY RELEVANT FOR PAPER/BOARD GRADES USING RECYCLED FIBRE PULP					
Substance	**Requirement**		**Source**	**Method**	**Food type**
	QMA	**SML**			
Polychlorinated Biphenyls (PCBs)	2 mg/kg paper or board 2 mg/kg paper or board	–	IT: DM 21.03.73 FR: DGCCRF	EN-ISO 15318[36] EN-ISO 15318	All All
4,4,-bis(dimethylamino)-benzophenone (Michlers ketone)	–	0.01 mg/kg food	DE:BfR XXXVI	Castle et al[37]	Moist and/or Fatty
Azo colourants/Primary Aromatic Amines (PAAs)	–	0.01 mg/kg food (sum of PAAs)[a] 0.002 mg/kg food (Individual PAAs)	DE:BfR XXXVI	prEN 17163[38]	All
Colour fastness[b c] (Dyes and Colourants)	No migration of colourants to the foodstuff (Value 5 acc. to EN 646)		DE:BfR XXXVI IT: DM 21.03.73 FR: DGCCRF	EN 646[39] EN 646 EN 646	Moist and/or Fatty
Fastness of fluorescent whitening agents (FWAs, OBAs)[b c]	No migration of OBAs/ FWAs to the foodstuff (Value of 5 acc. to EN 648)		DE:BFR XXXVI IT: DM 21.03.73 FR: DGCRF	EN 648[40] EN 648 EN 648	Moist and/or Fatty
Dibutylphthalate (DBP)		0.3 mg/kg food	DE:BFR XXXVI	EN 16453[41]	All
Diisobutyl phthalate (DIBP)		0.3 mg/kg food	DE:BFR XXXVI	EN 16453	All
Di(2-ethylhexyl)phthalate (DEHP)		1.5 mg/kg food	DE:BFR XXXVI	EN 16453	All
Sum DBP-DiBP		0.3 mg/kg food	DE:BFR XXXVI	EN 16453	All
Benzophenone		0.6 mg/kg food	DE:BFR XXXVI	Castle et.al[42]	All

[a] Sum of listed amines acc. to Regulation (EC) No 1907/2006 Annex XVII Appendix 9

[b] If colourants /Dyes or FWAs are intentionally added to paper and board this testing is mandatory also for paper and board solely made from fresh fibres.See 3.2.2 above

[c] For tissue materials and articles a value of 4 is acceptable

Sum: Benzophenone + 4-methybenzophenone		0.6 mg/kg food	DE:BFR XXXVI	Castle et al	All
Diisopropylnaphthalenes (DIPN)	As low as technically achievable		DE:BFR XXXVI	EN 14719[43]	All
Bisphenol A (BPA)	n.d. /2 mg/kg paper or board[d]	0.24 mg/kg food	DE:BFR XXXVI FR: DGCCRF	prEN[e] FR: Acetonitrile extraction 23ºC, 24 h[44]	Moist and/or Fatty FR: All food types
Polyaromatic Hydrocarbons (PAHs)		0,01 mg/kg food[f]	EFSA, BFR	prEN	All

[d] Requirement : Shall not be present. 2 mg / kg is an indicative threshold for recycled materials which if exceeded will not result in non-compliance

[e] Work in progress, EN standards under preparation by CEN TC 172, WG3.

[f] Sum of listed PAHs according to EN standard under preparation.

Notes for Table 1

1	The reason for some limits being quoted in units of weight/weight, weight/volume of extract and some in weight/kg food is the different sources for the limits. In practice, an analytical measurement will give a weight/weight result. A conversion to weight/surface area using the actual grammage of the paper and board will be required for comparison with limits expressed as weight/food. (See note in Figure 1 in Chapter 5.3.1 of this Section.)
2	If it is assumed that complete migration of a substance occurs from the paper and board to the food (worst case scenario) it is possible to convert limits in food (SMLs) to a total quantity of the substance in paper and board. The standard packaging/food ratio in EU risk assessment of migration is 6 dm2 packaging material in 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 dm2 of paper and board (QMA). The actual packaging to food ratio should be used instead of the standard ratio, if available. 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.
3	Studies on mineral oil hydrocarbons found in foodstuffs have raised questions about consumer safety. According to these studies, one possible source (but not the only one) of traces of mineral oils which migrate to food is mineral oil based cold offset printing ink (commonly used in newspapers). It is present both on the printed surface of packaging and in paper for recycling used in the production of packaging papers. CEPI and CITPA made a commitment in 2011 to use mineral oil free inks for printing of packaging and this commitment is widely followed by the producers of food packaging in Europe. The European Food Safety Authority (EFSA) published a scientific opinion on the topic in June 2012 (amended and updated in August 2013)[45]. In the absence of a nationally or internationally accepted test method and with the uncertainty continuing to surround the hazard posed by mineral oil hydrocarbons, it is not currently possible to include limits values in Table 1. The paper and board sector has, however, taken a number of measures to limit the presence of mineral oil hydrocarbons in the paper-based food contact materials and articles by making commitments to use only mineral oil-free inks for printing this packaging and using a careful selection of grades of paper for recycling.

3.3 RECOMMENDED TESTING/ASSESSMENT FOR MULTI-MATERIAL MULTI-LAYERS (MMML)

This clause provides recommendations for paper and board coated with a plastic layer (defined as MMML) when they are intended for food contact. MMML are composed of two or more layers of different types of materials which are intentionally bound together and where one of the layers is paper or board. The commonly used materials for such multi-layer constructions in combination with paper and board are various types of plastic films and/or aluminium foil.

A plastic layer laminated or extrusion-coated on to a paper web is considered to be plastic film in the context of this clause. It has to be noted that such products are often referred to as "coated paper" within the industry. However, a distinction should be made between the plastic coated papers covered by this clause and papers coated with minerals such as calcium carbonate or other dispersions. These latter materials are outside the scope of this clause and are covered by Section 3.2, above. Other non-plastic coatings, as well as printing inks, are not plastic layers in the context of this clause.

Constructions involving packaging applications, such as "bag-in-box" packaging, where the material layers are not intentionally bound together are not MMML.

MMML are required to comply with the *Framework Regulation* and the *GMP Regulation*. When MMML contain plastic as the food contact layer, this plastic layer or layers are required to meet specific compositional requirements imposed by the *Plastics Regulation*.

According to Article 14 of the *Plastics Regulation,* specific migration limits and overall migration limits do not apply to plastic layers in multi-material multi-layer materials and articles. However, an assessment of the final MMML construction may be required. Such an assessment can be carried out using various methodologies depending on the end use application, MMML construction, customer requirements, etc. Even though specific and overall migration limits do not apply, migration testing can be carried out on the plastic layer side under certain conditions. It is important to note that migration testing with vegetable oil is not technically feasible but appropriate alternative simulants include isooctane and 95% ethanol. It may also be possible to use 10% ethanol, 3% acetic acid, 20% ethanol, 50% ethanol and MPPO, depending on the conditions.

When considering the risk assessment of substances in MMML, it is important to remember the requirements for dual use and other restricted substances where the risk of exceeding a regulatory limit may depend on the cumulative presence of a substance in the various layers.

NB - the *Plastics Regulation* does not regulate the non-plastic layers or the finished MMML, other than the limit for vinyl chloride monomer.

3.4 RECOMMENDED TESTING FOR CONVERTED PAPER AND BOARD MATERIALS AND ARTICLES

3.4.1 General

Included here are printed, varnished and glued paper and board materials and articles such as corrugated board and boxes, cartons, sacks, bags, wrappings, cups, plates, etc. made of paper and board. Using the known, intended, end use application as a basis, the compliance assessment for converted paper and board articles starts by an assessment of information from suppliers of paper, board, MMML, inks, varnishes, glues/adhesives, etc. In addition to information on suitability for food contact applications and potential end use restrictions, the supplier should give information on critical substances (e.g. substances known to migrate in concentrations that could lead to limits being exceeded) in the materials supplied. This information can then be used for theoretical calculations based on the composition of the converted article, i.e. the amount of ink/varnish, adhesives, etc. applied. Testing is only required when compliance cannot be verified by calculation.

The application of GMP and the associated risk assessment is an important element to reduce the risk of migration from inks, varnishes and adhesives, for instance.

3.4.2 Testing Recommendations for Converted Paper and Board Materials and Articles

Such materials and articles will contain paper and/or MMML as a substrate and also printing inks, glues, adhesives, etc.; thus, extraction testing is not feasible. Substances included in inks and glues, which exist in structures where constituent transfer will not occur, can be partly or fully re-dissolved in the extraction solvent or react with the solvent. This does not reflect any real food contact situation for converted paper packaging materials and articles. Migration to MPPO applied on the food contact side is the only feasible method if and when testing of the converted food contact paper materials and articles is needed. If an MMML is part of the converted material and article, with the plastic layer in contact with food, then testing from the plastic layer can be carried out as outlined in Section 3.2 on MMML.

3.4.3 High temperature applications

Migration to MPPO according to EN 14338[11] can be used for compliance testing. This is similar to the approach for the testing of plastic materials and articles where MPPO is stipulated for high temperature applications.

