



GMP

**International Good Manufacturing
Practice Standard**






For Corrugated & Solid Board

QUALITY, SAFETY, HYGIENE



INTERNATIONAL GOOD MANUFACTURING
PRACTICE STANDARD FOR CORRUGATED
AND SOLID BOARD PACKAGING

CONTENTS

		Introduction	3
		Scope of the standard	4
		Food safety and the production of board	4
		Process description	5
		Process flow	7
1		QUALITY MANAGEMENT	
		1.1 Hazard inventory	10
		1.2 Management responsibility	10
		1.3 Quality manual (links to ISO 9000)	12
		1.4 Document control	12
		1.5 Complaint handling	12
		1.6 Specification	14
		1.7 Product recall	14
		1.8 Traceability	14
		1.9 Supplier monitoring	16
		1.10 Internal audits	16
2		FACTORY STANDARDS	
		2.1 Site and premises	18
		2.2 Floors, walls, doors, windows and ceilings	18
		2.3 Glass and lighting	18
		2.4 Equipment and material	20
3		CONTAMINATION CONTROL	
		3.1 Tidying and cleaning	22
		3.2 Pest control	22
		3.3 Waste control	24
		3.4 Transport, storage and distribution	24
4		PERSONAL HYGIENE	
		4.1 Staff premises/toilet facilities	26
		4.2 Personnel and visitors	26
		4.3 Food and drinks	28
		4.4 Jewellery	28
		4.5 Smoking	28
		4.6 Clothing	28
		4.7 Education and training	30
5		APPENDIX	
		Audit protocol	33
		Glossary of terms used	41

INTRODUCTION

Corrugated and Solid Board are used for the packaging of a variety of goods. Both offer unique properties making them ideal for, but not limited to, transit packaging. Corrugated and Solid Board are widely used in food packaging. Corrugated Board is not mainly used for food contact. However, Solid Board is widely used for direct food contact.

As the requirements for safe foodstuffs have gradually grown more precise, and although specific regulations are yet to be finalised, FEFCO & ESBO, as the representatives of the European Corrugated & Solid Board industries, realised that it was necessary to take action to anticipate their customers' requirements.

The members of FEFCO have representatives in four major working groups that created four different hygiene standards in the period 1997 to 2001 as follows:

1. «Guide for good manufacturing practice of paper and board articles intended for food contact use»
published by the Club MCAS (France)
2. «Hygiene Code for Dutch Corrugated Board Industry»
published by Vereniging Golfkarton (Netherlands)
3. Technical Standard and Protocol for Companies Manufacturing and Supplying Food Packaging Materials for Retailer Branded Products:
published by BRC/IOP (UK)
4. «French professional code of hygiene and cleanliness for the manufacture of corrugated board packaging»
published by ONDEF (France).

To arrive at a uniform approach FEFCO & ESBO decided to form a working group that would use the best of the existing standards, and taking into consideration other standards such as American Institute of Bakery (AIB) to produce an International GMP standard for Corrugated & Solid Board. Corrugated and solid board are referred to as Board in the rest of this standard.

The working group decided that the standard has to give certification bodies the possibility to audit against the standard with a pre-defined audit format so uniformity and transparency could be guaranteed to the users of board.

Note: In the technical standard, 5 criteria are identified as «critical». Refer to the protocol (section 6) for the explanation of this term.

SCOPE OF THE STANDARD

«To cover the manufacturing of packaging made of corrugated and solid board so as to satisfy market demands for hygienic requirements such as exist in the food industry»

FOOD SAFETY AND THE PRODUCTION OF BOARD

When customers began to ask whether producers of Board had carried out HACCP studies, several producers did carry out evaluations.

All these evaluations showed that there were some potential microbiological, chemical and physical hazards but that the production of Board is completely different from the production of food. Critical Control points as found in the Food Industry were not found in the Board Industry. Because all potential Hazards can be controlled by Good Manufacturing Practices, the Board industry uses the terminology «point of attention» to define these aspects.

The process of the production of board is in principle the same in all plants, and a description of the process is part of this standard. The plants however may differ in age and layout and therefore an inventory of the hazards is made on an individual basis.

This GMP standard for Board does not purport to address the compulsory conformance of fibreboard articles to food contact regulations. All manufactured materials and articles intended for food contact, placed on the market is required to comply with the principles of the EU Regulation 1935/2004, and the provisions of all transposed national legislation. In the absence of harmonisation, materials and articles are required to comply with national regulations of the member state on whose territory the products are marketed, supplemented when necessary, by the appropriate provisions of other member states regulations under the principle of mutual recognition, or by other internationally recognised regulations or agreements in force.

