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GOOD MANUFACTURING PRACTICE GUIDELINE

FOR THE MANUFACTURE OF PAPER AND BOARD FOR FOOD CONTACT

DISCLAIMER

The contents of this document are advisory and not legally binding.
It is ultimately the responsibility of each company to ensure compliance with the applicable rules and this Guideline is intended to help the paper and board industry to demonstrate such a compliance. Implementation of this Guideline as well as deviations from the latter nevertheless remain the responsibility and discretion of companies that are called to substantiate them.

This Guideline has been reviewed by the Keller and Heckman's Brussels office.
This company is an internationally renowned law firm with notably specific expertise in food and food packaging.

GOOD MANUFACTURING PRACTICE GUIDELINE

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Edition 2 - May 2023

This document is the first update to the Cepi GMP (Good Manufacturing Practice) guidance published in 2010 and benefits from the paper and board industry experience with GMP systems since that time and from the input of an internal food contact expert group.

It is intended to provide a road map for paper and board manufacturers for the implementation of a good manufacturing system for food contact materials and articles and as guidance for those who need to audit such systems. It should be read in conjunction with the Food Contact Guidelines for the Compliance of Paper & Board Materials and Articles[1], hereinafter referred to as Food Contact Guidelines, that has been recently published by the paper and board manufacturing industry, together with converting sectors including the tissue industry.

The document contains details of those concepts and methodologies required to ensure compliance with Commission Regulation (EC) No 2023/2006 as amended on good manufacturing practice for materials and articles intended to come into contact with food[2] (hereinafter referred to as the GMP Regulation). In addition, it covers the implementation of risk assessment within the GMP quality assurance system (not specifically dealt with in the GMP Regulation) which is an essential part of achieving effective GMP.

1. Food Contact Guidelines for the Compliance of Paper & Board Materials and Articles https://www.cepi.org/wp-content/uploads/2020/09/Food-Contact-Guidelines_2019.pdf
2. Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food – 22 December, 2006 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006R2023 3

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1. INTRODUCTION

It is a requirement of the Commission Regulation (EC) No 1935/2004[3], on materials and articles intended to come into contact with food (hereinafter referred to as the Framework Regulation), that all materials and articles intended for food contact "*shall be manufactured in accordance with Good Manufacturing Practice*" (GMP). The rules (components and principles) of such a GMP are described in the Regulation (EC) No 2023/20063 on good manufacturing practice for materials and articles intended to come into contact with food (hereinafter referred 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 advice on its implementation in each manufacturing sector. This paper and board Guideline provides advice for implementation for the paper and board manufacturing industry of a GMP system which is compliant with that Regulation.

In accordance with the definition of GMP given in Section 3, this Guideline does not contain details of manufacturing limits and quality standards which are normally part of national legislation, customer specifications and other relevant guidelines and recommendations for food contact paper and board.

The GMP Regulation provides a legal basis for GMP for the production of materials and articles in contact with food under the Framework Regulation. This Cepi GMP Guideline has been developed to provide specific details for the paper industry and uses section names and terms which are aligned with those used in the relevant legislation and are considered likely to be familiar to the paper industry. In order to ensure that all are fully aware of how this Cepi GMP Guideline links/provides information to ensure compliance with the legislation, a cross reference table (see Annex 3) showing how the different sections of the Regulation relate to sections in this Guideline is provided.

In addition to specific sections related to the GMP Regulation, this Cepi GMP Guideline together with the Food Contact Guidelines provides information on specific requirements set out in the Framework Regulation on Labelling, declaration of compliance and traceability. This is to ensure compliance with the Framework Regulation and appropriate information exchange between business parties along the food chain.

It should be noted that the GMP Regulation states that the GMP Quality Assurance System "*shall be applied taking account of the size of the business run by the operator, so as not to be an excessive burden on the business*" (article 5.1.b). Thus, the complexity and scope of the GMP system may be reduced to ensure it is appropriate for less complex businesses such as the ones of the small and medium-sized enterprises (SMEs).

2. SCOPE

This GMP guideline is intended to provide guidance on how to fulfil the requirements of the GMP Regulation in the manufacturing of paper and board intended to come into contact with food and the manufacturing of tissue paper intended for food contact. It does not cover the downstream operations outside the responsibility of the paper and board manufacturer.

The contents of this document assume that paper and board manufacturers have a documented quality management system based on the principles of a recognised system, such as ISO 9001[4] quality management system, or equivalent, in place. It has to be noted that the GMP Regulation does not require the obligatory adoption of that ISO standard, nor the certification of the system. Furthermore it is relevant to note that compliance with ISO 9001 in itself is not sufficient to claim compliance with the GMP Regulation; nevertheless, its adoption is strongly recommended.

The document applies to the manufacturing of paper and board (as stated in the definitions) intended for contact with all types of foodstuff and conditions for its use.

The document covers the entire production process as outlined in Annex 1. Any exemptions of applicability should be defined and confirmed by the risk assessment process. Any measure relevant to the implementation and maintenance of an effective GMP system should be derived from the risk assessment process and should take into account the intended use of the paper and board.

3. Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food – 27 October, 2004
4. ISO 9001 Quality management systems – Requirements

This document contains two main, operational parts. Firstly, Sections 4 - 7 describing the basic requirements of the GMP Regulation as well as some of the Framework Regulation and how they are to be interpreted and applied during paper production. Secondly, Section 8 contains a list of detailed actions which interpret these requirements for adoption within the paper and board manufacturing area to achieve compliance with the GMP Regulation. The latter is in the form of an indicative checklist for auditing purposes.

As the situation may be different in paper mills depending on the starting materials, the paper produced, the size of the manufacturing facility, the actual end use of the paper, etc., their various needs to fulfil the GMP Regulation may be different. Consequently, not all the measures described in Section 8 may be needed or exhaustive and advice on the different measures is given.

3. DEFINITIONS APPLIED IN THE CONTEXT OF THIS GMP GUIDELINE

Table 1 - Definitions

Dosing equipment	Equipment which automatically controls the addition of e.g. liquids or solids to the papermaking process.
Good Manufacturing Practice	Good Manufacturing Practice means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof.
Hazard	A biological (at macro or micro level), chemical (including allergens) or physical agent in food contact materials or a condition of use of food contact materials with the potential to cause an effect in the food leading to adverse health effects.
Hazard Inventory	Identification and documentation of all potential hazards in the paper and board making process which might affect the product, i.e. a list of hazards and where in the process they can potentially be present.
Hygiene	Conditions and practices affecting humans, machinery and premises involved in the production of paper and board for food contact that help to maintain health and prevent the spread of diseases. These could include, for instance, disease, bacteria, dirt, pests, insects, etc.
Management System	A set of interrelated or indicating elements of an organisation to establish policies and objectives and processes to achieve those objectives. A management system is the way in which an organisation manages the interrelated parts of its business to achieve its objectives.
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 to its physical, chemical or biological properties.
Paper and board for food contact	Paper and board food contact materials are made predominantly from cellulose-based virgin and/or recycled fibres and may also contain a range of different additives to suit the end application. Paper and board for food contact covers a wide range of applications. Examples include filtering and baking applications, tissue papers, uncoated and coated paper and board, carton and corrugated board.