3.4.4 Compliance Assessment of Converted Paper and Board Materials and Articles

Assessment of compliance with compositional limits (overall or specific limits) for each finished product manufactured is often difficult, given the range of packaging scenarios and food contact materials. A documented risk assessment should be undertaken to include:

- supplier compliance documentation in line with Section 8 on DoC confirming suitability of the materials for their intended or foreseeable uses, as well as dialogue with the subsequent business operator who is often best placed to carry out any migration testing specific to any end use of the packaging;
- a 'family approach', whereby all products within a suitable defined product family are considered to comply;
- a 'building blocks' concept where evidence of compliance with applicable restrictions for a number of products, using similar materials or combinations of materials, are considered to apply. This building blocks concept is seen as the core safety approach converters have to implement provided that end use conditions are efficiently covered.

Starting from minimum corporate standards, as described in general in Section 1.4 of this document, converters need to evaluate their packaging systems (i.e. a combination of paper, board, inks and glues/adhesives).

Once a packaging system has been thoroughly evaluated as compliant for a certain type of application, that combination of materials comprising the packaging system can be used safely for many customers. An application should be understood as a combination of certain types of food, storage and usage. The evaluation could be different for different types of packaging and applications (e.g. frozen food, dry food, chocolate, fruits and vegetables). Accurate compliance verification has to be in place in order to guarantee the safety of the packaging system over time.

3.5 RECOMMENDED TESTING FOR INTERMEDIATE AND CONVERTED TISSUE MATERIAL AND ARTICLES

Tissue paper and products have unique properties which are different from paper and board packaging materials. Standard testing conditions, as applied to paper and board, might not always be suitable, considering that tissue paper has a very low grammage, the contact time with food is very short and tissue usually absorbs fat and moisture from foods which minimises reverse extraction from the tissue.

The testing recommendations as outlined in Sections 3.2.2 (IAS), 3.2.3 (NIAS) and 3.4 (converted paper/board materials and articles) can be used as a reference. However, for the test scheme of intermediate and final tissue products, certain exemptions and differences in limits apply and also specific food contact applications must be taken into consideration. Usually, migration into food from tissue products is very low or does not even occur, thus the current methods (simulation of migration), as applied to paper and board, significantly overestimate the real substance transfer from lightweight papers in food contact for almost all applications.

If tissue products are printed, tests should be carried out on the printed area. In case migration tests are applicable (e.g. colour fastness), the printed surface should be in contact with the food or food simulant.

3.6 TESTING METHODS AND FREQUENCY

As a general principle, internationally recognised and validated methods should be used (e.g. EN, ISO or equivalent) if such methods are available.

For testing to ensure compliance with limits, the test methods listed in Table 1 and in the list of references are recommended. These testing methods are widely used within the paper and board industry and experts from the industry are often involved in their maintenance and the development of new standards. Consequently, those experts will endeavour, where possible, to ensure the list is up to date.

If the testing method covers several foreseen conditions, it is not needed to test all conditions provided that the worst conditions are covered in the testing protocol.

Testing must be performed at a frequency which is based on a risk assessment and relates to the likelihood of a particular restriction being exceeded. This frequency should have a statistical basis and will depend on a number of factors, e.g. raw material variability, process variability and testing accuracy. In certain cases, there may also be a need to align frequency with external factors such as customer requirements, change of suppliers and the Declarations of Compliance (DoC).

Once the initial frequency has been determined, the risk assessment which determined that frequency must be reviewed at least every 12 months. This may or may not result in the actual testing frequency being changed.

3.7 COMMUNICATION

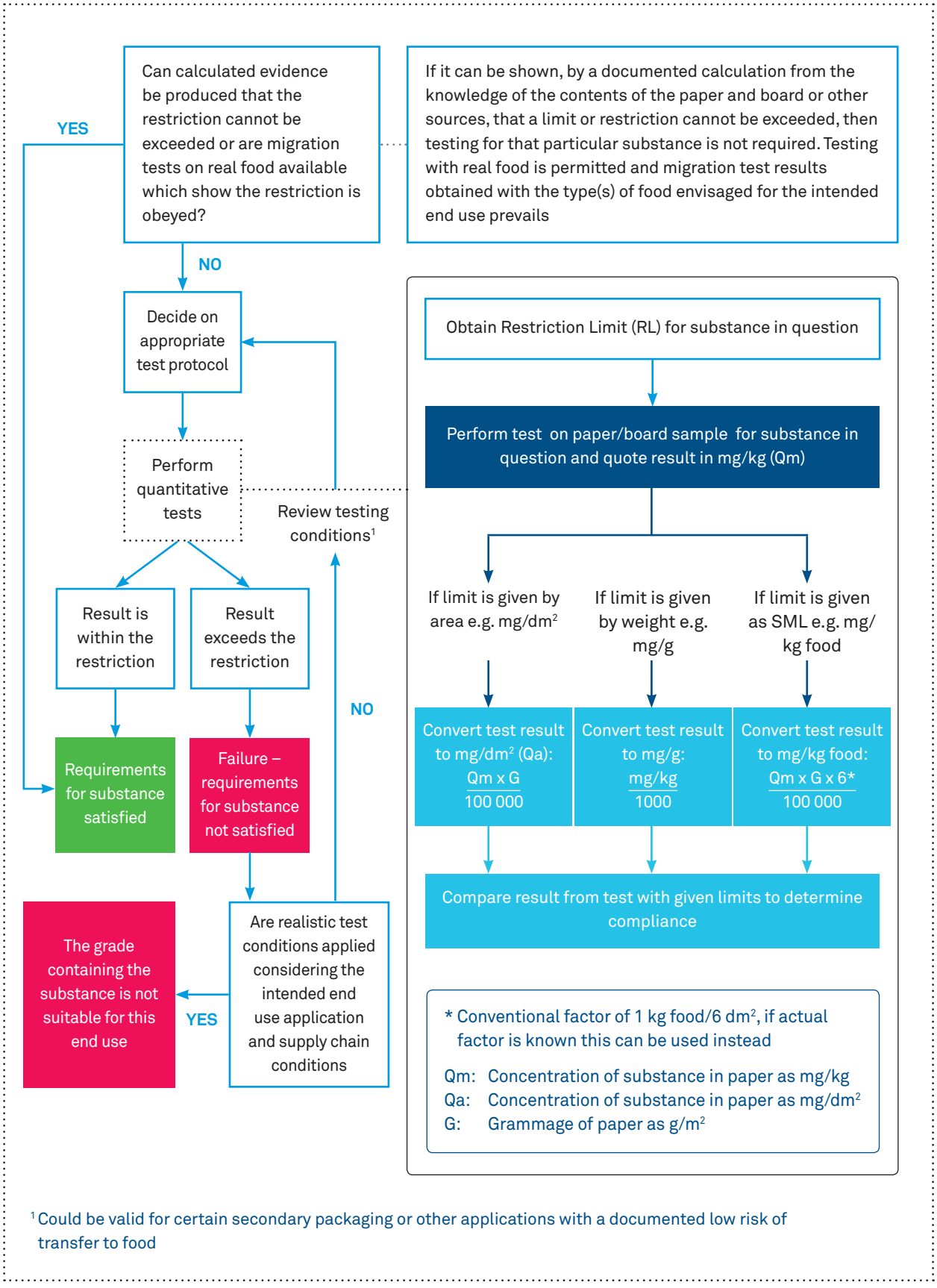
Normally, supporting documentation such as test reports do not need to be shared with downstream customers. The predominant raw materials for paper and board materials and articles are cellulose fibres from fresh or recycled sources which can have a natural variation. This, in combination with the variation in other materials used, processing parameters and testing methods, makes single test results less relevant and can be misinterpreted or misused if the statistical background is not known. Testing data can be shared on a case-by-case basis as part of a commercial agreement between customer and supplier and under non-disclosure agreements, if appropriate.

Statements on compliance with various regulations and recommendations which are communicated in the DoC should be understood as also including compliance with any restrictions set out for substances and raw materials used and hence do not need to be listed separately.

Restricted substances, which may have a potential to migrate, should be communicated to the customer due to the risk of multiple uses of those substances.

3.8 TESTING FRAMEWORK

Figure 2



[1] Could be valid for certain secondary packaging or other applications with a documented low risk of transfer to food

SECTION 4

Paper for Recycling

PAPER FOR RECYCLING – REQUIREMENTS FOR ITS USE IN FOOD CONTACT MATERIALS AND ARTICLES

4.1 GENERAL

To ensure the safety of paper and board manufactured from paper for recycling, the following aspects shall be considered when assessing the suitability of paper for recycling as a raw material for food contact paper and board materials and articles:

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

Further requirements and guidelines related to the application of this Section are covered in more detail in:

- sector-specific GMPs
- the responsible sourcing document from CEPI (Ref. 3);
- the "EN 643 standard" (Ref. 4);
- BfR Recommendation XXXVI [6].

Flow chart

The flow chart below outlines the relevant sequences of actions and infomation exchanged to ensure the safe use of paper for recycling in food contact paper and board materials and articles.

4.2 THE INTENDED USE OF THE MATERIAL

The suitability of paper for recycling for particular food contact applications depends on the type of food, contact time and temperature and conditions of storage. If paper for recycling is judged to be suitable, then those grades which are appropriate need to be determined according to the following section.

Risk assessment of paper for recycling shall cover risk of chemical, physical and microbiological contamination. This risk assessment should apply at a frequency that takes into consideration the likelihood of any changes occurring in the following elements of that material:

- new grades
- new supplier
- change of country of origin
- process modification
- new legislation
- new standard

The current best practice would be to:

- identify the source of any NIAS (contaminants);
- establish a methodology for controlling those NIAS (contaminants) to a safe level in the final product;
- state any restrictions on food type, temperature or contact time which might result from a risk assessment of the above steps.

