

# Food Contact

## Good Manufacturing Practice for the Manufacture of Paper and Board for Food Contact





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Issue 1 - September 2010

CEPI is publishing this document as there is a need to provide papermaking Good Manufacturing Practice in order to complement the contents of the recently published Industry Guideline<sup>1</sup>. The document contains a number of new concepts and methodologies, the detailed operation of which may be unfamiliar to some users. GMP is an essential part of the production of food contact paper and board and CEPI considers it essential that the principles contained in the document are accurate and practical, an ambition which cannot be fully realised until extensive, practical experience has been gained. CEPI would, therefore, welcome feedback on the operation of this GMP both from paper manufacturers and other interested stakeholders such as customers and regulatory authorities with a view to its review and revision by the end of 2011.

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1. Industry Guideline for the Compliance of Paper and Board Materials and Articles for Food Contact, published on 18 May 2010 and available at <http://www.cepi.org/Objects/1/files/Industry%20guideline-final.pdf>

## TABLE OF CONTENTS

1. Introduction	1
2. Scope	1
3. Definitions (as apply in the context of this GMP)	2
4. Quality Assurance	3
5. Quality Control System	5
6. Traceability	5
7. Documentation	5
8. Related Standards	6
9. Detailed requirements for Compliance with the GMP Regulation	6

## Diagrams

Table 1 - Definitions	2
Figure 1 - Principles of Control	3
Table 2 - Elements of the Papermaking GMP System	7
Figure 2 - Schematic Representation of the Papermaking Process	13
Figure 3 - Severity of Risk	14
Figure 4 - Steps in the Risk Assessment Process	16
Figure 5 - Flow Chart for Papermaking Process	17
Figure 6 - Risk Calculation Matrix	17
Table 3 - Examples of Documentation of Hazards and their Associated Remedial Actions	19
Table 4 - Glossary of Terms (applicable to the Traceability Guidelines)	26
Figure 7 - Paper & Board Manufacture - Flow Diagram	27

## Annexes

Annex 1 - Area Covered by this GMP	13
Annex 2 - Hazard Inventory and Risk Analysis	14
Annex 3 - Guidelines for Responsible Sourcing and Supply of Recovered Paper	21
Annex 4 - Traceability in the paper and board packaging chain	24

## 1. INTRODUCTION

It is a requirement of the Regulation (EC) No 1935/2004, on materials and articles intended to come into contact with food (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 Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (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 GMP gives that implementation advice for the paper and board manufacturing industry.

In accordance with the definition of GMP given in Section 3, it does not contain details of manufacturing limits and quality standards which are normally contained in national legislation, customer specifications and other quasi-legislative measures.

## 2. SCOPE

This GMP reference document 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 foodstuffs. It does not cover the operations of converters.

The contents of this document assume that operators have in place the ISO 9001 quality management system or equivalent in place.

The document applies to the manufacturing of paper and board suitable for contact with all types of foodstuff and conditions for its use.

The document covers the entire production process as outlined in Annex 1. Preventive measures are based on the intended use of the end product.

This document contains two main, operational parts. Firstly, Sections 4 - 8 describe the basic requirements of the GMP Regulation and how they are to be interpreted and applied during paper production. Secondly, Section 9 contains a list of detailed actions which interpret these requirements for adoption within the paper and board manufacturing area in order to achieve compliance with the GMP Regulation.

As the situation may be different in paper mills depending on the raw material, the paper produced, the size of the manufacturing facility, etc., their various needs to fulfil the GMP Regulation may be different and not all the measures described in Section 9 may be needed. Consequently, advice on the need for the different measures is given.

### 3. DEFINITIONS (as apply in the context of this GMP)

Table 1 - Definitions

Additives	Substances, other than fibre and minerals, which are added to the papermaking process to achieve either an improvement in that process or the modification of the properties of the product.
BfR Recommendation 36	A document produced by the German Federal Institute for Risk Assessment for the control of manufacture of food contact paper and board.
Control Point	The identified risk at that point should be controlled by a specific measure (for example a specific temperature, a specific process time, a specific dosage, etc.).
Dosing equipment	Equipment which automatically controls the addition of liquids or solids to the papermaking process.
EN 643	European list of standard grades of recovered paper and board.
External contractors	Companies which are commercially separate from the one operating the paper mill and which perform tasks within that paper mill.
Framework Regulation	Commission Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.
GMP Regulation	Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.
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.
Hazard	A biological, chemical or physical agent in, or condition of, food contact materials with the potential to cause an adverse health effect.
Hygiene	Elements of the condition of humans and premises which could influence the safety of food contact paper and board. These could include, for instance, disease, bacteria, dirt, pests, insects, etc.
Jumbo reel	A reel of paper produced directly at the end of a paper machine before any slitting or sheeting operations have been performed.
Labelling	The affixing of identification to reels and packets of paper or board.
Organoleptic	Relating to smell, texture, appearance or taste of food and detectable by human senses.
Point of Concern	The risk at that point should be controlled by a general measure, applied to the whole process as a preventive measure.
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	The 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.

Recovered paper	Paper or board, other than internal broke or scrap, which is recovered from an operation within the paper supply chain and returned to a paper mill for conversion back into new paper.
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in a food contact material.
Risk analysis	The process of defining the various threats to product safety, determining the extent of vulnerabilities and devising appropriate countermeasures.
Stock preparation	The addition of water to wood pulp and recovered paper and subsequent homogenisation and cleaning operations prior to processing on the paper machine wire.

## 4. QUALITY ASSURANCE

### 4.1 General

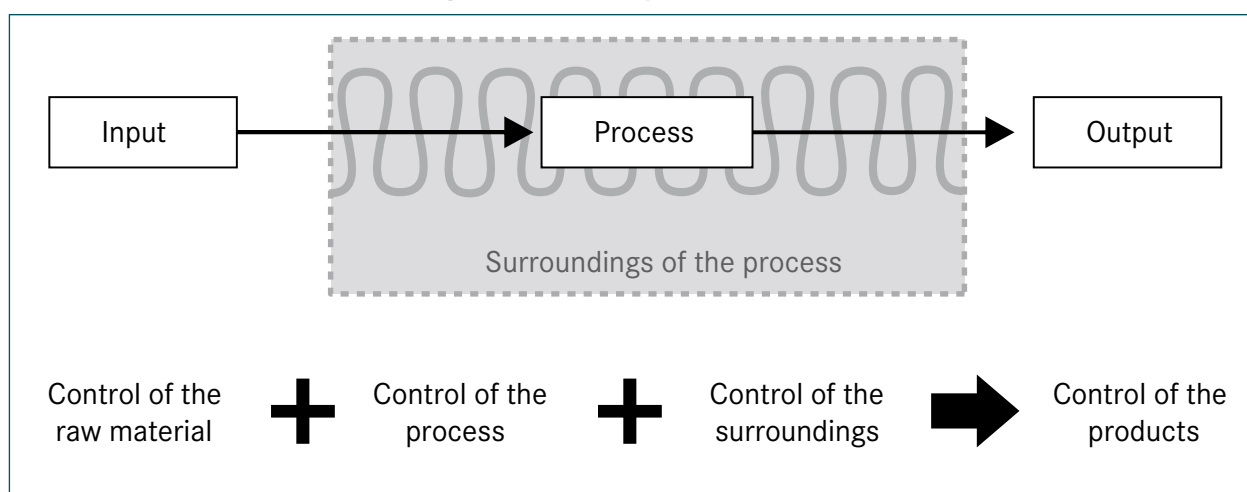
A documented quality management system, such as ISO 9001 or equivalent, forms the underlying basis for the procedures and instructions related to the GMP Regulation and the specific requirements for food packaging materials. The mill management system should be revised and amended to ensure that quality aspects related to food packaging applications are included in an appropriate way.