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 of any shape • products made predominantly from paper and board which may include other constituents that cannot be removed by dry sorting, such as coating and laminates, spiral bindings, etc.
Quality Assurance System	The total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.
Quality Control System	Systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system.
Risk	The outcome of the risk assessment, i.e. the result of the probability of an adverse health effect and the severity of its outcome on human health consequential to a hazard(s), if occurring. The extent to which a specific hazard is likely to adversely affect the safe use of paper and board in food contact applications, i.e. the potential exposure of the consumers to food safety risks posed by the supplied paper and board product.
Risk analysis	The process consisting of three interconnected components: risk assessment, risk management and risk communication.
Risk assessment	A scientifically-based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. In practice, it is the process of analysing the identified hazards (i.e. the hazard inventory), taking into account the severity of the hazard and the possibility of it occurring. During this stage, each potential hazard is evaluated based on the severity, i.e. the human health impact of the potential hazard and its likely occurrence and exposure to the consumers. The likelihood of occurrence should consider the possibility of the hazard being present in the supplied paper and board product thus potentially reaching consumers and affecting human health. The significance of identified risks could vary between different facilities as well as between different steps or locations within an operation/ facility depending on the product type, end use application or differences in equipment, maintenance programs etc.
Risk management	The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options. In practice, it consists in the formulation and implementation of a series of appropriate and necessary controls and measures during the manufacturing of paper and board to prevent the occurrence of a hazard or reduce its intensity in the paper and board in order to eliminate or reduce the effect of that hazard in the final food contact application.

Starting materials	The basic raw materials to produce pulp, paper and board can be split into two parts: fibres – or fibrous materials – and non-fibrous materials. Fibres • Natural fibres/fibrous materials from wood and non-wood fibre sources such as fibre crops (straw, bamboo, bagasse, etc.) or alternatively from paper for recycling through a recycling process. • Man-made fibres from polymers derived from crude oil or natural sources. Non-fibrous materials • *Functional additives* are added to paper stock during the papermaking process in order to impart special characteristics and are intended to stay in the final paper and board, e.g. sizing, filling and colouring additives. • *Process chemicals* (such as biocides, defoamers, etc) are chemicals used to improve the efficiency of the papermaking process but are not intended to be retained in the paper and board at the end of the production process.
Stock preparation	The addition of water to wood pulp and/or paper for recycling and subsequent homogenisation and cleaning operations prior to processing on the paper machine. Non fibrous materials are also added in this phase.
Subcontractors	External enterprises contracted to carry out certain work or services that may have an impact on the quality or safety of the product on- or off-site, for example, maintenance, transport, cleaning, sheeting, logistic operations, pest control, etc.
Suppliers	Upstream suppliers of starting materials.

4. IMPLEMENTATION OF A QUALITY ASSURANCE SYSTEM

A documented management system, based on the principles of a recognised quality management system, such as ISO 9001 or equivalent, forms the underlying basis for the procedures and instructions related to the GMP Regulation and the specific requirements for food contact materials. Many paper and board manufacturers have integrated management systems in place which contain a number of necessary procedures, instructions, routines and documents designed to achieve objectives of quality, hygiene, environment, health and safety, energy, etc. The level of complexity of a system depends on the size of an organisation and elements of the management system. The mill management system should be revised and amended to ensure that quality assurance and quality control aspects related to food contact applications are included in an appropriate way.

The requirements for paper and board for food contact applications are governed by the demands of the final application and aim to ensure suitable safety and quality for the intended use. This implies that the paper and board should be manufactured to an agreed quality standard, including the requirements in the Framework Regulation, GMP Regulation, Food Contact Guidelines and other relevant guidelines and recommendations for food contact.

Food and hygiene safety management standards[5][6][7][8] may also be used to demonstrate compliance with the GMP requirements. In this case it shall be ensured that the management system covers the GMP requirements. Section 8 of this GMP Guideline can be used as a check list. All GFSI (Global Food Safety Initiative) recognised standards and programmes for production of food packaging include the components needed to comply with the GMP requirements.

For areas of the management system which are generic and not specifically related to food contact (internal audits, complaint handling, document control, etc.) the existing

5. ISO 22000-4 Food Safety Management Systems – Requirements for any organisation in the food chain
6. ISO/TS 22002-4 Prerequisite programmes on food safety – Part 4: Food packaging manufacturing
7. EN 15593 Packaging. Management of the hygiene in the production of packaging for foodstuffs. Requirements
8. GFSI (Global Food Safety Initiative) recognised programmes for production of food packaging
   8.1 FSSC 22000 Food Safety System
   8.2 BRCGS Global Standard for Packaging Materials
   8.3 SQF Food Safety Code for Manufacture of Food Packaging
   8.4 IFS International Featured Standards; Food & Packaging Guideline

procedures in the company management system may be used. Therefore this Guideline does not address them.

4.1. Management Responsibility and Organisation

Management has the ultimate responsibility for the GMP system and should take steps to ensure that it is fully integrated into the management system. Management should ensure that correct systems are set up, maintained, reviewed and documented, with an adequate resources allocation. Management should ensure conformity of the manufacturing operations to pre-established and documented instructions and procedures supporting the GMP system. It should also ensure compliance of the paper and board with the rules applicable to them.

4.2. Adequacy, knowledge and skills of personnel. Training

Clear communication with all relevant personnel about GMP requirements is vital to ensure that the correct processes and procedures are properly understood and allow effective implementation and maintenance of the system.

Knowledge, skills and effective training of all mill personnel, including the food safety/hygiene team, are key factors in effective implementation and maintenance of the GMP system. Different levels of training can be established, appropriate to different roles in the organisation. Dedicated procedures, plans, records and training tools should be prepared. As a follow up to initial knowledge and skills training, regular refresher training is a key requirement. Annual frequency is a recommended practice.

Tools for informing visitors and subcontractors of their responsibilities, such as leaflets and contractual agreements should be prepared. Subcontracted operations may play an important role in the GMP system and could have a significant impact on the compliance of the paper and board and should therefore be managed under GMP.

4.3. Risk Analysis – Risk Assessment – Risk Management – Risk Communication

4.3.1 Risk Analysis

The foundation of a GMP system is the application of risk analysis principles. i.g. risk assessment, risk management and risk communication.

The starting point for implementing GMP is the performance of a specific risk assessment which then forms the basis for developing correct risk management practices and risk communication for a specific product and manufacturing process.

4.3.2 Risk Assessment

Risk assessment is a tool to ensure that all risks occurring during paper and board manufacture affecting the use of paper and board as food contact material are identified and that appropriate control measures and monitoring processes are established. Risk assessment should include, as a minimum, the conditions of the mill and the intended end use application for the paper and board.
Risk assessment should cover the entire production process, which is under the responsibility of the business operator, namely the paper and board manufacturer, from the procurement of starting materials to the shipping of the paper and board. Risk assessment should also cover subcontracted operations that could have an influence on the food safety of the paper and board.

According to Regulation 78/2002[9] the risk assessment consists of four main elements: hazard identification, hazard characterisation, exposure assessment and risk characterisation. These are described below.

a. An inventory is needed of all possible hazards along the production process which may, if were to occur, affect the safety of the supplied paper and board (the hazard **identification**). It should cover the physical, chemical (including food allergens) and biological hazards that may be caused by starting materials, production processes or storage and transportation, including subcontracted processes and services.
b. As a next step, each of those hazards is subjected to a hazard **characterisation** which is the evaluation of the nature and severity of the adverse health effects associated with the identified hazard which may be present in food as a consequence of having been in contact with the paper and board.
c. Then, the **exposure assessment** is performed. This is the evaluation of the likelihood of a hazard being present in the finished food contact material and/or article as a result of its occurrence during the manufacturing process.
d. Finally, the **risk characterisation** is made by combining the likelihood as described in the preceding paragraph with the severity of an adverse occurrence to which the consumer may be exposed.