The recycling operations are expected to ensure the application of best available techniques that would minimise or remove harmful ingredients from the supply chain of food contact materials. However, their existence does not remove the need for the other elements of risk assessment.

For converters, the suitability of paper types made from recycled paper grades in appropriate applications needs to be determined. This will be through an assessment taking into account the intended use of the material (including food type, contact time and temperature) and the likelihood of transfer of constituents during that use.

The principles concerning the use of paper for recycling contained in this Guideline and covered in detail in the CEPI GMP[5] should be cross-referenced with other organisations' documents on this topic. This represents a positive example of the cooperation taking place along the supply chain.

4.3 SAFETY OF THE RECYCLING LOOP OF PAPER FOR RECYCLING USED FOR FOOD CONTACT MATERIALS AND ARTICLES

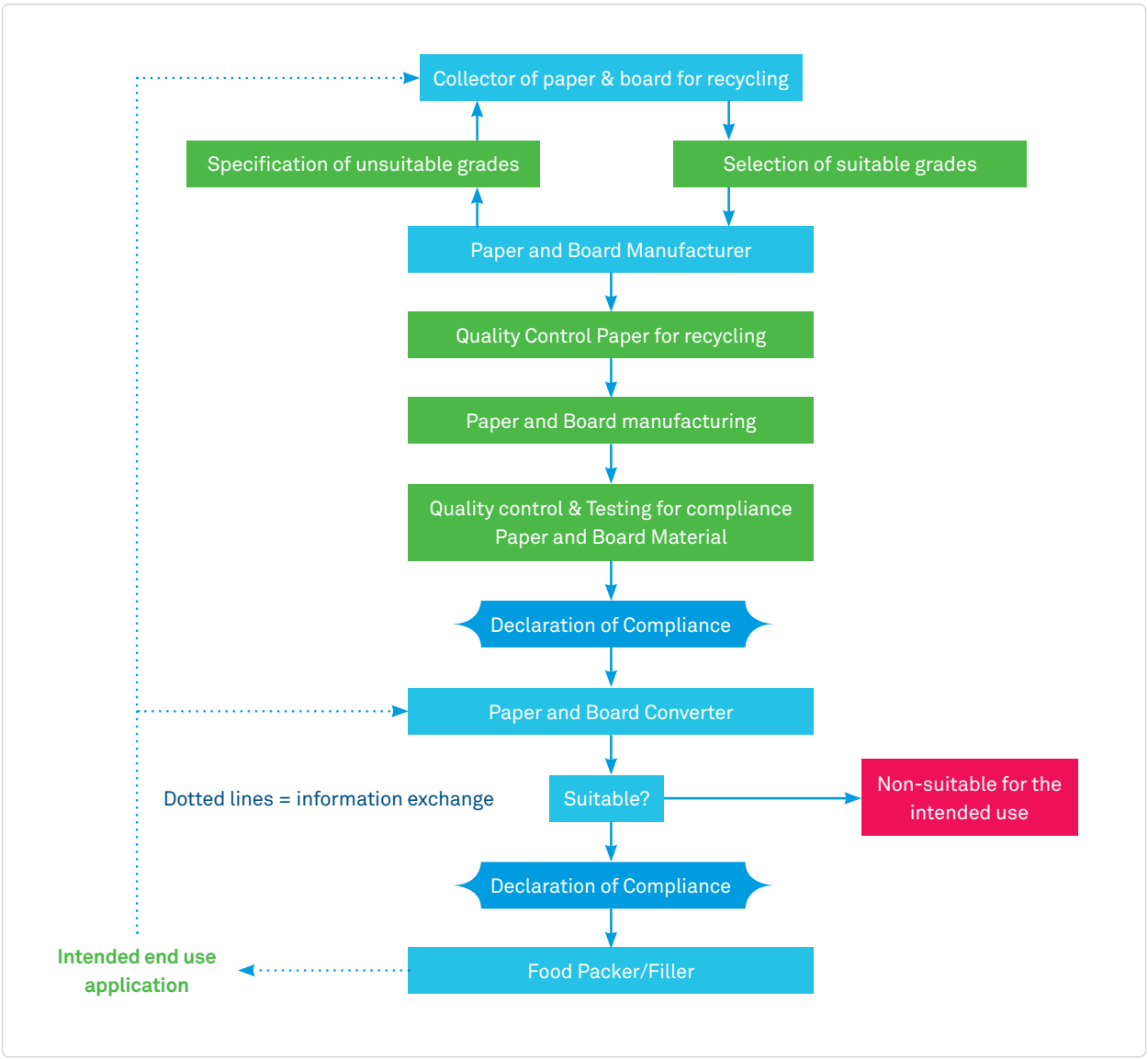
The paper-based supply chain, including manufacturers, converters and packers, has an impact on the contents of the paper and board which is later collected for recycling.

As most grades of paper and board can eventually become part of the recycling stream and thus find their way into food contact grades, every business operator in the supply chain is expected to maintain vigilance about the safety of its raw materials and communicate any concerns to the wider paper industry.

In particular, converters and packers 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 business operator, as the converted product may either be used as a food contact material or article or eventually returned to paper mills for recycling into food contact grades.

Knowledge about the safety of substances is always evolving due to scientific advances and, in cases where new toxicological evidence about substances becomes available, joint actions will be taken rapidly to ensure that food contact grades remain in compliance with all legislation.

Figure 3


Collector of paper & board for recycling
Specification of unsuitable grades
Selection of suitable grades
Paper and Board Manufacturer
Quality Control Paper for recycling
Paper and Board manufacturing
Quality control & Testing for compliance Paper and Board Material
Declaration of Compliance
Paper and Board Converter
Dotted lines = information exchange
Suitable?
Non-suitable for the intended use
Declaration of Compliance
Intended end use application
Food Packer/Filler

SECTION 5

Traceability

TRACEABILITY GUIDELINES

5.1 INTRODUCTION

Traceability is a requirement of the *Framework Regulation* and requires the existence of supply chain information in order to facilitate the recall of defective products and the attribution of responsibility for the cause of the defect.

For product recall the existing procedure in the ISO 9001 system or similar are recommended.

This document gives guidelines for product traceability within the manufacturing chain used for the production of paper and board food contact materials and articles.

5.2 SCOPE

These guidelines cover all paper and board materials and articles from the paper mill downstream to the packer-filler stage. In accordance with the *Framework Regulation*, manufacturers of materials, articles, substances and products covered by this Regulation are required to implement traceability and product recall measures.

It is recognised that detailed traceability back to raw materials may not always be possible. For instance, paper mills may use batches of wood pulp and paper for recycling across several orders of paper and board. Similarly, converters may use a delivery of a bulk chemical to fulfil a number of customer orders. (See Section 5.4, below, on bulk raw materials.) The Framework Regulation allows for these eventualities by stating that traceability systems should follow the principle of technological feasibility. This does not say that traceability need not be implemented; it says that the detail of the traceability system can be tailored to the particular way in which the raw material is delivered and used. The particular business operator, when designing a traceability system must always consider that the objective of the work is to "attribute responsibility" and "recall defective products". Considering the latter, a balance will have to be struck between the expense and difficulty of operating a very detailed system and the adverse impact on the business caused by having to recall unnecessarily large amounts of potentially defective products.

5.3 GENERAL INFORMATION

The processing chain for paper and board food contact materials and articles is extremely complex. There are literally thousands of different ways in which paper may be processed before use. Examples of these processes include: slitting reels to smaller reels, cutting to sheets, calendering, laminating to metal and plastic, corrugating operations, die cutting, printing, varnishing, gluing, box and carton making, packaging and labelling. As well as the processes themselves, there is a considerable overlap of the operations performed in different types of converting plants. For instance, coating operations can be performed both by paper mills as an integrated operation and by separate, independent operators. Also, some corrugating plants will produce only unprinted flat blanks whilst others will produce complete boxes and trays.

It is, therefore, impossible to produce guidelines covering all aspects of the production and converting process. Thus, these guidelines are restricted to explaining best practice and the types of tools and documentation which can be used in the paper and board supply chain. A generic representation is shown in Figure 4, below. Apart from facilitating product recall, a principle objective of any traceability system is to allow the identification and withdrawal from further processing of upstream raw materials in any manufacturing process where a safety issue is identified in a downstream material or article. The implementation of such a system will depend on the scale of risk and the complexity of the manufacturing process. Thus, all the components shown in Diagram 1 may not be necessary, provided the likely achievement of the above objective can, nevertheless, be demonstrated. It should also be remembered that identification information already being transferred along the supply chain as part of the Declaration of Compliance or labelling, for instance, can be used for traceability purposes also and need not be duplicated.

5.4 SPECIAL CONSIDERATION FOR BULK RAW MATERIALS

A feature of many operations, in the paper and board food contact chain, is the use of bulk raw materials such as pulp, paper for recycling and sizing agents during paper and board manufacture, starch during corrugated board production and clay for coating operations. The principles of traceability for these materials will differ from those applicable during small batch operations. It will be less precise as a large and possibly mixed input will be used in several different production batches. It must nevertheless be documented and capable of audit. In the above cases, the manufacturer and batch number will be known from identifications and accompanying documentation. Batches of bulk materials will be used, on a continuous basis, from silos or other storage devices and the link from these to the treated or finished product may be less precise. However, because all batch process additions are recorded in a timed log, it is possible to relate the times at which a specific batch of additives was introduced to the process and was thus at a significant concentration. From the timed log of the process concerned, these data can be related to the identification of the paper and board products. The achievement of higher precision is probably not "technologically feasible" in a continuous, industrial process.