The requirements on paper and board for food contact packaging are governed by the demands on the final packaging and aim to ensure suitable quality for the intended use. This implies that the paper and board must be manufactured to an agreed quality standard, including the requirements in the Framework Regulation and other quasi-legislation for food contact.

The existing procedures in the quality management system should be used for the areas which are not covered by this document.

The starting point for implementing GMP, in a paper and board mill, is to perform a risk analysis. Control of the raw material input, process and process surroundings leads to control of the final product. See Figure 1.

Figure 1 – Principles of Control



The outcome of the risk analysis will determine the measures which need to be implemented and the way to integrate them into the management system. The risk analysis should consider the local conditions and the intended end use application for the product.

#### **4.2 Management responsibility and organisation**

Mill management has the ultimate responsibility for the GMP system and must take steps to ensure that it is fully integrated into the quality management system. They must also ensure that correct systems are set up, maintained, reviewed and documented and that appropriate personnel are trained and given responsibilities under the system.

#### **4.3 Risk analysis**

Risk analysis is a tool to ensure that all risks related to the use of paper and board as food packaging material are identified and that appropriate control measures and monitoring are established.

The risk analysis should cover the entire production process, which is under the commercial responsibility of the operator, from raw material procurement to shipping of finished products and should be adapted to each site, the products manufactured at the site and the intended use of the products.

A risk analysis consists of two main elements. Firstly, an inventory must be made of all possible hazards along the production chain which might, if they occurred, affect the safety of the final product (the hazard inventory). Secondly, each of those hazards is subjected to a risk assessment which is aimed at quantifying the risk of an adverse occurrence and formulating measures necessary for reduction or prevention of such occurrences.

An example of a methodology to perform a risk analysis is found in Annex 2.

#### **4.4 Specifications**

Operators must produce and maintain specifications, according to relevant food contact legislation and the requirements for the finished product, for all raw materials and additives (functional and process) used in the production of the food contact material. Documented procedures must be in place to ensure that those raw materials are used in a way which is consistent with the requirements of the end use of the paper and board. Specifications should also be prepared for warehouses and transport facilities which are not under the direct control of the paper mill but which handle the food contact product.

#### **4.5 Testing Frequency**

In addition, consideration must be given to the testing scheme intended to analyse the end product for compliance with regulatory and customer specifications. Testing must therefore be performed at a frequency which relates to the likelihood of a particular restriction being exceeded. This frequency must have a demonstrable, statistical basis and will depend upon 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 and Declarations of Compliance.

Once the initial frequency has been determined, the risk assessment which determined that frequency must be reviewed at least every 12 months. However, if for instance it can be shown from calculations, from a knowledge of the constituents, or from other information giving conclusive evidence, that a particular substance could never exceed its restriction in the material or article, then the facts must be documented and testing would not be required.



#### **4.6 Suppliers**

The written procedures for the approval and monitoring of suppliers, described in the ISO 9001 management system, should be extended, if necessary, to cover the demands in the Framework Regulation and the GMP Regulation. The mill should ensure that the relevant suppliers work according to these regulations.

The mill should demand that the suppliers immediately inform the mill, and update the food contact documentation (e.g. certificates), whenever a modification of the raw material and/or additives is done or when changes have occurred in the regulations which are referred to in the certificates.

#### **4.7 Personal hygiene**

The mill should establish appropriate rules for personal hygiene based on the outcome of the risk analysis. In view of the large scale of the production facilities in paper mills where many departments are not directly involved in making the food contact product, the requirements for personal hygiene will vary greatly. In many cases, the risk assessment will show that no special rules are needed whilst in others, where contact with the product is intimate, full application of the rules will be necessary.

#### **4.8 Premises and Equipment**

The mill should establish appropriate rules for housekeeping and cleaning of production areas and equipment based on the outcome of the risk analysis. The rules should be proportionate and should be aimed principally at those areas directly involved in production of the food contact material. Control of other areas, e.g. offices and engineering facilities, which are remote from the production facility, is not normally needed.

### **5. QUALITY CONTROL SYSTEM**

Existing procedures in an ISO 9001 (or equivalent) system should be amended, if necessary, to integrate the monitoring and documentation of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP.

### **6. 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 the defect.

The European Commission has compiled a guide to traceability of food contact materials. An extract of the paper and board section of that guide is reproduced in Annex 4.

For product recall the existing procedure in the ISO 9001 system shall be used.

### **7. DOCUMENTATION**

There is a need for the maintenance of efficient documentation. Whilst it is not necessary to continuously produce and maintain a complete dossier of all information, operators must be able to compile the relevant information, on demand and within a reasonable time-frame, for the competent authorities. This might involve, for instance, making hard copy extracts of production data stored within a computer.

Paper and board manufacturers 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 packaging chain and the expected life of the foodstuffs which are packed should be considered when making a decision. However, it is considered that a recommendation about a minimum period should be made and this period is two years.

## 8. RELATED STANDARDS

Elements contained in the following standards, in addition to those found in the ISO 9001 system, are used by some paper manufacturers to assist in complying with GMP requirements:

**ISO 22000 - Food safety management systems – Requirements for any organisation in the food chain.**

**EN 15593 - Packaging - Management of Hygiene in the Production of Packaging for Foodstuffs**

**BRC/IoP Global Standard for Packaging and Packaging Materials**

**CAST- Linee guida per l'applicazione del Regolamento 2023/2006/CE alla filiera dei materiali e oggetti destinati al contatto con gli alimenti<sup>2</sup>**

It is not the intention to place extra administrative burdens on paper manufacturers and the above standards can continue to be used as a method of establishing Good Manufacturing Practice. However, the components of the above standards, if used, must be compared with those detailed in Section 9 which follows. If any are missing from the above standards, then compliance must be established using those components as shown in this GMP.

## 9. DETAILED REQUIREMENTS FOR COMPLIANCE WITH THE GMP REGULATION

The following table (Table 2) contains the elements of a GMP system which apply to the manufacture of paper and board for food contact. However, there is large diversity, within the industry, of manufacturing plant and production techniques. Also, the food uses of the final products cover a large range from direct contact with moist foods to indirect packaging which may be separated from the food by several layers of other material. Consequently, not all mills will need to implement all items in the table as some may be inappropriate and unnecessary in their particular businesses. The risk assessment will show whether or not they are needed. However, the table contains a certain number of items which are fundamental parts of the system and must be implemented in all cases. These items are indicated. So, the table can be regarded as a check-list which operators must consider when implementing a GMP system. If a decision is made that a particular item in the table is not to be used in the GMP system then the reasons must be documented.