PROCESS DESCRIPTION

Manufacturing of Corrugated Board

Corrugated Board is manufactured from a number of specially conditioned layers of recycled and/or virgin papers, called Fluting Medium and Linerboard. Reels of Fluting Medium and Linerboard are fed into a machine called a Corrugator. The Fluting Medium Paper is conditioned with heat and steam and fed between large corrugating rolls that give the paper its fluted shape in the Single Facer. Starch is applied to the tips of the flutes on one side and the inner liner is glued to the fluting. The corrugated fluting medium with one liner attached to it is called single face web and travels along the machine towards the Double Backer where the single face web meets the outer liner and forms corrugated board. A number of layers of single faced web may be built up to produce double and triple wall corrugated board. The corrugated board is slit into the required widths and cut into sheets where it is then stacked or palletised.

Manufacturing of Solid Board

Solid Board is manufactured from recycled cellulose fibres taken from waste paper and board. The waste paper and board is mixed with water and broken down in large tanks called Pulpers. The individual cellulose fibres are separated and cleaned by the combined action of water, chemicals, heat and mechanical energy. The resulting mixture is called pulp or stock. Contaminants such as plastic, metal, glass, polystyrene, etc. are removed from the mixture using screens and mechanical cleaners.

When the stock arrives at the board machine, its water content exceeds 97%. The mixture is sprayed or layered on to a moving screen called a wire. The filtering action of this wire, combined with vacuum, extracts a significant proportion of the water from the stock and forms a continuous sheet of board. The board is pressed between rolls to remove more water and then through a dryer where it comes into contact with large heated drums where much of the remaining water evaporates. State-of-the-art technologies such as infrared, air-knife and microwave drying are also used to ensure that the moisture content of the board is uniform. In-process checks are made on many of the important variables such as moisture content, smoothness, density and strength. The results are fed back to the control panel via computer where automatic adjustments are made. The board is slit into the required widths; it can be rewound onto reels or cut onto sheets and then palletised.

Laminating/Finishing (Solid Board)

Whilst the thickness of the Base Board may be adjusted on the board machine, it may also be built up by laminating several layers of Base Board together. To further enhance the properties of the Board such as strength, printability, aesthetics and water resistance, a variety of Papers or Liners are glued (laminated) on to the surface of the Base Board. Laminating may be done in-line on the board machine prior to slitting, or finished on a separate laminating machine by the converting plant.