5.5 PRODUCT RECALL

One of the main purposes of the traceability requirements within the *Framework Regulation* is to enable recall of defective products. Throughout all the stages of all the processes described in these guidelines, it can be seen that extensive documentation is in place both within operations and between organisations in the food packaging chain. In particular, there is a clause in the *Framework Regulation* which states:

With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied.

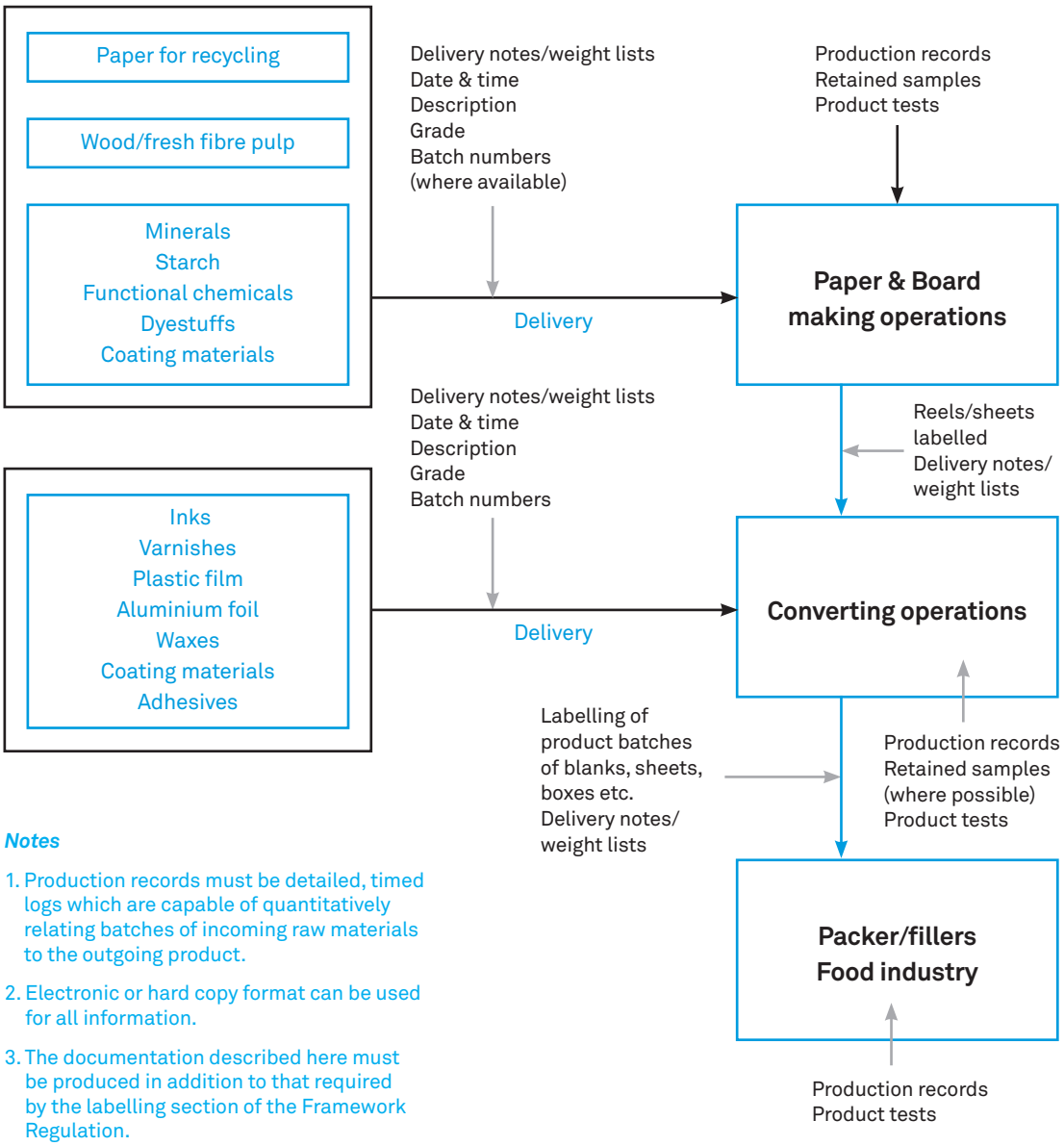
This requirement is fulfilled from the paper mill downstream to the final food contact product, including raw material supplies, either in the form of identification of the product itself or contained in the accompanying documentation.

Large reels produced in a paper mill are subdivided many times to produce the final paper and board packaging products. Because of extensive record keeping within all the processes of the paper packaging chain, both upstream and downstream product traceability and the identification of the source of any problem will be assured. The batch numbers and suppliers of all raw materials and starting materials are recorded and internal records relate these to the packaging product itself in dated production logs. Thus, using traceability, the identification of an affected product or raw material sent to other locations and customers is possible. This will define rapidly the full extent of any affected material in the market place or still in production, thus enabling full recall of any defective products.

Figure 4

TRACEABILITY IN THE PAPER & BOARD SUPPLY CHAIN

This diagram shows examples of the various documents and tools which are used to establish product traceability. The list is neither exhaustive nor compulsory as operators will decide which tools best enable the requirements of traceability, within the Framework Regulation, to be met.



Notes

1. Production records must be detailed, timed logs which are capable of quantitatively relating batches of incoming raw materials to the outgoing product.
2. Electronic or hard copy format can be used for all information.
3. The documentation described here must be produced in addition to that required by the labelling section of the Framework Regulation.

SECTION 6

Labelling Guidelines

LABELLING GUIDELINES

6.1 INTRODUCTION

The following is a summary of the labelling requirements contained in the *Framework Regulation.* They apply to food contact materials and articles (not yet in contact with food) marketed along the supply chain and to the retail sector.

These requirements must be shown in a format which shall be clearly visible, legible and indelible and in a language easily understood by the intended purchasers. It may be necessary to hold discussions with purchasers to ensure that the latter requirement is met. Additional labelling in other languages is, of course, permitted.

The requirements are extensive but there is considerable flexibility in how they can be implemented. The business operator has the responsibility to design a system which satisfies the overall labelling objectives but, at the same time, is appropriate in detail and scale to the operation in question.

6.2 REQUIREMENTS

The four main requirements are:

The words "for food contact" or a specific indication such as coffee machine filters, a wine bottle, a soup spoon, or the symbol shown below

A variety of locations for the information are given in the *Framework Regulation* but, at most points in the paper and board supply chain, it is recommended that this requirement is satisfied by the use of documentation, electronic or paper, accompanying the goods. (The Declaration of Compliance (DoC) could, for instance, be used for this purpose.) Before the retail stage, there is no requirement to place the labelling on the goods themselves if the information has been provided on accompanying documents. Paper and board articles marketed at the retail stage will be likely to have the labelling on the packaging or the articles themselves. However, in the latter case, if the appearance and characteristics of the article make it clear that it is intended to come into contact with food, then labelling is not required.

If necessary, relevant instructions to be observed for safe and appropriate use

Wherever possible, the producer should state for which food contact applications the paper and board materials or articles are suitable and/or not suitable. (Again, the DoC could be used for this purpose.)

Name or trade name and, in either case, the address or registered office of the manufacturer, processor or seller responsible for placing on the market

Again, at most points in the paper and board supply chain, it is recommended that this requirement is satisfied by the use of documentation, electronic or paper, accompanying the goods.

Adequate labelling or identification to ensure traceability

Again, at most points in the paper and board supply chain, it is recommended that this requirement is satisfied by the use of documentation, electronic or paper, accompanying the goods. It is recommended that the labelling and traceability guidance should be considered together to prevent duplication.

6.3 BEST PRACTICE EXAMPLES

For illustrative purposes, some examples of best practice labelling are described below:

Manufacturer of intermediate materials (e.g. paper reels or sheets) selling to converters
A statement of suitability for food contact together with any specific, suitable end uses or any restrictions on use (name/trade name, address or registered office and identification to ensure traceability shall be included on accompanying documents).

Manufacturer of tissue products
Kitchen towels and napkins can be labelled with an indication of their short term contact with food. This can be done by different means, such as the specification "for wiping" combined with the "glass and fork" pictogram.

Manufacturer of articles selling to packer/fillers
A graphic symbol or "for food contact", name/trade name and address or registered office displayed on the label, packaging or accompanying documentation.