Key to "Need" Column:

1 = fundamental part of GMP, must be implemented in all cases

2 = strongly advised

3 = needed only if called for by the risk assessment

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2. A guide to the application of Regulation (EC) No 2023/2006 to the supply chain of materials and articles intended to come into contact with food (applicable mainly to mills in Italy)

Table 2 – Elements of the Papermaking GMP System

Component of the GMP System	Need	Comments
<b>General</b>		
ISO 9001 or equivalent must be implemented.	1	
Align quality policy to include aspects specific to food contact including aspects of internal audit.	1	
Management backing for GMP systems.	1	
Appoint a person to be responsible for GMP implementation and maintenance.	2	Applies generally to larger operations although it is always advisable to have a named individual with nominal responsibility.
New and existing personnel and contractors should be trained on GMP requirements and hygiene aspects specific to the food contact product.	1	Needs apply only to personnel working in areas where the food contact product 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.	1	Could be a full training course record or a tick in a box depending on the circumstances.
Perform a risk analysis (see Annex 2) and review once per year.	1	
Revise risk analysis.	3	Only needed when any major product or process change takes place (but see special requirement regarding testing frequency stated in Section 4.5).
<b>Specifications</b>		
Review and implement changes in regulations, customer demands and other rules and procedures related to food contact materials. Communicate changes within the organisation.	1	It is not necessary to perform the review of regulations <u>within</u> the organisation. Instead, the knowledge could be acquired from elsewhere <sup>3</sup> .
The final product should be tested according to BfR Recommendation 36 or the Industry Guideline <sup>4</sup> or other relevant regulatory measures. The mill should have a documented procedure which defines which tests to carry out and the testing protocols to be used.	1	

3. For example from a specialist corporate department, a consultant or a trade association

4. Published 18 May 2010 and available at <http://www.cepi.org/Objects/1/files/Industry%20guideline-final.pdf>

Component of the GMP System	Need	Comments
The quality assurance system must contain guidelines for the determination of testing frequency for requirements contained in the regulatory measures.	2	
In cases where a decision has been taken to perform no tests on a particular requirement specified in the measure(s), documented reasoning must be prepared.	1	
Procedures for ensuring the accuracy of substance input using dosing equipment should be in place to ensure correct addition of chemicals with a compositional limit.	3	
<b>Quality Control</b>		
There must be a system in place to monitor and record the implementation and achievement of GMP. The system must 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.	1	
Document the food applications for which the end product can be used based on customer information or, in its absence, product knowledge. Document the effect which those applications might have on the selection of raw materials.	3	Ideally, the customer will provide details of end use but, if the customer is unable or unwilling to provide such information, then the customer must be told that he has responsibility for safe use of the product.
<b>Raw Materials</b>		
All raw materials and additives used in the production of the food contact material should be assessed to ensure accordance with current regulatory requirements <sup>5</sup> .	1	Suppliers must provide documentation showing conformity with current regulations. In cases where suppliers introduce new raw materials or additives to their products, where new suppliers are used or the regulations change, a fresh declaration of conformity must be sought.
Keep records of all raw material deliveries so that conformity with regulatory requirements can be checked.	1	

5. One method of achieving this is the use of established food contact lists such as those contained in BfR Recommendation 36, Council of Europe Resolution Ap (2002) 1 or the American FDA. However, if an operator is situated in a country where national regulations or recommendations exist, that operator shall use only the list contained in the text of the country concerned.

Component of the GMP System	Need	Comments
Recipes of the end product, showing raw materials and additives used along the process, must be compiled and retained.	2	Without this check, the operation will be unable to allocate responsibility to a supplier in the case of defective raw material.
Suppliers of recovered paper must supply documented evidence of conformity with the Responsible Sourcing Guidelines (see Annex 3) and the requirement for that conformity should be included in the contractual arrangements with those recovered paper suppliers.	1	
The operation of paper mills using recovered paper must be adapted, if necessary, to conform to the Responsible Sourcing Guidelines. (See Annex 3.)	1	
<b>Personal Hygiene</b>		
Personnel must wash their hands after using the toilet and any other activity that has caused dirty hands.	3	
Clean working clothes and working shoes should be worn in the production and storage areas.	3	
It is not permitted to wear any loose items such as jewellery, watches, etc.	3	
Open wounds shall 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.	3	
Personal belongings (such as coats, mobile phones, back packs, etc.) must not be taken into the production and storage areas.	3	
Working clothes should be selected with the safety of both the employee and the product in mind. There should be rules in place for effecting the upkeep and repair of these clothes.	3	
Employees suffering from injuries and/or diseases likely to be transmitted to the food contact material must be excluded from the workplace.	3	