The location of the hazard within the production process is important in determining the potential impact on the consumer. In general, the severity of the risk increases from the beginning to the end of the production process and the potential exposure to hazards located at the beginning of the production process may be reduced by subsequent processes further down the manufacturing steps. This needs consideration as part of the risk assessment. Another factor in the risk assessment is the end use of the paper and board.

9. Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety – 27 January, 2002 - https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178

For instance, the consumer exposure to a hazard is likely to be higher in case of direct or prolonged contact compared to indirect or short contact. An example of a methodology to perform a risk assessment is found in Annex 2.

4.3.3 Risk Management

Risk management involves formulation and implementation of a series of appropriate controls and measures necessary to reduce or prevent the occurrence of potential risks to food safety from the paper and board when used in the intended food contact application.

Measures should be put in place within the mill to ensure all potential risks resulting from the risk assessment are kept at the lowest possible level. A control system needs to be in place which includes the monitoring of measures needed to ensure the safety of the product according to the risk assessment. The frequency of operating those measures should be set according to the defined risk.

The risk assessment and the risk management systems should be regularly verified in order to maintain their effectiveness. A frequency of once per year is recommended.

4.3.4 Risk communication

Risk communication is the exchange of information during the risk analysis. The sharing of information along the value chain is two-directional and includes, as an example, relevant information for the risk assessment, new scientific evidence, findings of the risk assessment and measures of the risk management. Risk communication, therefore, may involve many different actors of the value chain, depending on the specific phase of the risk analysis and the kind of shared information, such as supplier, clients, consumers, employees, authorities and other stakeholders.

4.4. Organisation of the premises and equipment - hygiene and good housekeeping

An adequate organisation of the premises and equipment should be designed in order to ensure that finished materials and articles comply with the rules applicable to their use in contact with foods. If paper for recycling is used in the production of paper and board for food contact applications, the operation of paper mills using paper for recycling should conform to the Cepi Guidelines for Responsible Sourcing and Supply of Recovered Paper[10] (hereinafter referred to as the Guidelines for Responsible Sourcing).

The mill should establish appropriate rules for the hygiene of the premises, good housekeeping and cleaning of production facilities, internal storage and distribution areas. These rules should be based on the outcome of the risk assessment. The rules should be proportionate and aimed principally at those areas directly involved in the production of food contact material. As an example, it is likely that the risk assessment will bring to light that certain areas, e.g. offices facilities, may need less strict controls.

4.5. Personal hygiene

The mill should establish appropriate rules for personal hygiene for all areas and personnel on the site based on the outcome of the risk assessment. This also includes subcontractors onsite. An indicative checklist for personal hygiene control elements for a GMP system is provided in the relevant section of Table 2.

Due to the number of different mill departments involved either directly in the manufacturing process or as service functions to the manufacturing process areas, it is likely that the level of personal hygiene requirements needed to ensure product safety will vary significantly within a site. The strictest controls will be necessary in areas where there is direct contact and handling of the paper and board. However, the risk assessment would be expected to show that less stringent personal hygiene controls will provide good control in other areas.

4.6. Suppliers and Subcontractors

The components which form the input to pulp, paper and board manufacturing processes include fibres/fibrous materials, functional additives and process chemicals (starting materials) as well as water, energy and labour.

All suppliers should be carefully selected. The written procedures for the approval and monitoring of suppliers and subcontractors, described in the management system, should be extended to cover the demands in the Framework Regulation and the GMP Regulation.

The selection of the suppliers of starting materials should be carried out according to specific documented procedures. The suppliers should ensure the compliance of their products with agreed specifications and with the rules on food contact use applicable to them. This could be done, for instance, by releasing a declaration of compliance or equivalent confirming their suitability and possible usage limitations for food contact applications according to the positive lists in recognised national legislations.

If paper for recycling is used in the production of paper and board for food contact applications, they should come from the qualified suppliers. Documentary evidence from those suppliers regarding the compliance of their supplies with the Guidelines for Responsible Sourcing is required and kept. The requirement for this compliance should be included in the contractual arrangements.

All starting materials used in the manufacture of paper and board for food contact applications should be of a suitable purity for the intended purpose.

10. Cepi Guidelines for Responsible Sourcing and Supply of Recovered Paper
https://www.cepi.org/guidelines-for-responsible-sourcing-and-supply-of-recovered-paper/

Specifications should be set for all of them and a notification from the supplier is needed in case of a change of formulation. All documents relevant to the selection of the suppliers and the starting materials should be updated (once per year is recommended) or modified to coincide immediately with any changes made to the product, legal requirements or relevant scientific findings.

Documented instructions for suppliers and subcontractors working on the premises of the paper and board manufacturer should exist in order to ensure the defined GMP rules are followed. The mill should ensure that suppliers and subcontractors work according to these requirements. Documented requirements should also be prepared for warehouses, transport facilities and other externally subcontracted processes (such as rewinding or cutting), which are not under the direct control of the paper mill, but which handle and/or could affect the quality and safety of the food contact paper and board.

4.7. Conformity to pre-established instructions and procedures

For the management of the GMP system, it is necessary that documented instructions and procedures are prepared and implemented as required by the GMP Regulation. These should cover all the operations and it is fundamental that they are derived from the risk assessment results. All the instructions and procedures should be available in a "GMP Manual", and/or in the quality management system.

4.8. Storage, shipment, transport and delivery

Documented instructions and procedures should be prepared and implemented for storage, shipment and transport operations, including such operations which may not be under the direct control of the site, such as warehouses and transports. They should define the operations required for the correct management of the storage facilities, defining the different phases of identification, handling, packaging, storage of the starting materials, the semi-finished and the final products as well as those relevant to shipment and transport to the customers. Their purpose is to guarantee the correct management of these phases and prevent possible contamination that could lead to the product being unsuitable for its intended use or even unsafe.

The same level of instruction and procedures should also be prepared for warehouse and transport facilities, which are not under the direct control of the site.

5. IMPLEMENTATION OF A QUALITY CONTROL SYSTEM

An effective mill quality control system should be established further to a risk assessment to ensure the quality of the mill's product conforms to relevant, pre-established specifications.

The quality control system should cover the production controls in any relevant steps in the process and the quality controls of finished products. It should make it possible to intervene in the production process in the event that conditions causing a failure to comply with the product specifications can be resolved quickly.

5.1. Quality controls along the process – Control and testing of finished products

Documented instructions and procedures should be prepared and implemented for controls of all phases of the production process, from starting materials' deliveries, to finished products and storage. A non-exhaustive list of controls may include the quality of starting materials at their arrival and their storage conditions and compliance with the recipes including dosing equipment and dosage of starting materials, process parameters, testing of the semi-finished and finished products, storage conditions and conditions of the means of transport.

This should also cover the tests required for semi-finished and finished products and the testing frequency for compliance with the requirements of the regulations. Also included should be checks to ensure any legislative changes, specifications and contractual agreements with suppliers and customers are adopted.