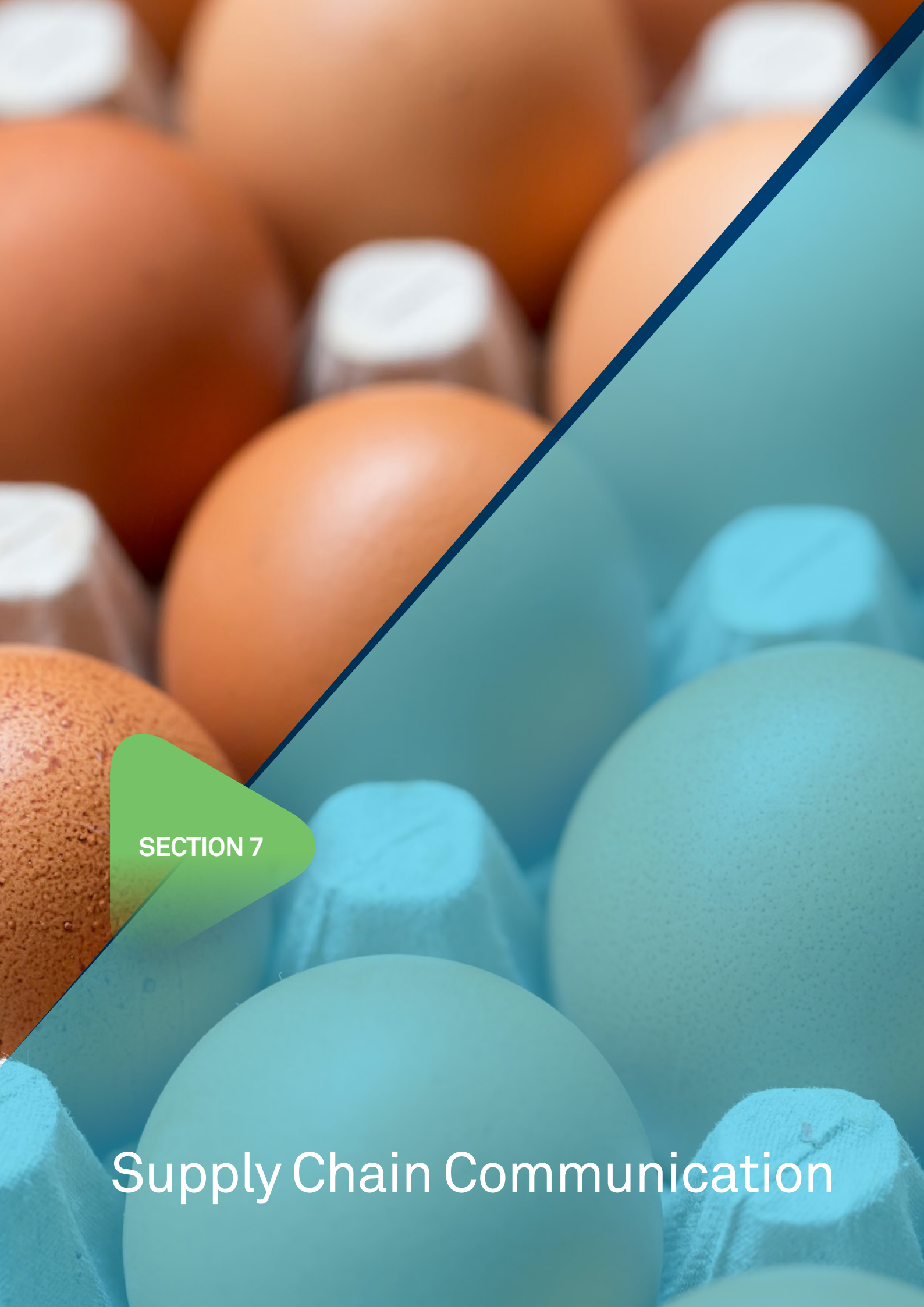
If necessary, identification to ensure traceability displayed on the product or its packaging.

Please note that all the information shown on the product should first be agreed with the customer.

Manufacturer of articles selling to food retailers (e.g. cartons, trays for catering, etc.)
If the appearance of the article makes it clear that it is intended to come into contact with food, then no written indication on the article is necessary and only traceability information may be required.

Otherwise, a graphic symbol or "for food contact", name/trade name, address or registered office displayed on label or packaging and, if necessary, special instructions for use displayed on the product.

Please note that all the information shown on the product should be agreed with the customer.



SECTION 7

Supply Chain Communication

SUPPLY CHAIN COMMUNICATION

7.1 INTRODUCTION

The compliance of the final material and article with EU provisions can only be assured if, along the supply chain, relevant information exchange takes place between the supplier and the customer and *vice versa*. The Declaration of Compliance is the main tool for supply chain communication and is compulsory for all business operators supplying food contact paper and board to other business operators. It confirms to the customer the compliance of the material or article with the relevant requirements of the *Framework Regulation*. It also provides the customer with relevant information necessary to establish or check the compliance of the material or article with relevant legislation.

The obligations on business operators, in the context of the information in the supply chain, depend on the type of material or article being delivered to the direct customer as well as on the role and the position of the business operator in the supply chain.

Sections 7 and 8 give guidance on the information that needs to be generated and exchanged in the supply chain in order to ensure that only safe and appropriate paper and board food contact materials and articles are supplied into the market. Every business operator in the supply chain is responsible for its own manufacturing step and the related compliance work and supporting documentation.

7.2 INFORMATION TO BE EXCHANGED

Converters are encouraged to request information about the items listed below from packer/fillers and materials' suppliers and pass the relevant information along the supply chain to enable each business operator to perform appropriate compliance work in relation to the actual end use application. The list may vary depending upon the type of food contact material or article and its intended use. Depending on the intended use, the list may not be fully applied to paper and board articles, e.g. materials intended to have only occasional short-term contact with food. For guidance purposes only, the list is divided into items which are generally provided by suppliers (i.e. sent in the downstream direction) and by customers (i.e. sent in the upstream direction).

7.2.1 Provided by Suppliers

- compliance of all used materials and components (paper, board, inks, adhesives, varnishes etc.) with regulations and possible limitations
- unusual and non-standard issues and events occurring at and between business operators, which may affect product safety
- relevant changes affecting compliance
- testing requirements where relevant

7.2.2 Provided by Customers (not applicable to tissue products)

- characteristics of the food to be packaged
- intended conditions of use (contact time and temperature including filling/packing, storage and time of consumption)
- the highest food contact surface area to volume ratio for which compliance has been verified
- type of materials and components to be used in the final packaging material or article
- information about any functional barrier used
- testing requirements including, for example, migration and sensory testing if needed
- unusual and non-standard issues and events occurring at and between business operators, which may affect product safety
- relevant changes affecting compliance

7.3 STATEMENT OF END USE

In the packaging supply chain communication, a statement of end use may be used. (This is not applicable to tissue.) This statement should list the intended end use of the material or article to enable the safe and appropriate choice of materials and articles for the intended food contact use. The statement is designed to be passed back up the supply chain. It is the responsibility of the food business operators to complete the statement and all business operators should pass a copy back up the supply chain. The statement may contain, for example, the following items:

- name of foodstuff or generic type of food for which the material or article is required
- type of foodstuff (e.g. dry, fatty, moist/aqueous, acidic)
- intended time of contact or storage
- intended storage temperature and/or conditions of use
- will the material or article be capable of transferring its constituents to the food?
- details of any other packaging which could influence the transfer of constituents from the materials or articles in question to the food

SECTION 8

Declaration of Compliance

GUIDANCE ON PREPARING A DECLARATION OF COMPLIANCE

8.1 INTRODUCTION

The Declaration of Compliance (DoC) is the core document which the manufacturer of paper and board materials and articles is expected to produce in order to communicate compliance with the *Framework Regulation.* There is a de-facto obligation on the manufacturer to issue a DoC and pass it on to the downstream business operator when the material or article is placed on the market. When the food contact material or article is further processed and/or modified in a downstream process, the downstream business operator must issue a further DoC. This requires that the downstream business operator must obtain adequate information from their suppliers which allows them to perform their own compliance work. Consequently, each manufacturer has to declare compliance with GMP and the compliance of the materials or articles supplied downstream. DoCs can be made available at a frequency and in a format (paper or electronic), depending on discussions with downstream users.

As for many complex manufacturing processes and supply chains, usually no single stage can perform the complete compliance work. Therefore a structured exchange of information in the supply chain is a prerequisite to ensure the compliance of the final article. Communication up and down the supply chain will enable all stages in the supply chain to perform their own compliance work.

A necessary prerequisite of producing a DoC is the production and gathering of relevant supporting documentation and information which serves as evidence of the statements made in the DoC. The DoC and its supporting documents form a fundamental part of compliance activities. Competent authorities have the legal right to inspect them upon request. The business operators may indicate to the authorities which information is to be treated as confidential on the grounds that its disclosure may significantly harm their competitive position. The documentation may be provided in electronic or paper format or a combination of both. Examples of the supporting documents could include formulations, analysis reports, calculations, certificates and DoCs from upstream suppliers, information on intended uses from downstream business operators, toxicological information on substances, testing certificates from third party laboratories and institutes and/or other evidence of safety which demonstrates the accuracy of the DoC. See Table 4 for more details.

8.2 DOC CONTENTS

A contents check list for preparing a DoC is shown in Table 3. This list should be used also for checking the completeness of any DoCs which are supplied by upstream business operators. In view of the specific contents of the DoC, it can apply to one or several products. It is the decision of the one who releases it to issue one per product or one for a group of similar products, based on risk assessment. It should be noted that the elements to be included may vary depending on the intended end use of the materials and articles, customer requirements, product type, etc. The 'Comments' column shows what is understood to be best practice in this regard.

The DoC should be reviewed periodically and renewed at least every two years or when substantial changes in production occur, when new scientific evidence is available or when there is a change in the applicable regulations.

8.2.1 Possible Additional Information

In addition, it is recommended that all business operators include information in the DoC on the intended end uses, where these are available. This is to provide the customer with relevant information to ensure the compliance and safety of their product with relevant legislation. This information should contain information on the type of food, storage time and temperature as well as any special conditions of use where the material or article can be used in its final food contact application (e.g. maximum baking temperature). The exact content is dependent on the role and position of the business operator in the supply chain.

Because of variations in the characteristics of foodstuffs, storage conditions and conditions of use, this information must be regarded as a guide only. It does not remove the necessity for a risk analysis to be performed by the supplier of the final material or article to the food industry. It should be noted that subsequent treatments to the material or article may change the intended food contact applications so the DoC must be read in conjunction with any others issued further along the production chain.