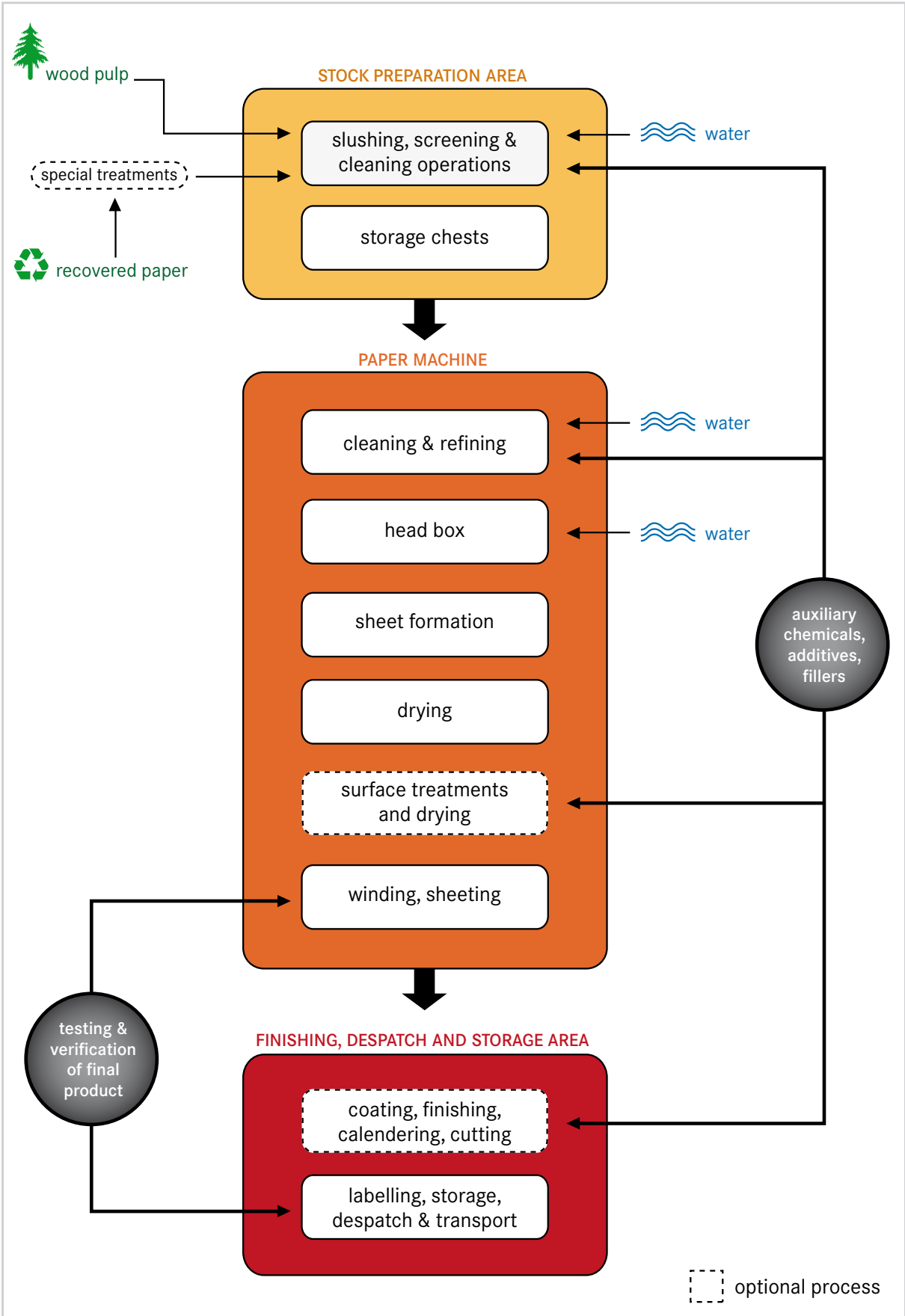
Component of the GMP System	Need	Comments
Eating, drinking, sweets, chewing gum and smoking are allowed in designated areas only.	3	
Rules shall be in place to ensure that visitors to the workplace wear appropriate clothing and remove jewellery and other loose items. Personnel accompanying visitors must have sufficient knowledge to pass on to them the special requirements needed when working close to a food contact product.	3	
<b>Premises and Equipment</b>		
All premises, such as personal working spaces and lockers, toilet areas and other amenity areas used by personnel working on food contact material, must be kept clean and tidy in accordance with a pre-determined schedule.	1	Applies only to the production areas. The “Need” will probably be 3 in non-production areas of a paper mill.
Buildings, machinery, conveyors, transport devices, etc. must 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 product is not adversely affected.	1	Applies only to the production areas. The “Need” will probably be 3 in non-production areas of a paper mill.
Regular maintenance and inspection of facilities for hygiene purposes should form part of the quality management system.	2	Applies only to the production areas. The “Need” will probably be 3 in non-production areas of a paper mill.
Engineering, maintenance and technical equipment together with any necessary temporary construction arrangements used for specific, short-term tasks close to the production facilities should be removed when the task is complete. Delays to this procedure must be referred to the person having responsibility for the GMP system.	1	Applies only to the production areas. The “Need” will probably be 3 in non-production areas of a paper mill.
Lighting equipment, glass and plastic materials must be shatterproof.	1	Applies only in areas where the risk analysis has shown that debris from breakages could enter the food contact product.

Component of the GMP System	Need	Comments
All unnecessary glass and clear hard plastic should be removed from production and storage areas.	1	Applies only in areas where the risk analysis has shown that debris from breakages could enter the food contact product.
Hand knives used in production areas must be of an authorised type. Snap-off blades are specifically prohibited.	1	Applies only in areas where the risk analysis has shown that debris from blades could enter the food contact product.
In the event of the breakage of glass, plastic, knives, etc. in the area of the food contact product, a procedure must be implemented to ensure that the food contact product being produced at the time of the incident is free of such debris.	1	This will require liaison between affected departments in the paper mill and may require the affected product to be destroyed.
A documented pest control system must be in place. Execution of the system must be by specialist contractors or personnel trained in the necessary techniques. There should be a recognised system for taking action where evidence of pests is noted.	1	The system must ensure that pests cannot adversely affect the food contact product or its raw materials.
Wherever possible, doors and windows should be screened or closed to prevent pest ingress.	1	Does not apply to areas not used for production or product storage.

Component of the GMP System	Need	Comments
<b>Documentation</b>		
<p>Arrangements must be implemented to produce documentation for external inspection.</p>	1	<p>Continuous production of documentation is not needed and reports could, for example, be produced in retrospect from computer records. Examples of the required information are:</p> <ul style="list-style-type: none"> <li>• results of risk analysis;</li> <li>• changes in supply and suppliers;</li> <li>• raw material usage;</li> <li>• manufacturing and traceability documentation (mainly machine logs);</li> <li>• occurrences of deviation from specification and corrective measures (including changes required by new requirements from legislators);</li> <li>• results of testing within quality control systems and all ISO 9001 (or equivalent) documentation.</li> </ul>
<b>Miscellaneous</b>		
<p>All vehicles used for transporting finished paper should be suitable for the purpose, well maintained and in a state of good hygiene. Ongoing contractual arrangements with transport companies shall include requirements for hygiene and cleaning. There should be a procedure in place for checking transport of finished products for cleanliness and water tightness.</p>	2	
<p>All external warehouses should be suitable for the purpose, have appropriate atmospheric conditions, be well maintained and in a clean state. Contractual arrangements with the supplier of warehousing facilities shall include requirements for hygiene and cleaning.</p>	2	



Figure 2 – Schematic Representation of the Papermaking Process



**Annex 2 – Hazard Inventory and Risk analysis**

**A2.1 Introduction**

Article 3 (a) of Regulation (EC) No 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 in packaging which might cause organoleptic changes could be chemical, physical and/or microbiological.

To fulfil the 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 about the possibility that contaminants might be introduced, 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, should be carried out in order to control product safety aspects in paper and board mills. The diagram below (Figure 3) illustrates, in general terms, how severity of risk varies according to production location and product application.

**Figure 3 – Severity of Risk**

 <p><b>Increasing risk</b></p>	Premises	Final use - configuration	Final use – foodstuff type
	Storage areas for raw materials and pulp preparation	Indirect food contact	Foods likely to be washed or peeled before consumption
	Paper machine and any on-line coating process		Dry, non fatty food
	Areas used for slitting, winding and storing customer reels	Direct food contact	Fatty and moist food

## A2.2. General Considerations of the Risk Analysis

In a risk analysis, every step of the process, from procurement of raw materials to delivery of products, is categorised for production and contamination hazards which could affect the safety of the end product and thus pose a potential risk. All identified potential hazards must be described and then undergo a risk assessment. This risk assessment is based on the likelihood of the occurrence of the hazard and the effect the hazard might have on consumer health if it occurred. The combination of these two underlined factors gives the risk.

It is accepted that the risk posed by contaminants may change over time and this may require rapid response by mills<sup>6</sup>. All defined measures and procedures shall be documented through the management system.

The decisions taken in the risk analysis, and the reasons, including when the effect/occurrence is seen as negligible or will be eliminated in a next process step, have to be documented in the hazard inventory overview.

The hazard inventory and risk analysis have to be carried out by qualified persons.

The validity of the risk analysis shall be reviewed regularly, at least once per year and always when a major process change takes place. Depending upon the result of the review (which should be documented), a repeated risk analysis may be required either in part, in full or it may not be needed at all.