Referring to the starting materials' compliance documents and the regulatory and customer specifications, chemical testing should be performed at a frequency which relates to the likelihood of a particular restriction being exceeded (a review every 12 months is recommended and in any case when the process or composition changes or new scientific/technical knowledge becomes available). However, if, for instance, it can be shown from calculations (worst case calculations, migration modelling), from a knowledge of the constituents, or from other information giving conclusive evidence, that a particular substance could never exceed its restriction in the supplied paper and board products, then the facts should be documented, and testing would not be required. Relevant information should be part of the declaration of compliance communicated to the next level of the value chain.

5.2. Monitoring of GMP implementation and effectiveness achievement – auditing and management of changes

The quality control system should include activities to check the implementation and achievement of the GMP. In this context, auditing of the GMP system to verify conformity with procedures and processes to ensure compliance of the paper and board is important in effective maintenance of the GMP system. It is recommended to use the existing procedures of the Quality Management System also for internal audits of the GMP system. Regular internal and external audits are recommended to verify that quality assurance and control systems conform to legal, customer and other interest parties' requirements and are effectively implemented and maintained.

The quality control system should have clear instructions and practices in place how to deal with nonconforming products, identify and eliminate the cause of nonconformity and prevent recurrence.

In line with best quality management practice, procedures for effective change management should be in place, ensuring that any planned changes are accompanied with a risk assessment before the change is implemented. From this new risk assessment a decision should be made on the necessity, or not, to amend the risk management processes and procedures to address the outcome of the revised risk assessment. The output of this risk assessment review and any change to the risk management controls should be documented and implemented in the appropriate instructions and documentation. Any changes to procedures should be effectively communicated and relevant staff trained as appropriate.

6. DOCUMENTATION

There should be an appropriate documentation system in place to demonstrate the conformity of the mill's GMP system to the requirements of the GMP Regulation.

Efficient documentation is important. Whilst it is not necessary to continuously produce and maintain a complete dossier of all information, paper and board manufacturers should be able to compile the relevant information, on demand and within a reasonable timeframe, for the competent authorities. Paper and board companies will decide on the period for which documentation should be retained according to local requirements. Factors such as the period during which the paper and board is stored within the supply chain and the expected shelf life of the intended food which is packed should be part of the decision. It is considered that a retention period of two years is recommendable.

7. LABELLING, DECLARATION OF COMPLIANCE AND TRACEABILITY

7.1. Introduction

The rules covered in Sections 7.2 to 7.4 are not laid down in the GMP Regulation but are part of the Framework Regulation (respectively, Articles 15, 16 and 17). They have been inserted in this GMP guideline to provide additional helpful information as they are usually part of the quality management system These aspects are dealt with in a more exhaustive way in the Food Contact Guidelines.

7.2. Labelling

Labelling supports users in the correct use of the materials and articles. Methods used for such labelling may vary according to the user and are explained in Article 15 of the Framework Regulation which requires materials and articles destined for food contact applications to be accompanied along the supply chain by labelling and/or documentation which indicates its suitability for that use. For more guidance, please refer to the relevant chapter of the Food Contact Guidelines.

7.3. Declaration of compliance

Authorities, customers and certification bodies may require information about the GMP process and how the compliance status of the supplied paper and board is ensured.

Declaration of compliance documents which are in line with applicable legal requirements and that of the Food Contact Guidelines are a key method of providing communication about a food contact material to downstream business operators. In this sense they are important parts of **risk communication**. These documents need to be updated as new, relevant information becomes available, particularly due to a modification in scientific knowledge, regulatory guidance or best practice recommendations. For more guidance, please refer to the relevant chapter of the Food Contact Guidelines where instructions on how to manage the relevant supporting documentation and content of the declaration of compliance can be found.

7.4. Traceability

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 any defects. Traceability needs to be ensured from the paper and board mills through to the final packaging or article either in the form of identification/labelling on the product itself or contained in the accompanying documentation.

Traceability guidelines for paper and board materials are described in more detail in the Food Contact Guidelines.

For product recall, the adopted procedure should be described in the management system and tested regularly. This Cepi GMP Guideline covers paper, board and tissue production as well as starting materials which are used in the manufacturing process of food contact materials. Therefore, paper mills should be able to trace starting materials through the process up to the dispatch of goods. This means one step upstream and to the next step in the value chain.

8. DETAILED REQUIREMENTS FOR COMPLIANCE WITH THE GMP REGULATION – INDICATIVE CHECKLIST FOR AUDITING PURPOSES

The following table (Table 2) contains elements of a GMP system which apply to the manufacture of paper and board for food contact. However, there is wide diversity within the industry, e.g. manufacturing plant, production techniques and size of the business. The food contact uses of the paper and board material and articles cover a large range from high-risk applications such as hot filtration and baking papers or contact with moist and/or fatty foods to packaging which may be separated from the food by several layers of other materials. Consequently, not all mills need to implement all items in the table as some may be inappropriate and unnecessary for a particular business, while for other mills the list may be too limited. The risk assessment will define the list of those that are needed. The table can thus be regarded as an Indicative (and not exhaustive) checklist which paper and board manufacturers may consider when implementing a GMP system as well as for auditing purposes. If a decision is made that a particular item in the table is not included in the GMP system, the reasoning should be documented.

Table 2 - Indicative Checklist for Elements of the GMP System

Component of the GMP System	Section of the GMP Guidelines	Comments
Implementation of a Quality Management System		
ISO 9001 or equivalent quality management system should be implemented.	4.	
Quality policy should include aspects specific to food contact.	4.	
Management Responsibility and Organisation		
Management should show leadership and commitment to GMP systems and ensure conformity of the operations and supplied paper and board to the relevant requirements.	4.1	
A food/product safety/hygiene team and/or a designated person for GMP implementation and maintenance should be appointed.	4.1	The requirement should be proportional to the size of the business.
Adequacy, knowledge, and skills of personnel. Training		
New and existing personnel including subcontractors should be trained on GMP requirements and hygiene aspects specific to the food contact material.	4.2	Needs to apply only to personnel working in areas where the food contact material could be affected. Informal briefings may suffice in circumstances where the risk is low.
Training records should be maintained for all personnel that have been trained.	4.2	
There should be clear internal communication with all appropriate staff and personnel about the GMP requirements and any relevant changes to the GMP practices.	4.2/5.2	
Risk Analysis, Risk Assessment, Risk Management		
Risk assessment (see Annex 2) should be performed an annual review is required.	4.3	Implication of changes likely to affect product safety should be reviewed on an ongoing basis .
For the risk management there should be a plan and implemented controls and measures to manage the observed risks in order to maintain the necessary level of safety and compliance with legal and customer requirements.	4.3	

Organisation of the premises and equipment – Hygiene and housekeeping		
All premises, such as personal working spaces and lockers, toilet areas and other amenity areas used by personnel should be kept clean and tidy in accordance with a pre-determined schedule and the site risk assessment.	4.4	
Buildings, machinery, conveyors, transport devices, etc. should be cleaned regularly using a pre-determined schedule. Cleaning equipment and materials should be selected, used and stored in such a way that the food contact material is not adversely affected.	4.4	Less strict rules for certain areas may be appropriate depending on the risk assessment
Regular maintenance and inspection of the integrity of buildings, production environment and equipment for hygiene purposes should form part of the management system.	4.4	This requirement may not be applicable or less strict rules for certain areas may be appropriate depending on the risk assessment.
Engineering, maintenance and technical equipment together with any necessary temporary repairs used for specific, short-term tasks close to the production facilities should be removed when the task is complete. Deviations to this procedure should be addressed to the person who has responsibility for the GMP system.	4.4	Applies only to the production areas where impact on product quality may occur.
Lighting equipment, glass and hard plastic materials should be shatterproof.	4.4	Applies only in areas where the risk assessment has shown that debris from breakages could enter the food contact material.
All unnecessary and unprotected glass and clear hard plastic should be removed from production and storage areas.	4.4	Applies only in areas where the risk assessment has shown that debris from breakages could enter the food contact material.
Hand knives used in production areas should be of an authorised type. Snap-off blades are specifically prohibited.	4.4	Applies only in areas where the risk assessment has shown that debris from blades could enter the food contact material.
In the event of the breakage of glass, hard plastic, knives, etc., a procedure should be implemented to ensure that the food contact material being produced at the time of the incident is free of such debris.	4.4	This will require liaison between affected departments in the paper mill and may require the affected material to be destroyed.
A documented pest control system should be in place. Execution of the system should be by specialist subcontractors or personnel trained in the necessary techniques. There should be a recognised system for taking action where evidence of pests is noted.	4.4	The system should ensure that pests cannot adversely affect the food contact material or its starting materials.