8.3 DOC SUPPORTING DOCUMENTATION

In order to provide evidence of compliance with the *Framework Regulation*, business operators must maintain relevant documentation and records which serve as evidence of the statements made in the DoC. The documentation is required to support mainly the *Confirmation of compliance with legislation* section of the DoC. The documentation is also relevant to support the 'glass and fork' symbol used as part of downstream direction labelling and communication. It does not form part of the supply chain documentation but must be retained and produced for inspection by the competent authorities, on demand. There is no legal requirement to share this information with any other organisation. The data can be held in any format, for instance paper,

electronic, etc., which the business operator favours. However, that format must be easily understandable and accessible to the documentation.

Supporting documents shall be kept for the minimum period requested by national legislation, where applicable; if not applicable, the period must be defined within the existing management system of the business operator.

Table 4 gives a non-exhaustive list of the necessary supporting materials which enforcement authorities may ask to inspect.

Table 3. Declaration of Compliance – List of Contents

MAIN ELEMENT	DETAILS	COMMENTS
Date	1. Date of Declaration of Compliance (DoC)	
Business operator issuing the DoC	2. Identity and address of the organisation which manufactures the materials or articles	
	3. The address of the manufacturing site. The address of the manufacturer.	Only if different from the first address
Identity of the materials and articles	4. Generic product description	
	5. Trade name or grade description, including other relevant identifying information. Description of the product.	
Confirmation of compliance with legislation and Food Contact Guidelines	6. Statement that the product complies with the relevant requirements of the Framework Regulation and relevant Food Contact Guidelines	
	7. Statement that the different non-harmonised materials (paper and board, inks, adhesives, coatings) as well as polymer layers in MMMLs comply with existing reference legislation and food contact guidelines, when these exist	
	8. Known migrants with SML restrictions for paper and board in BfR XXXVI or other relevant lists of authorised substances, and intentionally added substances that, based on risk assessment can potentially migrate to food, should be communicated to downstream operators	Compulsory
	9. Dual use substances (deliberately added only) with quantitative restrictions in food legislation	When risk assessment indicates that there is a risk of transfer to food
	10. Statement on end uses or the restrictions of use, if any (e.g. food type, temperature)	

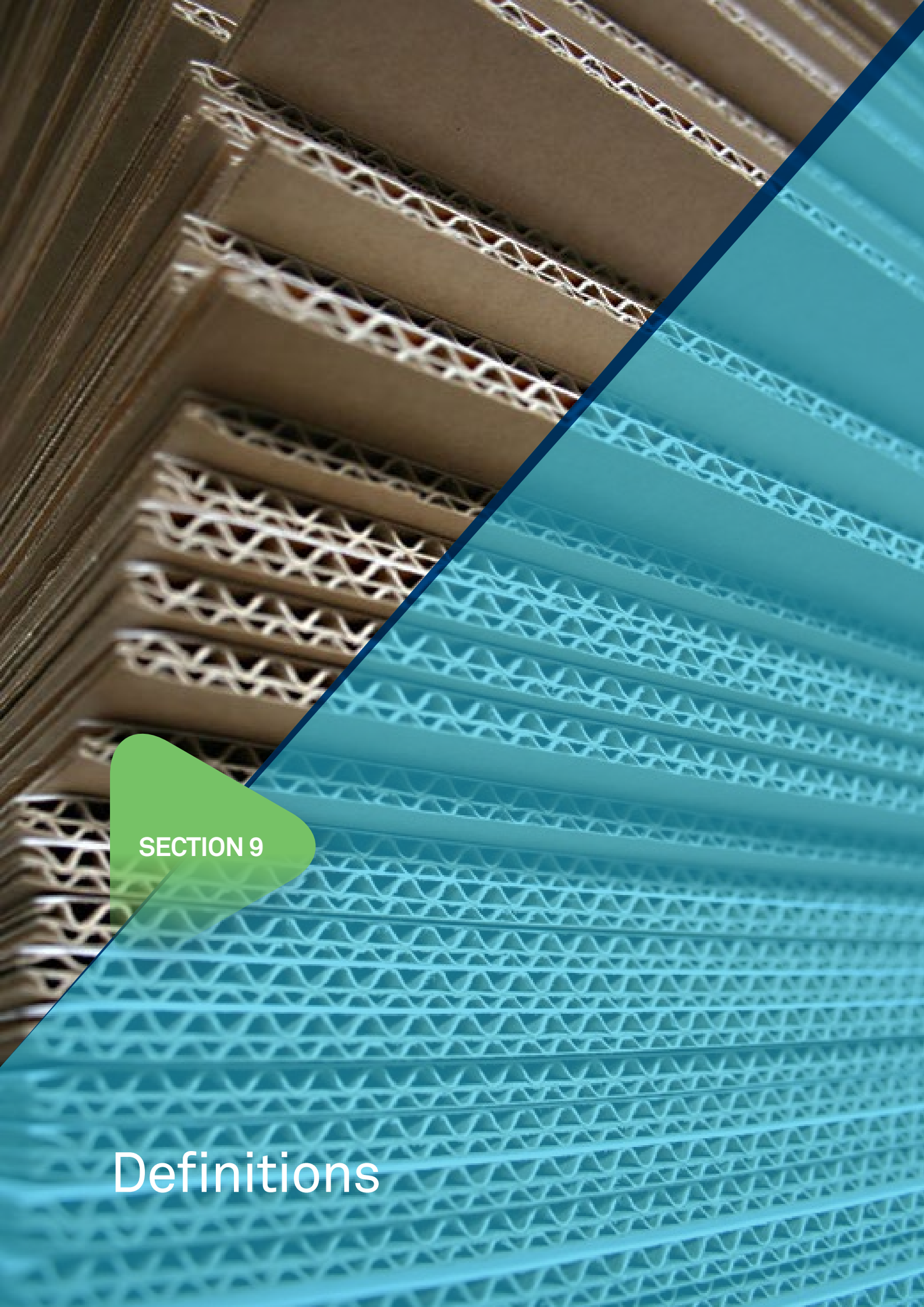
Table 4. Declaration of Compliance – List of Supporting Documentation

COMPLIANCE ELEMENT	DETAILS	COMMENT
Labelling	General details of the system used to label materials and articles which are not yet in contact with food when placed on the market.	Compulsory. Illustrates how the labelling requirement is being complied with.
Traceability	Documented routine for recall of products including the appropriate information needed for traceability as described in Section 5.	Compulsory. Illustrates how the traceability requirement is being complied with.
Documented risk assessment and/or evaluation of the product for which the DoC is issued based on Section 3 of this Guideline	Adequate information on potential migrants in the intended end use as defined in upstream DoCs or similar documents. May include concentration and/or migration testing, sensory testing, and/or worst case calculations based on risk assessment of intentionally added substances and NIAS. The risk assessment also covers the overall compliance of the material/article taking into account the multiple sources of substances. The same substance may originate from different materials used.	Compulsory. Illustrates how Article 3 of the Framework Regulation is complied with. See Section 3 for possible testing methods.
Identification and verification of the authorisation status of intentionally added substances and raw materials used in the formulation of the material/article	• Composition of the material/article. • DoC from upstream suppliers of chemicals authorised for use. • DoC from upstream suppliers of polymers if MMMLs are produced. • DoC or similar document with adequate information from upstream suppliers of materials which are not covered by a specific measure such as paper and board, inks, adhesives, varnishes, etc.	Compulsory
Identification and verification of quality and purity criteria for authorised substances	• DoC from upstream suppliers of chemicals.	Compulsory for business operators adding chemicals to their product. Otherwise not needed. Upstream DoC should provide the necessary information.
Dual use substances[(a)]	• DoC from upstream suppliers of chemicals and polymers used in MMMLs. • DoC or similar document with adequate information from upstream suppliers of materials which are not covered by a specific measure such as paper and board, inks, adhesives, varnishes, etc. • Risk assessment to see if there is a risk of transfer to food	Compulsory.
Identification and risk assessment of NIAS	• Scientific literature. • Results from testing of known NIAS. • Migration modeling. • Toxicological information of a substance.	Probably not possible at the current time until a realistic method is available.

COMPLIANCE ELEMENT	DETAILS	COMMENT
Substances intended to be used behind a functional barrier which are not authorised for use in paper and board materials and articles	• Adequate written information confirming that the substance does not meet the criteria for classification as mutagenic, carcinogenic or toxic to reproduction according to Reference 15. • Confirmation that the substance is not intentionally manufactured to be in nanoform.	Compulsory but there are unlikely to be many affected materials or articles.
Good Manufacturing Practice	Business operators must keep documentation on the application of the quality assurance and quality control systems which they use, as set out in Reference 3.	Compulsory.

(a) Certain substances used in food contact paper and board are, at the same time, food additives or flavourings authorised respectively by Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives or Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods or their implementing measures.

- These substances are called dual use additives.
- To avoid the unauthorised presence of food additives or flavourings in food, specific requirements are set out for the migration of these substances from food contact materials. The substances shall not be released into foods in quantities which have a technological function in the food.
- To decide if a substance can be considered as a dual use additive, it is sufficient that the chemical identity of the paper and board additive matches that of an authorised food additive or flavouring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the paper and board.
- In the case of salts, it is the salt that matters, not the authorised acid, phenol or alcohol. Example: sodium acetate is a dual use additive (E262), but zinc acetate is not. The substance included in Union List of the Plastics Regulation is acetic acid. Note that sodium acetate is identified as E262, even if the purity does not match that of its use in food.