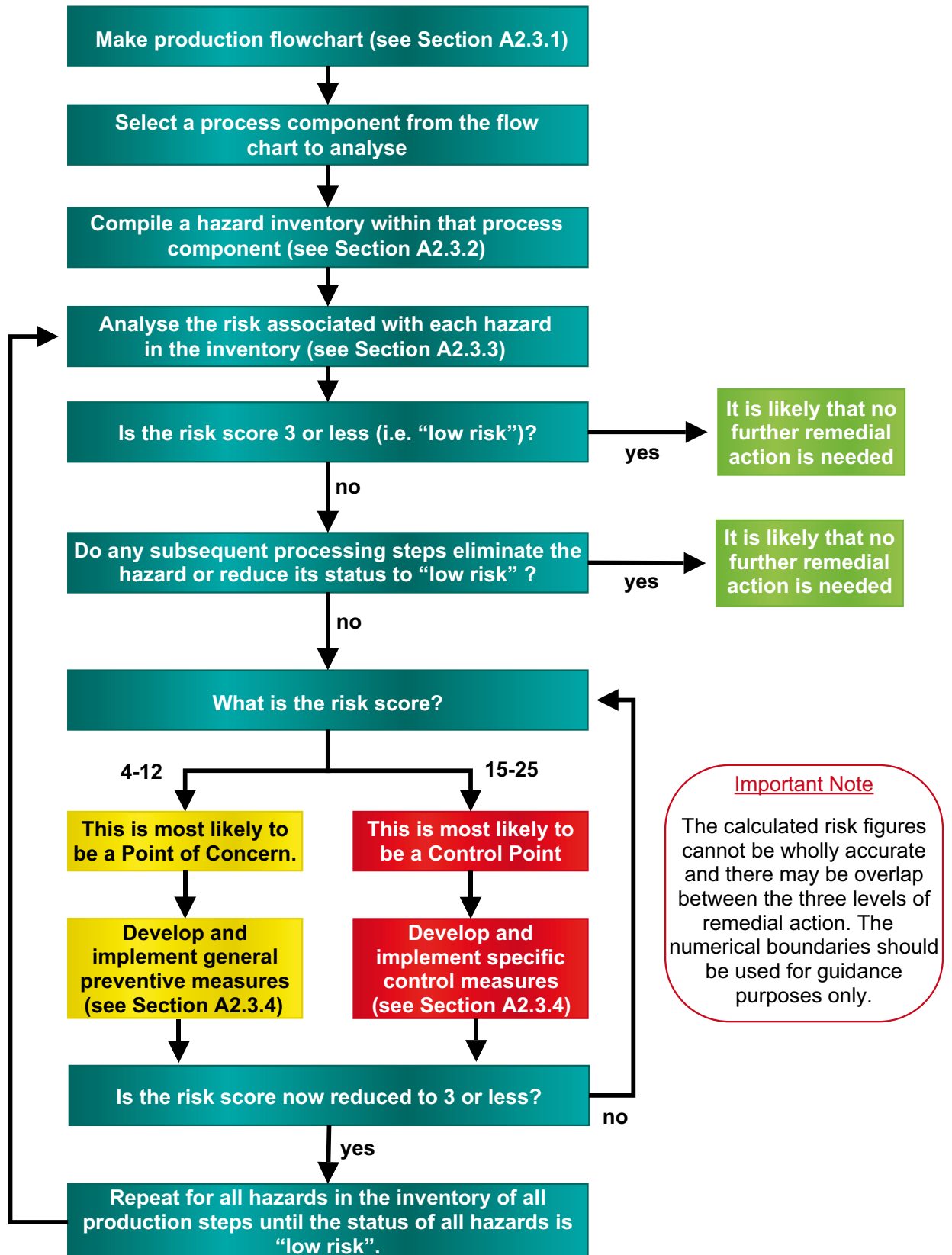
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<sup>6</sup>. Traces of non intentionally added substances (NIASs) will occur in all packaging materials and their complete identification and total elimination is not possible. The mill should select its raw materials to ensure NIASs in its products are present at extremely low levels. In cases where new toxicological evidence is confirmed for NIASs, the mill will take action, if necessary, to rapidly restore its products to compliance.

### A2.3. Performing the Risk Analysis

Follow the steps shown in the figure below:

Figure 4 – Steps in the Risk Assessment Process



**Important Note**  
 The calculated risk figures cannot be wholly accurate and there may be overlap between the three levels of remedial action. The numerical boundaries should be used for guidance purposes only.

### A2.3.1 Describe the Manufacturing Scheme

Make a flowchart of the entire paper production process from procurement of raw materials to shipping. Use the main steps of the manufacturing process (shown schematically in Figure 5) as the basis:

Figure 5 – Flow Chart for Papermaking Process



### A2.3.2 Construct a Hazard Inventory

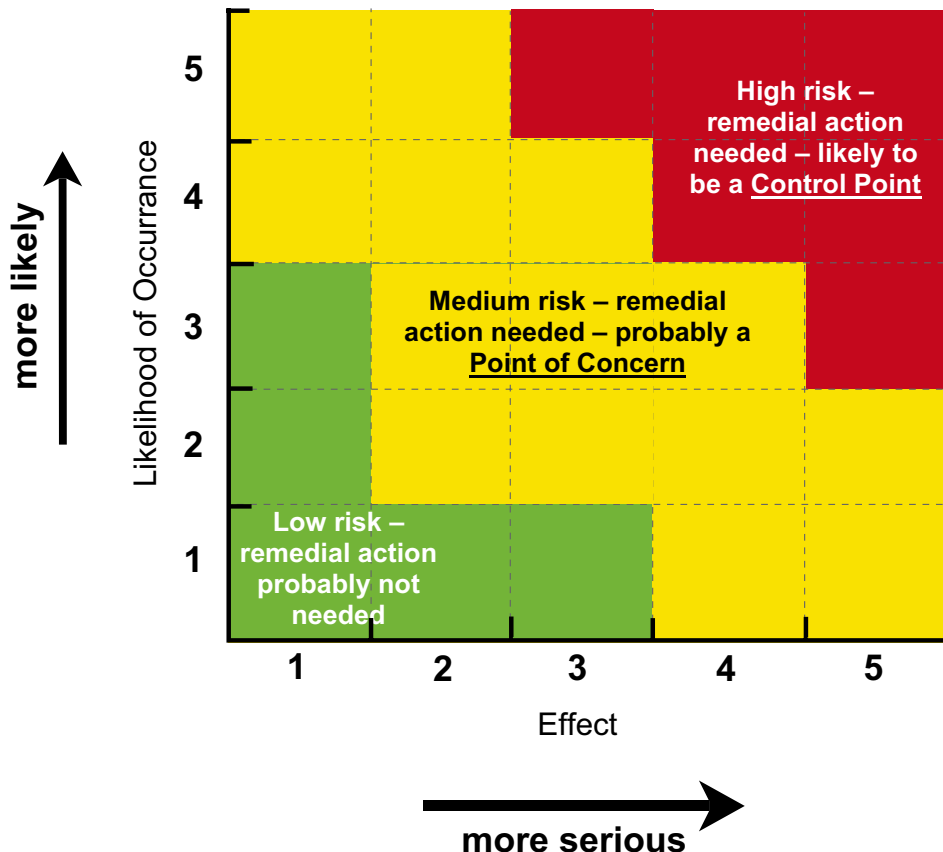
Details must be recorded of all points in all the above manufacturing steps where a hazard could occur which might affect the safety of the product. Examples are shown in columns 1 and 2 of Table 3 at the end of this annex.