Doors and windows in the production area should be screened or closed to prevent pest ingress.	4.4	
The operation of paper mills using paper for recycling should conform to the Cepi Guidelines for Responsible Sourcing.	4.4	
Personal Hygiene		
Personnel should clean their hands after using the toilet and any other activity that could compromise hygiene (e.g. eating, smoking, etc.).	4.5	
Clean working clothes and working shoes should be worn in the production and storage areas.	4.5	
It is not permitted to wear any loose items such as jewellery, watches, etc.	4.5	This requirement may be not applicable or less strict rules for certain areas may be appropriate depending on the risk assessment.
Open wounds should be covered with plasters having a deep, distinctive colour. If any subsequent processing equipment has a metal detection system, the plasters should be metal detectable.	4.5	This requirement may be not applicable or less strict rules for certain areas may be appropriate depending on the risk assessment.
Personal belongings (such as coats, mobile phones, back packs, etc.) should not be stored in the production and storage areas.	4.5	This requirement may be not applicable or less strict rules for certain areas may be appropriate depending on the risk assessment.
Working clothes should be selected with the safety of both the employee and the produced material in mind. There should be rules in place for cleaning and repair of these clothes.	4.5	This requirement may be not applicable or less strict rules for certain areas may be appropriate depending on the risk assessment.
Employees suffering from notifiable diseases likely to be transmitted through the food contact material should be excluded from the workplace.	4.5	This requirement may be not applicable or less strict rules for certain areas may be appropriate depending on the risk assessment. Return to work procedures are important.
Eating, drinking, sweets, chewing gum and smoking are not allowed in the production and storage areas. Drinking of water may be allowed in circumstances where a risk assessment has shown it to be safe.	4.5	Eating and drinking may be allowed in designated areas.
There should be clear rules regarding personal hygiene for all visitors and subcontractors.	4.5	

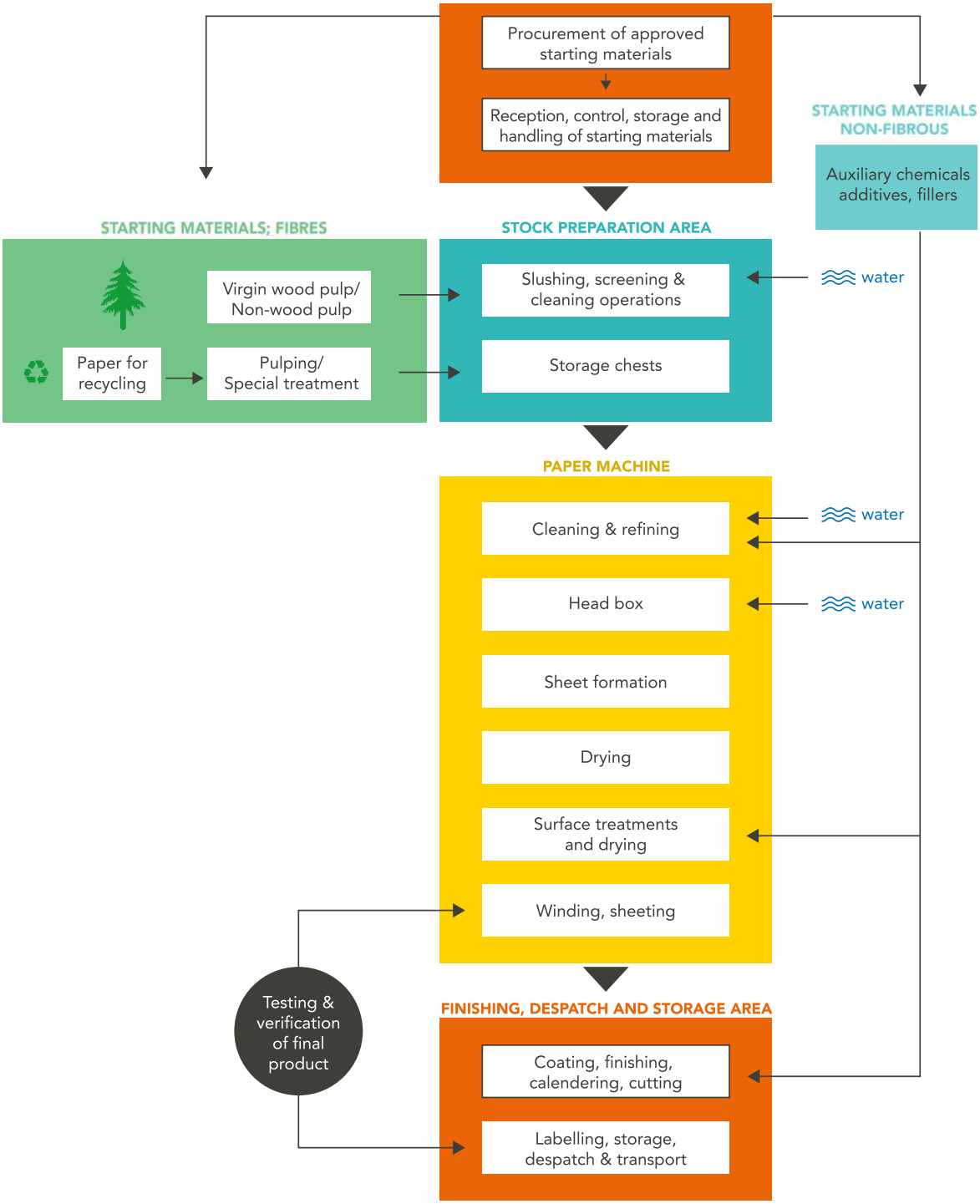
Selection of Suppliers – Compliance of starting materials		
All starting materials used in the production of the food contact material should be assessed to ensure compliance with the current regulatory requirements and the intended end use application.	4.6	Suppliers should provide documentation showing conformity with the current regulations. In cases where suppliers change the composition and/or introduce new raw materials or additives to their products, where new suppliers are used or the regulations change, a compliance documentation has to be updated accordingly.
The requirements for individual non-fibrous raw materials should be specified using a risk assessment. A specific factor to consider would be whether the process chemical is likely to remain in the supplied food contact paper and board.	4.6	
Records of all starting materials and relevant process chemical deliveries should be kept so that conformity with regulatory requirements can be checked.	4.6/6	
Suppliers of paper for recycling should supply documented evidence of conformity with the Cepi Guidelines for Responsible Sourcing. The requirement for this conformity should be included in the contractual arrangements.	4.6	
There should be documented requirements, approval procedures and monitoring for all suppliers and subcontractors.	4.6	
Conformity to pre-established instructions and procedures		
Procedures for ensuring the accuracy of substance input using dosing equipment should be in place to ensure correct addition of functional additives and process chemicals having a compositional limit in the final product.	4.7/5.1	
Storage, shipment, transport and delivery		
All vehicles used for transporting mill finished product should be suitable for the purpose, well maintained and in a good state of hygiene. Contractual arrangements with transport companies should include requirements for hygiene and cleaning. There should be a preloading check procedure in place for checking transport of finished products paper and board for cleanliness and water tightness.	4.8/4.6	
All external warehouses should be suitable for the purpose, well maintained and clean. Contractual arrangements with the supplier of warehousing facilities should include requirements for hygiene, pest control and cleaning.	4.8/4.6	