Converting Corrugated and Solid Board into Packaging

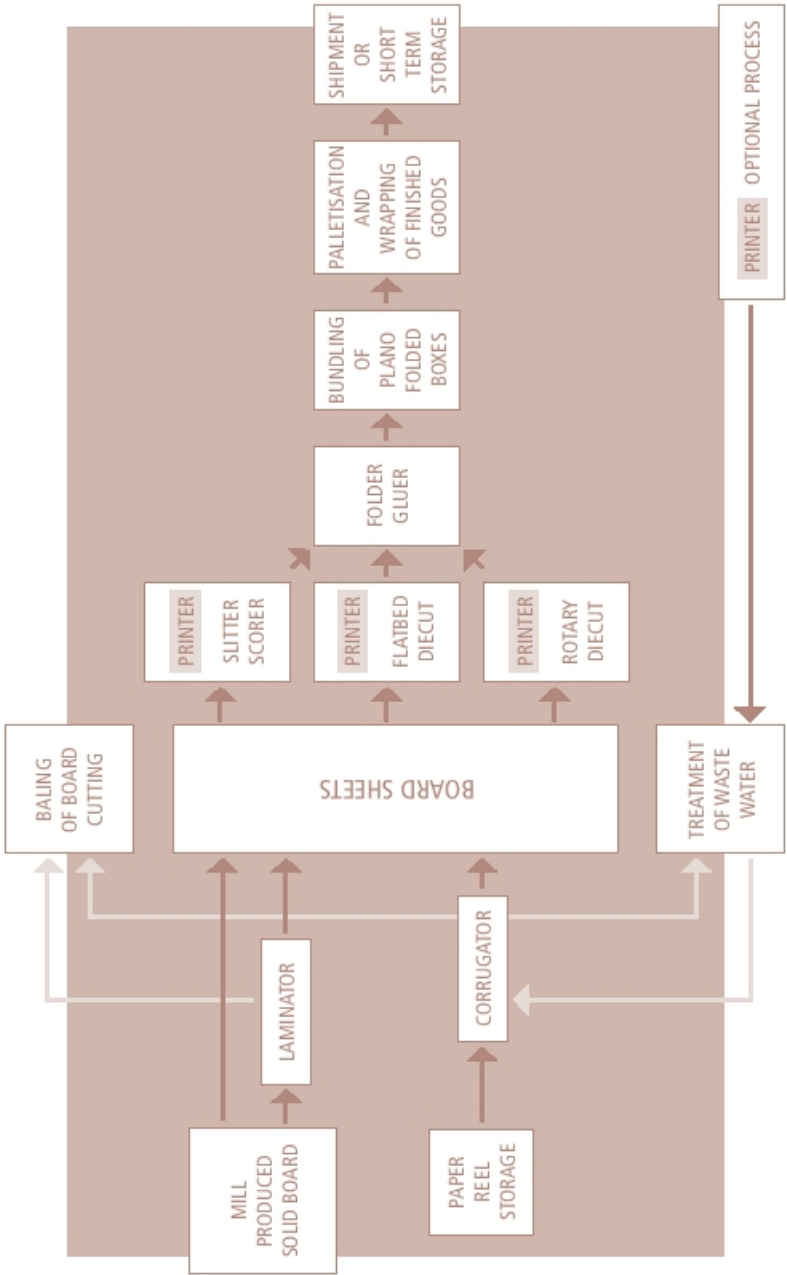
Board sheets where required may be printed to a Customer's design. The most common printing process is Flexographic. The sheets are then passed through a diecutting or a flexo folder gluer machine, where they are cut and creased to the required blank shape needed for folding into the final product. The equipment for printing and die cutting varies from individual manually operated machines to fully automatic in-line processes.

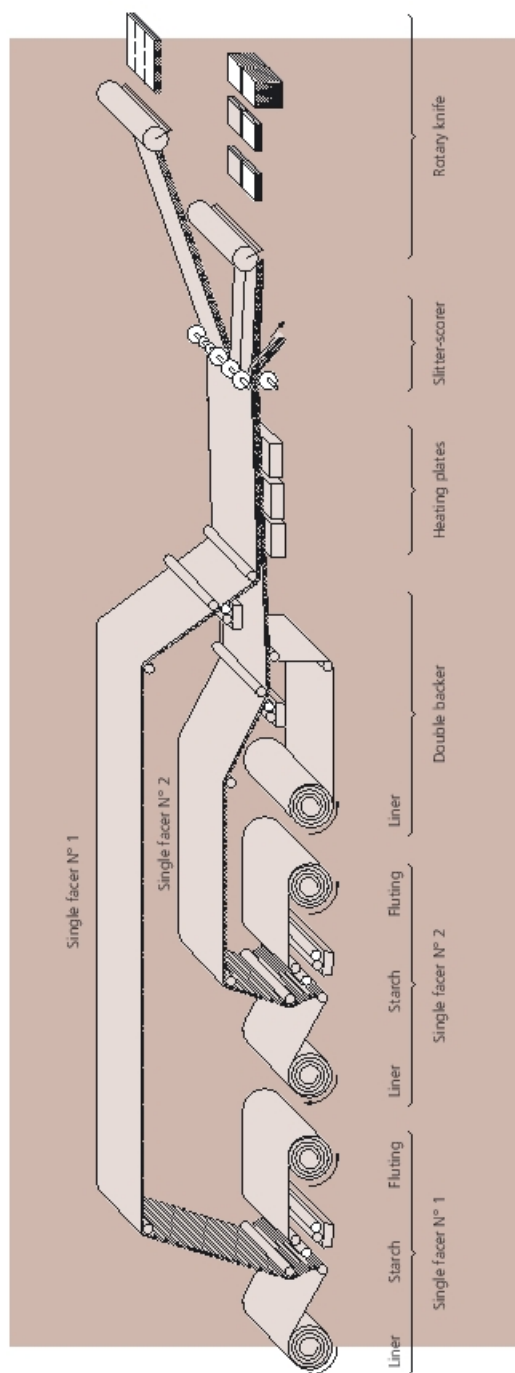
Die cut blanks may be supplied direct to customers, or passed through a Folder Gluer for converting into a variety of Box/Packaging types. After folder gluing the product is collated, bundled and strapped prior to palletisation and wrapping where it is ready for despatch.