### A2.3.3 Calculate the Risk

Using Figure 6, calculate the risk associated with each hazard by multiplying the likelihood of the occurrence of that hazard by the effect that hazard would have if it occurred. (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 risk areas shown in Figure 2 may overlap and should be used for guidance only. Experience may indicate that the level of remedial action may differ from that which is given by the numbers.

Figure 6 – Risk Calculation Matrix



## Notes to Figure 6

**Effect** means the effect of the process or contamination hazard on the consumer via the packed food.

The key to the Effects rating is given below.

Rating	Effects
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 too 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) limited number of consumers get ill.
4	Very serious illness (but not life-threatening) and/or hospitalisation, medical treatment, temporary injuries, large number of consumers become ill.
5	Status of major disaster. Serious illness, permanent and/or serious physical injury, fatal illness or injury.

**Occurrence** means the probability of the hazard occurring.

The key to the Likelihood of Occurrence rating is given below.

Rating	Likelihood of Occurrence
1	Extremely unlikely
2	Unlikely, perhaps every 6 months
3	Possible, once per month
4	Probable, maybe once per week or more
5	Frequent, up to several times per hour

**Effects** will be, in theory, identical for all mills whereas the likelihood of **occurrence** can vary from mill to mill, depending on local conditions.

The **green area** of the figure indicates low risk where remedial action is 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 remedial action is necessary. In general, a result in this area will be indicative of a Point of Concern which can be overcome by a general remedial measure, applied to the whole process. This might consist, for instance, of changes to manufacturing specifications or storage arrangements for raw materials.

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

### A2.3.4 Decide on Remedial Actions to be adopted

Examples of the documentation of hazards and associated remedial actions are given in Table 3, shown below. The effectiveness of the measures shall be controlled by internal audits.

**Table 3 - Examples of Documentation of Hazards and their Associated Remedial Actions**

Process step	Hazard and cause	Effect	Likelihood (give arguments)	Risk	CP	PoC	Remedial Actions	Residual Risk (after remedial action)	
Raw material (fibrous)	Selection prior to purchasing	Prohibited grades (C)	5	2 Washing + high dilution	10	No	Yes	Supplier agreement to change grades	Effect reduced to 1 so new risk acceptable at value of $1 \times 2 = 2$
	Selection prior to purchasing	Prohibited grades (M)	4	2 High temperature in drying section kills many micro-organisms	8	No	Yes	Supplier agreement to change grades	Effect reduced to 1 so new risk acceptable at value of $1 \times 2 = 2$
	Storage	Incorrect grade withdrawn from recovered paper store	1	2	2	No	No	Non required	risk value remains at 2
	Reception, storage and handling	Ageing due to long storage (M)	3	2 High temperature in drying section kills many micro-organisms	6	No	Yes	Storage specifications First in-first out procedure	Effect reduced to 2 and likelihood reduced to 1 so new risk value is acceptable at $2 \times 1 = 2$

Process step	Hazard and cause	Effect	Likelihood (give arguments)	Risk	CP	PoC	Remedial Actions	Residual Risk (after remedial action)	
Stock preparation	Preparation and introduction of additives	Addition of wrong additive (C)	3	2 High dilution  Retention in paper not 100%	6	No	Yes	Manufacturing specifications  Storage of chemicals organised to avoid mix-up	Likelihood of occurrence reduced to 1 so new risk value is $3 \times 1 = 3$ . Further reduction not considered possible so remains as a low risk.
	Preparation and introduction of additives	Wrong dosage of approved additive (C)	3	2 Pumps have a limited working range  High dilution	6	No	Yes	Manufacturing specifications and checks on usage of bulk supplies	Effect reduced to 2 and likelihood of occurrence reduced to 1 so new risk value is acceptable at $2 \times 1 = 2$
Winder area	Use of snap-off blade knives	Blades breaking or get loose (P)	4	2 Unlikely to be retained to final product stage	8	No	Yes	General rules. Snap-off blade knives not allowed in production area	Likelihood reduced to 1 by prohibiting blades and subsequent processing steps reduce the hazard to low risk
	Machine log	Incorrect details entered	1	2	2	No	No	Non required	risk value remains at 2

**Key:**

C = Chemical contamination

P = Physical contamination

M = Microbiological contamination



# Guidelines for Responsible Sourcing and Supply of Recovered Paper<sup>7</sup>

## Introduction

Paper recycling has a rich history and has been a respected industrial activity for more than a century. Under new environmental, health, safety and trans-frontier shipment regulations, this economic activity has acquired a civic and legal dimension, which when coupled with the developments in further regulations, demands an increase in responsibility from all parties involved in the recovery and recycling of paper.

Different recovered paper grades are used for manufacturing different paper and board products. In Europe, recovered paper purchasing is based on the European standard EN 643, European List of Standard Grades of Recovered Paper and Board, and these guidelines assume the use of that Standard. The “Recovered Paper Quality Control Guidelines” (CEPI and ERPA, 2004) also apply.

Successful paper and board recycling depends largely on the quality of recovered paper. As recovery rates increase, there is a tendency for the quality of the collected material to deteriorate. For this reason, a good working relationship between mills, merchants, and other involved parties is essential to ensure the responsible sourcing and supply of recovered paper.

Responsible collection of paper and board using efficient management and quality control systems, demands that all players involved recognise that they are handling a valuable secondary raw material. Separate collection (from other dry recyclables) should be strongly encouraged to maintain the quality of recovered paper.

Rapid technological development in the paper and board manufacturing and converting industries, increasing demands from final users of paper and board products, as well as existing and emerging legal requirements, require a more stringent approach towards the collection and handling of recovered paper.

Recovered paper collection systems vary according to country and source. Each source constitutes a different channel of collection, yielding different grades and qualities of recovered paper with different characteristics, which after separation (segregation at source) or sorting, are classified according to EN 643. As it would be impossible to give a description of all used paper collection systems in operation, the following guidelines for responsible sourcing of recovered paper list the steps that normally occur along the paper recovery chain. These guidelines also lay down additional steps paper mills should follow when producing paper and board for food contact.

These guidelines apply to any source and for any application. It may be that national legislation or practices require modifications to these guidelines.

### A3.1. Making used paper available for collection

The whole paper chain has a responsibility to make information available in order to facilitate responsible sourcing and recycling of recovered paper. This information can be different for the various types of consumer groups (e.g. business and industry outlets, households, (local) authorities) and shall at least cover the following:

- The importance of paper recycling and quality requirements of recovered paper;
- Which types of paper are suitable for recycling and which are not;
- The need to keep paper separate from unusable materials for paper recycling (as described in EN 643);

7. This is one of a number of documents making up the CEPI series offering guidance on the responsible management of recovered paper in all sectors of the paper & board manufacturing business. The whole series is available at <http://www.cepi.org/content/default.asp?pageid=7>

- Best practices for collection schemes;
- Adherence to all national and international environmental legislation with respect to storage and transportation.