Quality Control along the process – Control and testing of finished products		
The finished paper and board should be tested according to relevant regulatory measures. Testing in accordance to other relevant guidelines such as BfR Recommendation XXXVI, the Food Contact Guidelines, etc. may also be relevant.	5.1	Pertinent to the end-use application and particular regulation.
The Quality Assurance System should contain a documented procedure on which tests to carry out, testing protocols to be used and the testing frequency for requirements contained in the regulatory measures.	5.1	
In cases where a decision has been taken to perform no tests on a particular requirement specified in the relevant regulatory measures or other relevant guidelines, documented reasoning should be prepared.	5.1	
Recipes of the produced paper and board, showing fibrous and non-fibrous raw materials used along the process, should be compiled and retained.	5.1	
Monitoring of GMP implementation and achievement - auditing and management of changes		
There should be a system in place to monitor and record the implementation and achievement of the GMP system. The system should also identify measures to correct any failure to achieve GMP and monitor the effectiveness of those measures. The system should cover also cases of non-conformity with regulatory, internal and customer specifications.	5.2	
Any changes e.g. in regulations, customer demands, production equipment, production process related to food contact materials should be reviewed, assessed and any necessary actions implemented.	5.2	
Any changes to procedures should be effectively communicated within the organisation.	5.2	
Aspects emerging from internal and external auditing activities (Audit plans, Records, Corrective actions) should be reviewed and assessed.	5.2	

Documentation		
Arrangements should be implemented to produce documentation for internal and external evaluation of the effectiveness of the GMP system.	6	Continuous production of documentation is not needed, and reports could, for example, be produced in retrospect from computer records. Examples of the required documentation include: • results of risk assessment; • changes in supply and suppliers; • starting material usage; • manufacturing and traceability documentation (mainly machine logs) including documentation of traceability tests; • occurrences of deviation from specification and corrective measures (including changes required by new requirements from legislators); • results of testing within the quality assurance system and all management system (as ISO 9001 or equivalent) documentation.
Labelling		
Labelling should be aligned with the requirements of the Framework Regulation. A link between traceability information and the labelling process should exist and be demonstrated.	7.2	
Declaration of Compliance		
Declaration of compliance (DoC) should be delivered to downstream business operators.	7.3	See more information on the content of the DoC and the relevant supporting documentation in the Food Contact Guidelines.
Traceability		
The correct operation of the existing traceability system should be tested (once a year is recommended).	7.4	See further guidance in the Food Contact Guidelines.

Annex 1
AREA COVERED BY THIS GMP GUIDELINE

Figure 1 - Schematic Representation of the Activities covered by this GMP Guideline



In addition, all activities that are subcontracted to third and/or external parties (e.g. storage/handling of final paper and board, despatch and transport, maintenance, etc.)

Annex 2
HAZARD INVENTORY AND RISK ASSESSMENT

A2.1 Introduction

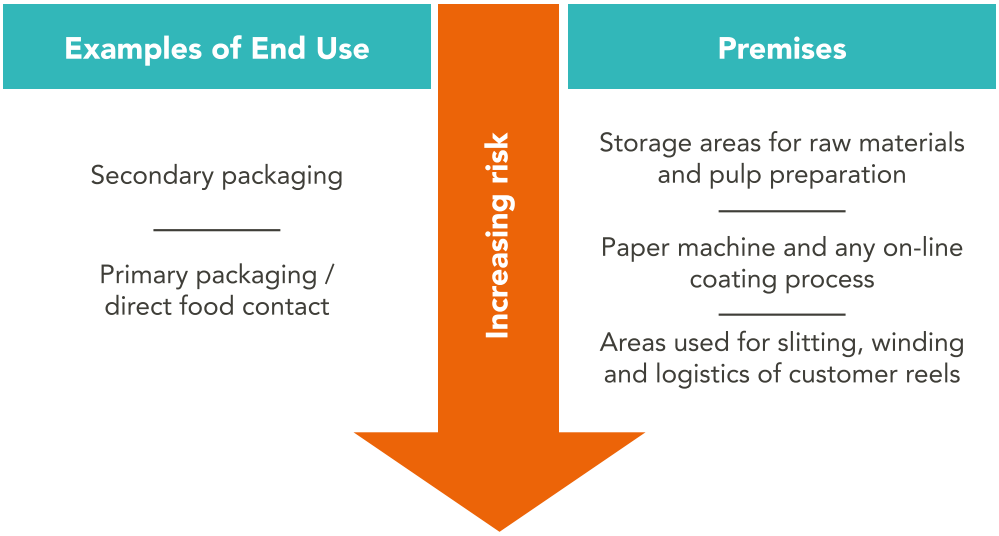
Article 3 (a) of the GMP Regulation 2023/2006 states:
Good manufacturing practice (GMP) means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof.

The adverse elements (potential contaminants) in food contact paper and board could cause chemical, physical and biological risks.

In order to comply with the GMP Regulation, it is essential to know how the composition of the paper or board is controlled and how process variables affect that composition. It is also necessary to know if contaminants will be introduced, how and where they may occur, what risk they pose to the finished paper and board and how that risk can be controlled.

When implementing GMP, a risk assessment, through the whole process, should be carried out in order to control product and food safety aspects in paper and board mills. The diagram below (Figure 2) illustrates, in general terms, how severity of risk varies according to paper and board application and production location. It illustrates that hazards and their results can have different outcomes for consumer safety depending on production location and product application.

Figure 2 - Severity of Risk



A2.2. General Considerations of the Risk Assessment

In a risk assessment, every step of the process, from procurement of starting materials to delivery of paper and board, is assessed for all production and contamination hazards which could affect the safety of the end product and thus pose a potential risk to health. All identified potential hazards should be described and undergo a risk assessment.

This risk assessment is based on the likelihood of the potential exposure of the final consumer to the hazard as well as its occurrence at the mill combined with the severity of the hazard for consumer health.

Thus:

risk = hazard severity x likelihood

The risk posed by contaminants may change over time and this may require a rapid response from a mill. Traces of non-intentionally added substances (NIAS) may occur in all food contact paper and board and their complete identification and total elimination is impossible. Any risk concerning NIAS should be managed following, for example, the procedure given in the Food Contact Guidelines.

The decisions taken in the risk assessment, and the reasons, including when a risk is managed to an acceptable level in a subsequent process step or judged to represent a negligible effect on consumer safety, must be documented.