SECTION 9

Definitions

DEFINITIONS

The definitions in this section have been taken from a number of sources. Some have been taken from recognised standards and regulations and others have been specially written. In some cases there are alternative definitions which may apply in different contexts. The definitions shown in this section have been chosen to be relevant when used in the context of the scope of this Guideline and may not necessarily apply elsewhere.

TERM USED	DEFINITION
adhesive	non metallic substances capable of joining materials with surface bonding (adhesion) and the bond possessing adequate internal strength (cohesion)
blank	a shaped, flat piece of paper or board for use in a subsequent process e.g. folding/gluing into a frozen food box or milk carton
bleaching (of wood pulp/ fibres)	removal or modification, to a greater or lesser extent, of coloured components of pulp with a view to increasing its brightness
board	generic term applied to certain types of paper frequently characterised by their relative high rigidity. The primary distinction between paper and board is normally based upon thickness or grammage, though in some instances the distinction will be based on the characteristics and/or end use. For example, some materials of lower grammage, such as certain grades of folding boxboard and corrugated raw materials, are generally referred to as “board”, while other materials of higher grammage, such as certain grades of blotting paper, felt paper and drawing paper, are generally referred to as “paper”
business operator	any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing and distribution of materials and articles
bulk chemical	a chemical or substance which is supplied to an operator in large quantities and is then stored by that operator in a holding tank, warehouse or silo. Thus, a given batch of that chemical could be used in the manufacture of multiple product orders. Because the storage vessel may hold multiple deliveries of the chemical, it may not be possible to accurately correlate a particular delivery with a specific product order
calendering	passing a web of paper between metal or fibre rollers in order to produce a more smooth or glossy appearance
cellulose-based natural fibres	individual fibres, normally those present in wood pulp prior to papermaking
coating	a process of applying to the surface of paper or board one or more layers of a liquid suspension of pigment or other material in a fluid form. The purpose is to improve printability or other properties such as grease or water resistance
competent authorities	enforcement authorities, normally working for national or local governments, responsible for the enforcement (for the purposes of this document) of food contact legislation
converting	any operation, applied after the normal paper or board manufacturing process, which changes the physical shape or appearance of paper and board e.g. slitting, cutting into sheets, bag and box manufacture, printing, etc.
die cutting	cutting or stamping a sheet or web of paper or board with a shaped knife to produce a special shape or blank

TERM USED	DEFINITION
dispersion coating	a non-self-supporting layer composed of substances applied as liquid dispersion to an existing paper and board substrate in order to impart special properties or improve technical performance of the finished article. Such coatings are not capable of acting by itself as a main structural component of a final material or article. These can be inorganic coatings consisting of inorganic pigments together with a polymeric binder (pigment coating for improved print surface) or organic coatings consisting of resinous or polymeric preparations (to improve e.g. barriers properties)
distributor	any business operator who supplies final materials or articles as defined in this document to a business operator without having manufactured the product himself. If the business operator is selling to consumers, he has the role of a retailer instead. Depending on the country of origin of the products sold, the distributor may additionally have the role of importer
dual use substances	additives which are covered by Section 1.4.3 and which are also listed as food additives or flavourings in Regulations (EC) No 1333/2008 and (EC) No 1334/2008 and their implementing measures
extrusion coating	a self-supporting layer of plastic polymers which are melted and extruded onto an existing paper and board substrate
family approach	the collecting together of a group of products having similar properties and/or composition such that they can be regarded as one for the purposes of assessing compliance
final consumer	final consumer is not a business operator, but a private person buying food or food contact materials and articles, or the two combined as packaged foods, from a retailer or "user". The consumer should follow the instructions of use
final paper and board material or article	any paper and board material or article which is ready for the market without any further change. This can be: i. the finished paper and board food contact material or article (e.g. packaging material, storage containers for food, bulk food or food ingredients, tray, food preparation surface); ii. the paper and board layers inside a finished multi-material multi-layer; iii. finished paper and board components of the final food contact material or article which only need to be brought together or assembled, either during packing/filling or before, to make the final article
food contact materials and articles	materials and articles, which in their finished state: (a) are intended to be brought into contact with food; or (b) are already in contact with food and were intended for that purpose; or (c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use. (interpretation of art. 1.2 of the Framework Regulation
food simulant	a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials
functional additives	additives intended to stay in the paper and board in order to attribute specific properties
functional barrier	a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of the Framework Regulation.

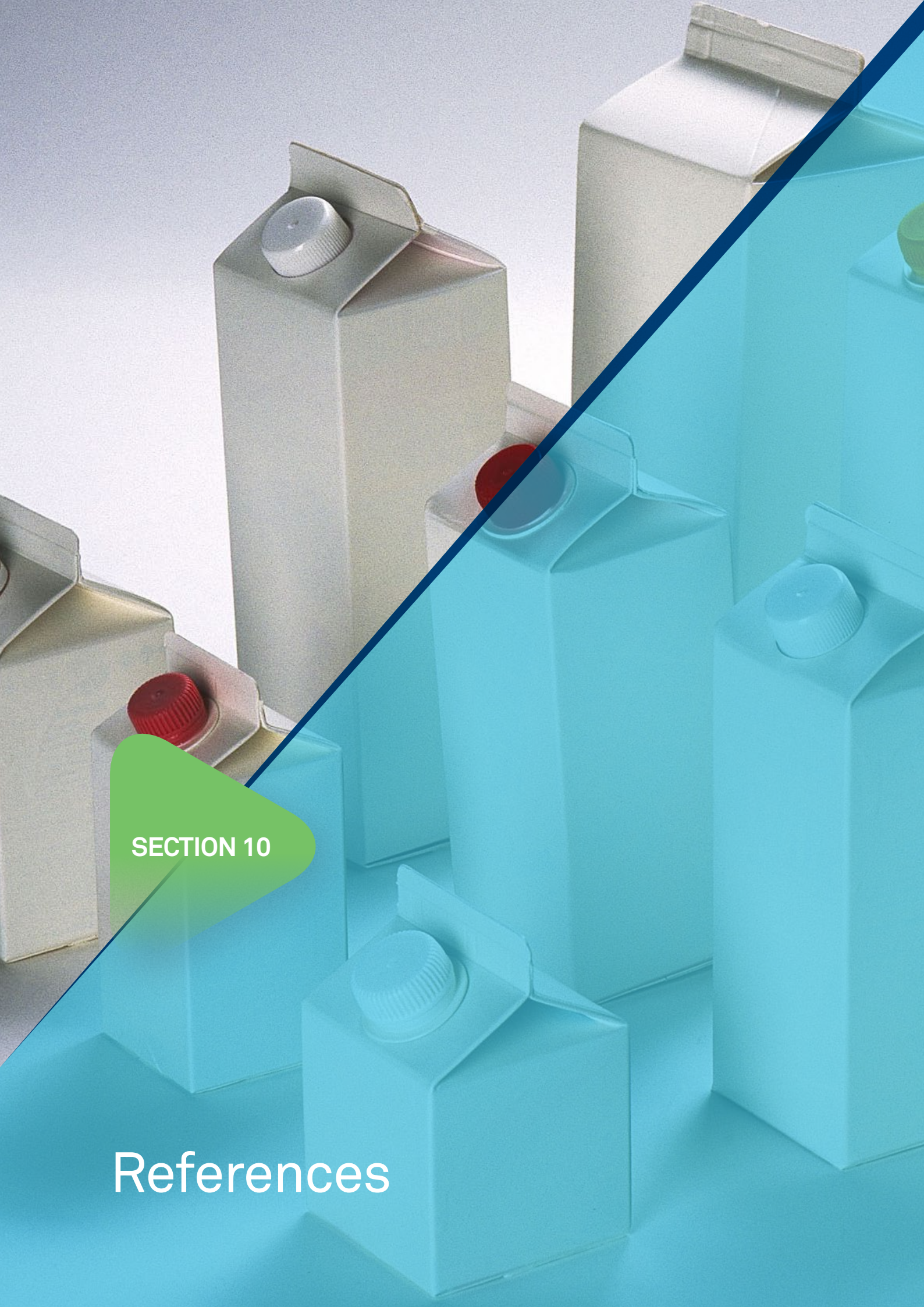
TERM USED	DEFINITION
Good Manufacturing Practice	those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure compliance with the rules applicable to them and with the quality standards appropriate to their intended use
grouped packaging	see secondary packaging
importer	any business operator who releases or intends to release into free circulation in the EU final materials or articles as defined in this document from countries or territories not forming part of the customs territory of the EU. Purchasing from a representative of the third-country seller located within the customs territory of the EU, is not importing; instead the representative would be the importer. Purchasing from a seller located in another country within the customs territory of the EU is not importing; instead the purchaser may have the role of a distributor or any other role, depending on his activities
intermediate paper and board material	any semi-finished paper and board material or article requiring further processing/re-formulation steps to become a "finished" material or article
lamination	the fixing of a ready-formed layer of plastic, paper, metal, etc. to paper or board, normally using an adhesive
man-made fibres	modified or regenerated fibres (e.g. acetate, viscose, etc.) obtained by extrusion of polymers from natural plant materials such as cellulose; synthetic or chemical fibres (e.g. polyester, polyamide, etc.) obtained by extrusion from polymers, usually from oil
migration	the transfer of chemical substances from food contact materials into food
mixture	means a mixture or solution composed of two or more substances (as defined under the REACH Regulation EC 1907/2006)
MPPO	modified polyphenylene oxide with IUPAC name Poly (2,6-diphenyl-p-phenylene oxide). Food simulant used to measure migration of chemicals from food contact materials and articles. It is often known by its trade name, Tenax®
multi-material multi-layer (MMML)	a material or article composed of two or more layers of different types of materials which are intentionally bound together and where one of the layers is paper. Constructions involving packaging applications, such as "bag-in-box" packaging or other combinations of primary and secondary packaging where the material layers are not intentionally bound together are not MMML
nanomaterial	a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%. By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials
non intentionally added substance	an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product
organoleptic	the aspects of food as experienced by the senses, including taste, sight, smell, and touch. The organoleptic characteristics of food are likely to be affected by adverse changes its physical, chemical or microbiological properties