### **A3.2. Collection**

- Bins and containers must be suitable for retaining paper and board for recycling in order to maintain quality requirements
- Separate collection of paper should be strongly encouraged to maintain the quality of recovered paper. Recovered paper originating from multi-material collection systems, containing only material of a valuable recyclable nature, has to be specifically marked (see EN 643). It is not permissible to mix unmarked collections with other recovered paper and board.
- Recovered paper for recycling has to be collected separately from refuse (see EN 643). Collected paper segregated from refuse sorting stations is not suitable for use in the paper and board industry (see EN 643).
- The following paper streams are prohibited as raw materials for the production of paper and board intended to come into contact with foodstuffs by the Council of Europe Resolution 1:
  1. Contaminated waste paper and board from hospitals;
  2. Recovered paper and board which has been mixed with garbage and subsequently sorted out;
  3. Used stained sacks which have contained for example chemicals and foodstuffs;
  4. Covering materials, such as paper used for covering furniture during repair and painting work;
  5. Batches mainly consisting of carbonless copy paper;
  6. Waste paper from households containing used hygienic paper, such as used kitchen towels, handkerchiefs and facial tissue;
  7. Old archives from libraries, offices etc., if they contain PCBs.
- Recovered paper and board from households collected separately from other materials, if it is to be used in the production of food contact grades, must be inspected and if necessary sorted.

### **A3.3. Sorting-stations**

- Equipment and facilities are either used exclusively for sorting paper and board or, when used for sorting other materials, must be appropriately cleaned before sorting paper and board.
- Health, environment and safety procedures must apply.
- Adequate pest-control measures are taken.
- Sorted paper is properly classified according to the recovered paper grades established in EN643 or other agreed specifications.
- All paper mills, which produce paper and board that comes in direct contact with foodstuffs should be identified to the supplier.
- “Best Practice Recovered Paper Baling Conditions” are applied.

### **A3.4. Transportation**

- All transportation should conform to national and international transport and customs legislation.
- Transport conditions should be suitable to maintain quality requirements.

- Recovered paper for a mill producing paper and board, which comes into contact with foodstuffs, is to be clearly identified on the transport documents.

#### **A3.5. Recovered paper management systems**

- Suppliers of recovered paper should have a quality management system or nationally accredited system in place, which details how the above mentioned (items 2-4) are managed.

#### **A3.6. Purchasing of recovered paper**

- The relationship between suppliers of recovered paper and paper mills should take place according to the “Recovered Paper Quality Control Guidelines”.
- Any paper mill producing paper, which comes into contact with food, shall advise its suppliers of this fact.
- If recovered paper from households is to be used for the production of food contact grades of paper and board it is strongly recommended that it is collected separately from other dry recyclables. For such applications the industry’s intention is to phase out the use of material collected with other dry recyclables as soon as possible.
- Suppliers to mills have to be assessed.
- Purchaser can check suppliers’ management- system certificates and keep a record of suppliers’ performance. The mill will make information available to assist the supplier.

#### **A3.7. Mill gate**

- The delivery is checked against agreed conditions or according to the “Recovered Paper Quality Control Guidelines”.
- Control upon reception of raw materials must be carried out.
- Claims have to be made on receipt of the delivery; the supplier must have the chance to inspect the material together with the mill-staff and to take it back, if necessary.
- If there is a reason to believe that the lot includes paper from prohibited sources as defined under the Council of Europe resolution on food contact, the whole load will be taken back.

#### **A3.8. Storage at paper mills**

- Appropriate cleanliness and hygiene are to be maintained in raw material storage areas.
- Adequate pest control measures are taken.
- Where a mill produces both food and non food contact grades, appropriate measures must be in place to ensure that only the appropriate grades of recovered paper are used to produce food contact material.

#### **A3.9. Quality management at paper mills**

Mills would be expected to include procedures covering paper within their quality management systems, including:

- Purchasing;
- Receipt;
- Quality control;
- Storage of recovered paper and;
- Assessment of new recovered paper suppliers.

Mill sites producing paper and board intended to come into contact with foodstuffs must be operating the Good Manufacturing Practice (GMP) for paper and board for food contact.

### Traceability in the paper and board packaging chain<sup>8</sup>

#### A4.1 Purpose

This document gives guidelines for product traceability within the paper and board food packaging chain<sup>9</sup>.

#### A4.2 Scope

The guidelines cover paper and board and its converted products from the paper mill forward to the packer-filler stage. In accordance with EU Regulation 1831/2003, traceability and product recall cover *.....the materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture.....* Thus, these guidelines are principally to demonstrate full traceability and recall along the supply chain of the paper and board itself. Papermaking raw materials and certain additives used in subsequent processes are not materials and articles within the meaning of this Regulation. However, it may be necessary for the authorities or the manufacturer concerned to establish links to such materials to determine commercial or legal liability and details are included to facilitate how this might work in practice.

These guidelines do not cover tissue products.

#### A4.3 Food Uses of Paper and Board and its Converted Products

Although sold as “intended to come into contact with food” the physical properties of paper and board, as it leaves the paper mill, prevent any applications as a food packaging material until its dimensions have been reduced and it has been converted in some way. Examples of the food applications for the converted product include bags for confectionery, pizza boxes, bread wrap, chocolate interleaving, frozen food containers, vegetable boxes, sugar bags, beverage cartons and food service boards.

#### A4.4 Overview of the Flow Line

The processing chain for paper and board food packaging 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, both paper mills and separate companies will perform coating operations and some corrugating plants will produce only unprinted flat blanks whilst others will produce complete boxes and trays.

It is, thus, impossible to produce guidelines covering all aspects of the production and converting process. These guidelines can only explain best practice and the main principles are shown in Diagram 1 (not shown here). These principles will apply to any specific process, irrespective of the particular material flow and the type of plant in which it is performed.

8. This is an extract from EU Guidelines. The introductory text is shown in full but the diagrams referring to conversion processes are not shown as this GMP covers paper manufacture only.

9. Information provided, on behalf of their respective members, by the Confederation of European Paper Industries (CEPI) and the International Confederation of Paper and Board Converters in Europe (CITPA).

#### **A4.5 Examples of Packaging Processes and Products**

To illustrate the details of traceability, four typical packaging products have been selected (cartons for liquid food, corrugated boxes, paper for hot filtration and folding box board cartons) and the operation of traceability during their manufacture is shown in Diagrams 3 to 6 (not shown here). In addition, equivalent information for the papermaking process (which precedes all of the above operations) is shown in Figure 7. A Glossary of Terms is given in Table 4.

#### **A4.6 Special Consideration of Bulk Raw Materials**

A feature of many operations, in the paper and board packaging chain, is the use of bulk additives such as 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 batch operations. In both 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 recoded in a timed log, it is possible to relate the times at which the batch of additive concerned 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 not technologically feasible in a continuous, industrial process.