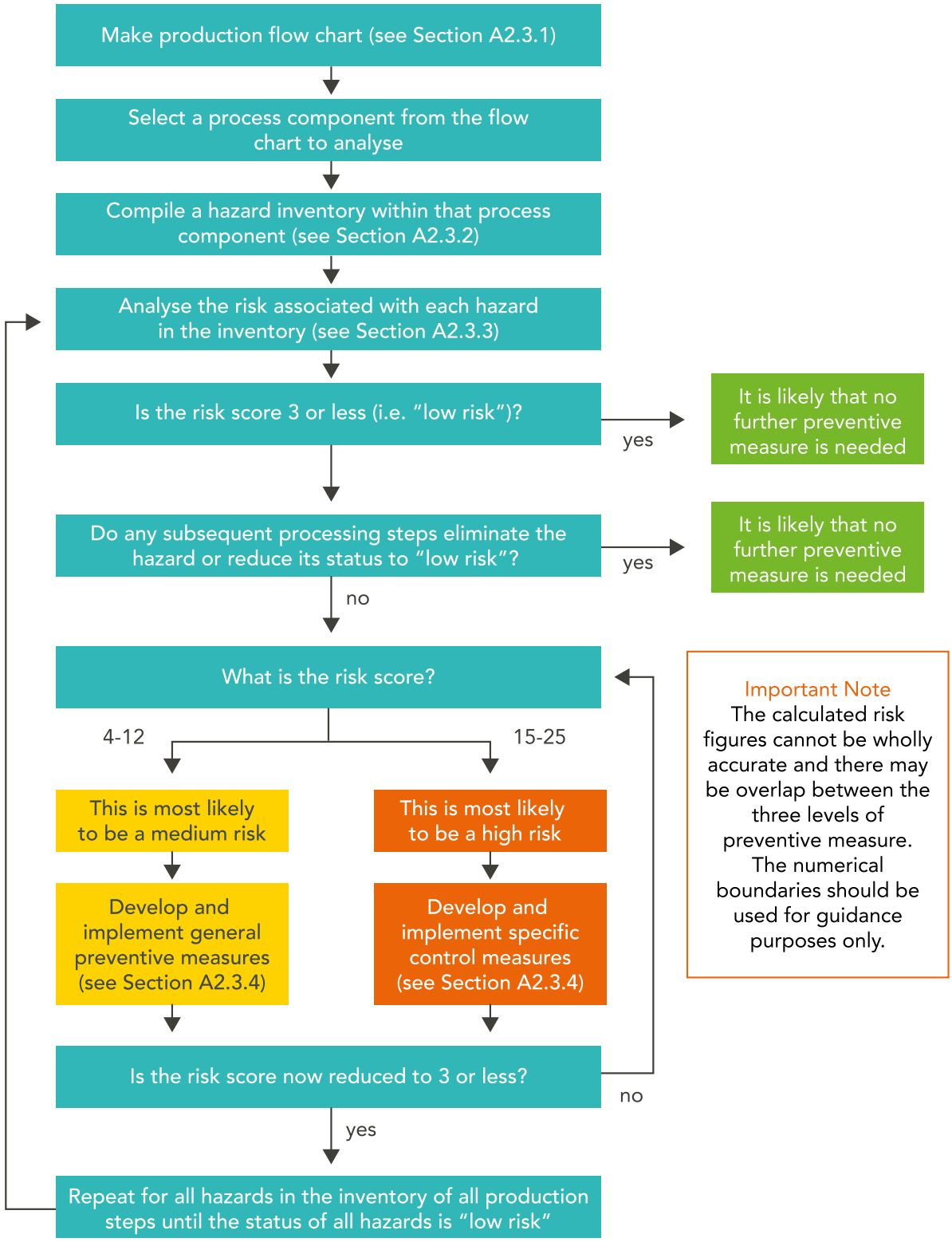
The conduct of all the risk assessment-related activities has to be carried out by qualified persons.

The validity of the risk assessment should be reviewed regularly, at least once per year, and always when any process or starting material change takes place or new scientific/technical knowledge becomes available. Depending on the result of that review, new preventive measures may be necessary.

A2.3. Performing the Risk Assessment

Follow the steps shown in Figure 3

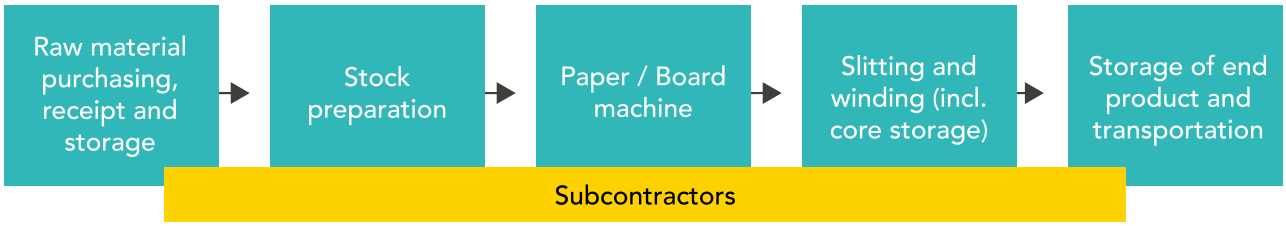
Figure 3 - Steps in the Risk Assessment Process



A2.3.1 Describe the Manufacturing Scheme

Make a flow chart of the entire paper production process from procurement of starting materials to shipping, including all subcontracted processes. Use the main steps of the manufacturing process (shown schematically in Figure 4) as a basis.

Figure 4 - Flow Chart for Papermaking Process



A2.3.2 Construct a Hazard Inventory

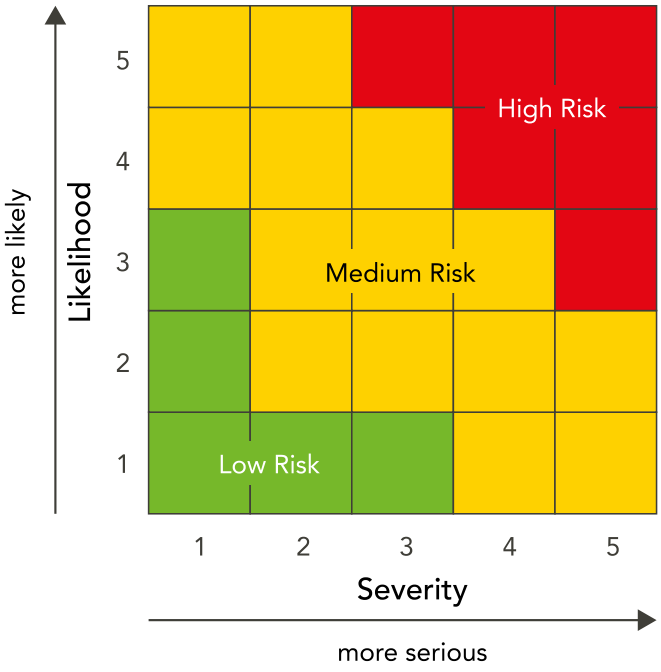
Details should be recorded of all points in all the above manufacturing steps where a hazard could occur and affect the safety of the paper and board during its end use. Examples are shown in columns 1 and 2 of Table 3 at the end of this annex.

A2.3.3 Calculate the Risk

Using Figure 5, calculate the risk associated with each hazard by multiplying the likelihood of the estimated consumer exposure to that hazard and its occurrence at the mill by the severity that hazard would have if the consumer were exposed to it. (Other methods of calculating risk are available and may be used if they are documented and result in effective preventive measures.)

It is important to note that the three areas of activity shown in Figure 5 may overlap each other and should be used for guidance only. Experience may indicate that the level of preventive measure may differ from that which is given by the numbers.