TERM USED	DEFINITION
overall migration limit (OML)	the maximum permitted amount of non-volatile substances released from a material or article into or feed simulants
paper	generic term for a range of materials in the form of a coherent sheet or web, excluding sheets or laps of pulp as commonly understood for papermaking or dissolving purposes and non-woven products, made by deposition of vegetable, mineral, animal or man-made fibres, or their mixtures, from an aqueous suspension onto a suitable forming device, with or without the addition of other substances. Paper may be coated, impregnated or otherwise converted, during or after its manufacture, without necessarily losing its identity as paper
paper for recycling	natural fibre based paper and board collected and prepared to be suitable for recycling into recycled pulp which can be used for the manufacturing of new paper and board It consists of: paper and board in any shape products made predominantly from paper and board which may include other constituents that cannot be removed by dry sorting, such as coatings and laminates, spiral bindings, etc.
paperboard	see board
paper mill/manufacturer	a paper mill is a factory or plant location where various pulps in slurry form are mechanically treated, mixed with the proper dyes, additives, and chemicals, and converted into a sheet of paper by the processes of drainage, formation, and drying on a paper machine. Some paper mills also finish the paper in various ways
paper converter	processor of paper or board as a raw material (such as packaging, printing)
paper and board articles	articles produced predominantly from paper and board materials and additives used during the conversion process
paper and board materials	consists predominantly of cellulose fibre, naturally occurring minerals such as calcium carbonate and natural polymers such as starch
pigment	normally a powdered substance that is mixed with a liquid in which it is relatively insoluble and used to impart black or white or colour to paper or more commonly to coating materials
placing on the market	the holding of materials and articles for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves (art.3.1(b) of the Framework Regulation)
plastic	polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles
plastic materials and articles	food contact materials and articles which are manufactured wholly from plastic and, under the Framework Regulation, are covered by the Plastics Regulation
polymer	any macromolecular substance obtained by: (a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or (b) chemical modification of natural or man-made macromolecules; or (c) microbial fermentation

TERM USED	DEFINITION
polymeric binder	the film-forming element of a coating or adhesive. It provides adhesion to the substrate, normally paper or board, binds pigments and extenders together, and determines important properties of the coating such as durability, flexibility and gloss (see also polymer)
primary packaging	sales packaging or primary packaging, i.e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase
printing inks	printing inks are: (a) mixtures of colourants with other substances which are applied on materials to form a graphic or decorative design together with or without (b) other coloured or uncoloured overprint varnishes/coating, or primers which are normally applied in combination with (a) in order to enable the printed design to achieve specific functions such as ink adhesion or rub resistance, gloss, slip/friction, durability etc.
process chemicals	materials used to improve the efficiency of the papermaking process but not intended to stay in the paper and board, usually they are washed out during the papermaking process
pulp	see wood pulp
purity (of substances)	the degree to which chemicals, inks, adhesives and other substances, used in the manufacture of paper and board materials and articles, are free of background, non-functional components
purity (of materials and articles)	a measure of the degree to which intentionally added substances are in compliance with specified, maximum, qualitative limits or the extent to which non intentionally added substances are present in paper and board materials and articles
QM	maximum permitted residual content of a substance in the final material or article expressed as weight per weight concentration in the final material/ article
raw materials	the input to pulp and paper manufacturing include (raw) materials and chemicals as well as water, energy and labour. The basic (raw) materials to produce pulp and paper can be split into two parts: fibres – or fibrous materials – and non-fibrous materials. In the case of non-integrated paper and board mills, i.e. mills not producing their pulp, pulp can be considered as a raw material too. Fibres – or lignocellulosic fibrous materials – are derived from wood, non-wood fibre sources such as fibre crops (straw, bamboo, bagasse, etc.) or alternatively paper for recycling, through a recycling process. Today, wood and paper for recycling are the main fibre sources used in Europe. Non-fibrous materials are added to paper stock during the papermaking process in order to impart special characteristics to the final product. There are materials for sizing, loading and filling, colouring and other additives. Non-fibrous materials are therefore constituted by coating chemicals and some functional chemicals. Other functional chemicals and process chemicals have to be considered as well in order to have the full picture
restriction	limitation of use of a substance or migration limit or limit of content of the substance in the material or article
recycled paper & board	paper & board manufactured from recycled pulp
recycled pulp	pulp manufactured from paper for recycling and used for the manufacture of paper, paperboard and fibreboard. It excludes pulp made from straw; bamboo; bagasse; esparto; other reeds or grasses; cotton fibres; flax; hemp; rags; and other textile wastes

TERM USED	DEFINITION
retailer	any business operator selling final materials and articles as defined in this document (with or without food) to the final consumer only. Distribution terminals of supermarkets and wholesale outlets are also retailers
sales packaging	see primary packaging
secondary packaging	grouped packaging or secondary packaging, i.e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics
set-off	the phenomenon of the transfer of substances from the outer layer of materials and articles to the inner food contact layer through direct contact and not via diffusion through the material. Set-off may occur where there is a contact between the outside and inside of the material or article during, for example, storage and transport. Such direct contact may occur when materials are wound in reels or stacked in sheets or when articles such as trays, cups, etc. are nested inside each other. Unlike migration under these conditions, set-off may occur in both materials and articles with and without functional barrier
sizing	addition of materials either to the stock pulp (internal sizing) or to the surface of paper or board (surface sizing), in order to increase its resistance to the penetration and spreading of aqueous liquids, for example writing ink. Surface sizing may also be used to increase the surface strength of paper and board
sizing agent	materials used in papermaking to control the absorbency of paper with regards to liquids such as water or ink. Rosin, alum, starch and gelatine are the most commonly used materials for this purpose
slitting	the passing of a moving web of paper or board from a reel though knives resulting in the production of a number of reels of smaller width and/or diameter
specific migration limit (SML)	the maximum permitted amount of a given substance released from a material or article into food or food simulants
specification	composition of a substance, purity criteria for a substance, physico-chemical characteristics of a substance, details concerning the manufacturing process of a substance or further information concerning the expression of migration limits
substance	means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition; (as defined under the REACH Regulation EC 1907/2006)
supply chain operators	any business operator involved in the production of paper and board from pulp through to the final material or article; includes also organisations supplying raw materials to these business operators
tertiary packaging	transport packaging or tertiary packaging, i.e. packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packaging in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers
tissue paper	lightweight paper (typically between 10 g/m² and 50 g/m²) made of virgin and/or recovered pulp (bleached/unbleached) that may be dry, wet creped or non-creped

TERM USED	DEFINITION
tissue products	converted products made of tissue paper in one or several plies, folded or unfolded, embossed or un-embossed, with or without lamination, printed or not printed and possibly finished by post-treatment. They are intended for end user purposes; examples are toilet paper, paper towels, napkins, facials
total specific migration limit (SML(T))	the maximum permitted sum of particular substances released in food or food simulants expressed as the total of the moiety of the substances indicated
traceability	the ability to trace and follow a material or article through all stages of manufacture, processing and distribution (art. 2.1(a) of the Framework Regulation)
transport packaging	see tertiary packaging
treatment agents	substances added to paper and board materials and articles to modify their properties
unbleached wood pulp/fibres	pulp that has not been subjected to any treatment which is intended primarily to increase its brightness (see also bleaching)
Union List	a list that includes the substances that are authorised at EU level for being intentionally used for the manufacture of food contact materials and articles
untreated paper and board	paper and board which has received no treatment operations after coming off the paper machine
usage rate	the amount of a chemical substance or chemicals mixture that is added to paper and board materials and articles during the manufacturing process
user	any business operator or person who puts food or food ingredients/ intermediates in contact with a final material or article as defined in this document. This includes the food industry and their ingredient suppliers, retailers with an additional role of user, and food vendors (catering, restaurants, canteens, baker/butcher stores and other food outlets). Users of food contact materials who sell food to consumers have an additional role as “retailers”
waxed paper	paper coated or treated with wax to make it resistant to water and grease and then used as a food wrapping
web	a continuous length of paper or board travelling along a paper machine, a corrugator or through converting equipment
wood pulp	fibrous material prepared from pulpwood, wood chips or residues by mechanical and/or chemical process for further manufacture into paper, paperboard, fibreboard or other cellulose products. It is an aggregate comprising mechanical wood pulp; semi-chemical wood pulp; chemical wood pulp; and dissolving wood pulp



SECTION 10

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NOTES

MARCH 2019

THE ALLIANCE FOR BEVERAGE CARTONS AND THE ENVIRONMENT

CCB
Cepi ContainerBoard

cepi

ditpa

ETS

EUROPEAN CARTON MAKERS ASSOCIATION

FEFCO
Corrugated Packaging