#### **A4.7 Product Recall**

One of the main purposes of the traceability requirements within Regulation 1935/2004 is to enable recall of defective product. Throughout all the stages of all the processes described in these guidelines, it can be seen that extensive documentation is in place both within the operations themselves and between organisations in the packaging chain. In particular, there is a clause in the Regulation which states:

*..... 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.*

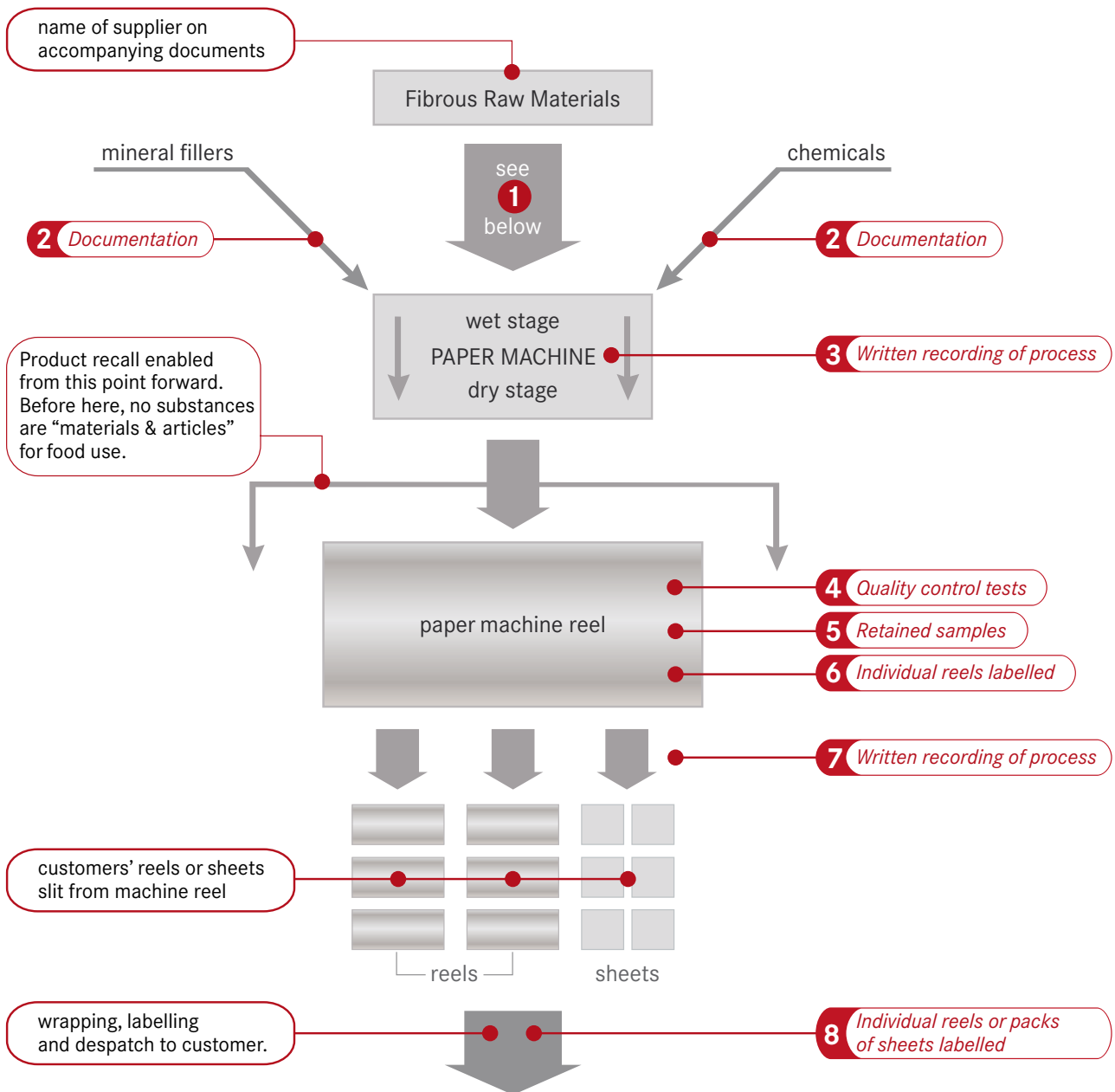
This requirement is fulfilled from the paper mill through to the final packaging product either in the form of identification on the product itself or contained in the accompanying documentation. It can be seen, in the diagrams, that large reels produced in a paper mill are subdivided many times to produce the final paper and board packaging products. Because of the extensive record keeping within all the processes of the paper packaging chain, both backward and forward product traceability and the identification of the source of any problem will be assured. The batch numbers and suppliers of all starting materials are recorded and internal records relate these to the packaging product itself. Thus, using forward traceability, the identification of affected product or starting materials 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 product.

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**Table 4 - Glossary of Terms (applicable to the Traceability Guidelines)**

<b>blank</b>	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
<b>calendering</b>	passing a <i>web</i> of paper between metal or fibre rollers in order to produce a more smooth or glossy appearance
<b>coating</b>	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
<b>converting</b>	any operation, applied after the normal paper or board manufacturing process, which changes the physical shape or appearance of paper and board e.g. <i>slitting</i> , cutting into sheets, bag and box manufacture, printing, etc.
<b>creasing</b>	the process of making an indentation in board materials in order to produce a line along which it may be folded. This enables the folding of a <i>blank</i> to produce a shaped package
<b>die cutting</b>	cutting or stamping a sheet or <i>web</i> of paper or board with a shaped knife to produce a special shape or <i>blank</i>
<b>extruder</b>	equipment used to produce a layer of plastic prior to <i>laminating</i>
<b>laminating</b>	the fixing of a ready-formed layer of plastic, paper, metal, etc. to paper or board normally using an adhesive
<b>palletising</b>	placing paper and board packaging products on to a pallet and then wrapping and labelling the whole unit
<b>sizing agent</b>	a liquid material applied to paper or board and used to improve its resistance to the penetration and spread of aqueous liquids, for example printing inks
<b>slitting</b>	the passing of a moving <i>web</i> of paper or board from a reel through knives resulting in the production of a number of reels of smaller width and/or diameter
<b>web</b>	a continuous length of paper or board travelling along a paper machine or through <i>converting</i> equipment

Figure 7 - Paper & Board Manufacture - Flow Diagram



**Details of Traceability Tools**

- 1 Woodpulp comes either from adjacent pulp mill or from pulp agent/importer. Recovered Paper is purchased according to industry guidelines for "Responsible Sourcing" which uses the "approved supplier" principle and covers, amongst other items, sorting, hygiene, transport, inspections and control of prohibited grades.
- 2 All batches of auxiliary raw materials are labelled with supplier name and batch number and accompanied by documentation stating, additionally, customer order number and date of supply.
- 3 A detailed, timed log is kept which records all relevant production activities and relates time of production to batch numbers of raw materials and final product reel numbers.
- 4 Quality control tests are performed. Records will show time of production as well as testing results.
- 5 Samples are taken from each paper machine reel and retained for a period appropriate to the packaging life-cycle. Examination of samples will enable identification and isolation of any defective material.
- 6 All paper machine reels are sequentially numbered, thus linking raw materials to customer orders.
- 7 Paper machine reels are slit into smaller reels. A timed log is kept which records machine reel number and defines from where, inside it, the slit reel originates and allocates a unique number to the latter.
- 8 All reels are marked and/or labelled with a unique number and supplier name. They may also carry order numbers and batch numbers. Bar code systems are normally used also. Documents accompany the order giving numbers and weights and/or lengths of reels, supplier and customer name.

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