Figure 5 - Risk Calculation Matrix



Notes to Figure 5

Severity means the effect that the process hazard or contamination hazard has on consumer safety via food that has been in contact with paper and board.

Severity rating is given on page 25.

Table 3 - Risk Calculation Matrix - Severity Rating

Rating	Severity
1	Minor/small discomfort, but no negative effect on health such as injury or symptom of disease.
2	Less serious/health problem; consumer is not feeling well, possible stomach disorder, mild pain or slight allergic reaction.
3	Illness (possibly consulting a doctor) or injury (such as damaged teeth, mouth or throat), a limited number of consumers fall ill.
4	Very serious illness (but not life-threatening) and/or hospitalisation, medical treatment, temporary injuries, a large number of consumers fall ill.
5	Status of major disaster, serious illness, permanent and/or serious physical injury, fatal illness, or injury.

Likelihood means the probability of the hazard occurring in the supplied paper and board and constituting a risk of exposure to the hazard. Likelihood rating is given below.

The indications in brackets refer to the frequency of occurrence at the mill and can be used to plan the frequency of controls, if relevant to the risk calculation.

Table 4 - Risk Calculation Matrix - Likelihood

Rating	Likelihood
1	Extremely unlikely (maximum once/10 years)
2	Unlikely (maximum once per year)
3	Likely (maximum once per month)
4	Very likely (maybe once per week to maximum once per month)
5	Frequent (almost certain to happen)

Where there is negligible identified severity or negligible likelihood of occurrence this specific hazard has negligible risk and can be removed from the hazard inventory.

Severity depends on the end use of the product whereas the likelihood of **occurrence** can vary from mill to mill, depending also on local conditions.

The green area of the figure indicates low risk where relevant measures other than those to maintain it low are not normally required. A risk score of up to three is possible in this area but the aim should be to achieve two or less.

The yellow area of the figure indicates that a medium risk exists and a preventive measure is necessary. In general, a result in this area will be indicative of a risk which can be addressed by a general preventive measure, applied to the whole process. This may consist, for instance, of changes to manufacturing specifications or storage arrangements for starting materials.

The red area of the figure indicates that a high risk exists, and a preventive measure is necessary. In general, a result in this area can be overcome by the application of a preventive measure which is specific to the hazard in question. This may consist, for instance, of removing a lighting installation or changing an additive dosing rate. In general, the existence of high risks in a paper manufacturing process would be an indication of poor manufacturing control and is unlikely to be found in correctly run operations, even those not making food contact grades. If such high risks were found, preventive measures would have to be completed and documented as a matter of urgency.

A2.3.4 Decide on Preventive Measures to be Adopted

Examples of the documentation of hazards, risk assessment and associated preventive measures are given in Table 5, below. The effectiveness of the measures should be controlled and verified by audits.

Table 5 - Examples of Documentation of Hazards, Risk Assessment and their Associated Preventive Measures

Process Step	Hazard		Severity	Likelihood	Risk	Low Risk	Medium Risk	High Risk	Preventive Measures	Residual Likelihood (after Preventive Measures)	Residual Risk (after Preventive Measure)
raw material purchasing	incorrect pulp	C	3	2	6		X		define/document process (procedure) incl. checklist	1	3 (low)
	starch out of microbiological specs	B	3	2	6		X		define specification with supplier, verify starch quality risk based-periodically in the lab	1	3 (low)
stock preparation & paper/board machine	use wrong additive	C	3	2	6		X		define/document process (procedure) incl. checklist, evaluate all chemicals prior sourcing	1	3 (low)
	incorrect dosage	C	3	2	6		X		install inline flow meter (control & document dosage)	1	3 (low)
slitting & winding	metal part of snap off blade in finished pallet	P	5	4	20			X	nosnap off blades to be used onsite (metal policy)	1	5 (medium)
transportation	paper is contaminated with chemicals during transportation	C	5	3	15			X	define hygiene transport criteria with the logistics partner in the contract, check/document hygiene of each transportation device	1	5 (medium)

Key: C = Chemical contamination P = Physical contamination B = Biological contamination

Annex 3
CROSS REFERENCE TABLE

Table 6 - Cross Reference Table with Regulation (EU) 2023/2006

Cepi GMP Guideline	GMP Regulation 2023/2006	Comments
1. Introduction	Article 1	
2. Scope	Article 2	
3. Definitions	Article 3	
4. Implementation of a Quality Assurance System	Article 5, paragraph 1	
4.1 Management Responsibility and Organisation	Article 5, paragraph 1	
4.2 Adequacy, knowledge and skills of personnel. Training	Article 5, paragraph 1 - (a)	
4.3 Risk Analysis, Risk Assessment, Risk Management, Risk Communication	Not specifically described	Risk assessment and management are functional steps in meeting article 4 requirements
4.4 Organisation of the premises and equipment – Hygiene and housekeeping	Article 5, paragraph 1 – (a)	
4.5 Personal Hygiene	Article 5, paragraph 1 – (a)	
4.6 Selection of suppliers – Compliance of starting materials	Article 5, paragraph 2	"Starting substances" in Regulation (EU) 2023/2006
4.7 Conformity to pre-established instructions and procedures	Article 5, paragraph 3	
4.8 Storage, shipment, transport and delivery	Article 5, paragraph 3	
5. Implementation of a Quality Control System	Article 6 paragraph 1	
5.1 Quality controls along the process – Control and testing of finished products	Article 6, paragraph 1	
5.2 Monitoring of GMP implementation and achievement – auditing and management of changes	Article 6, paragraph 2	
6. Documentation	Article 7	
7.2 Labelling	Not specifically described	Covered in article 15 of Framework Regulation 1935/2004
7.3 Declaration of compliance	Not specifically described	Covered in article 16 of Framework Regulation 1935/2004

Cepi GMP Guideline	GMP Regulation 2023/2006	Comments
7.3 Traceability	Not specifically described	Covered in article 17 of Framework Regulation 1935/2004
8. Detailed requirements for Compliance with GMP Regulation – Indicative Checklist	Not included. This is advice for the implementation of GMP specifically within paper and board mills and would not be expected to appear in a general Regulation.	
9. Communication	Not specifically described	

References

1. Food Contact Guidelines for the Compliance of Paper & Board Materials and Articles https://www.cepi.org/wp-content/uploads/2020/09/Food-Contact-Guidelines_2019.pdf
2. Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food – 22 December, 2006 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006R2023
3. Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food – 27 October, 2004
4. ISO 9001 Quality management systems – Requirements
5. ISO 22000 –4 Food Safety Management Systems – Requirements for any organisation in the food chain
6. ISO/TS 22002-4 Prerequisite programmes on food safety – Part 4: Food packaging manufacturing
7. EN 15593 Packaging. Management of the hygiene in the production of packaging for foodstuffs. Requirements
8. GFSI (Global Food Safety Initiative) recognised programmes for production of food packaging
    - 8.1 FSSC 22000 Food Safety System
    - 8.2 BRCGS Global Standard for Packaging Materials
    - 8.3 SQF Food Safety Code for Manufacture of Food Packaging
    - 8.4 IFS International Featured Standards; Food & Packaging Guideline
9. Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety – 27 January, 2002 - https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178
10. Cepi Guidelines for Responsible Sourcing and Supply of Recovered Paper https://www.cepi.org/guidelines-for-responsible-sourcing-and-supply-of-recovered-paper/

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