Both Corrugated Board and Solid Board may be supplied to the customer at any stage of the process; as corrugated sheet, base board or laminated sheet; die cut blank; pre-converted packaging or finished boxes.

PROCESS FLOW

Flow Chart of a Typical Corrugated or Solid Board Converting Plant





International GMP Standard

QUALITY MANAGEMENT

1.1 HAZARD INVENTORY

- 1.1.1 The Company shall make an inventory of the hazards relevant to this Standard in its plant that can affect consumer safety and product integrity.
- 1.1.2 The hazard inventory shall be based on the range and the intended use of products that are manufactured.
- 1.1.3 The Company shall be able to demonstrate that appropriate controls and preventive measures for the identified hazards, as described in this Standard, are established. Important preventive measures shall be indicated as «points of attention».
- 1.1.4 A review of the hazard inventory should be carried out at least once per year or when any process changes.

1.2 MANAGEMENT RESPONSIBILITY

- 1.2.1 Senior management shall define the Company's Quality and Hygiene policy ensuring that the company meets its obligation to manufacture safe product in accordance with the relevant legislation. This policy shall be documented, implemented, maintained and communicated to all employees.
- 1.2.2 The controls and procedures, resulting from the hazard inventory, shall have Senior Management commitment, and shall be implemented through the Company's documented management systems.
- 1.2.3 The company shall have a person who is responsible for maintaining the hygiene and quality system.
- 1.2.4 The company shall periodically review customer complaints, claims, audit results and corrective actions.
- 1.2.5 The company should implement a system for continuous improvement.
- 1.2.6 The policy shall be regularly reviewed.
- 1.2.7 The company shall include duties related to this standard in the job descriptions of the staff.

PARA.	COMMENTS	+	-
1.1 HAZARD INVENTORY			
1.1.1			
1.1.2			
1.1.3			
1.1.4			
1.2 MANAGEMENT RESPONSIBILITY			
1.2.1			
1.2.2			
1.2.3			
1.2.4			
1.2.5			
1.2.6			
1.2.7			

1.3 QUALITY MANUAL

- 1.3.1 The Company shall have a Manual that states the Company's commitment to Good Manufacturing Practice and has a scope that covers the requirements of this Standard.
- 1.3.2 A Manual shall be maintained as an essential element of demonstrating compliance with this Standard.
- 1.3.3 Documents shall be clearly legible, unambiguous and sufficiently detailed to enable their correct application by appropriate personnel and shall be readily accessible at all times.

1.4 DOCUMENT CONTROL

- 1.4.1 The company shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this Standard.
- 1.4.2 Records shall be maintained in order to prove that technical and hygiene procedures have been followed. Records shall be kept for an appropriate period.
- 1.4.3 All documents in use shall be properly authorised and be the current version.
- 1.4.4 All changes and amendments to documents critical to product safety or quality system procedures and covered by the Standard's requirements shall be recorded.

1.5 COMPLAINT HANDLING

- 1.5.1 The Company shall have a system for the management of complaints.
- 1.5.2 Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively.
- 1.5.3 Complaint data shall, where appropriate, be used to implement ongoing improvements to safety and quality and action taken to seek actively to avoid recurrence.

PARA.	COMMENTS	+	-
-------	----------	---	---

1.3 QUALITY MANUAL

1.3.1			
1.3.2			
1.3.3			

1.4 DOCUMENT CONTROL

1.4.1			
1.4.2			
1.4.3			
1.4.4			

1.5 COMPLAINT HANDLING

1.5.1			
1.5.2			
1.5.3			

1.6 SPECIFICATION

- 1.6.1 The Company shall ensure that appropriate specifications exist for incoming materials and finished goods and that these specifications are adequate and accurate.
- 1.6.2 Specifications shall, where appropriate, be formally agreed with relevant parties.
- 1.6.3 The Company shall operate a specification review procedure.

1.7 PRODUCT RECALL

- 1.7.1 The company shall have an effective product recall procedure for all products.
- 1.7.2 The Company shall provide written guidance to relevant staff regarding the type of event that would constitute an «incident» and a documented incident reporting procedure shall be in place.
- 1.7.3 Procedures shall exist to ensure that customers are notified should an incident take place which has potentially contaminated the product that has been delivered to the customer.
- 1.7.4 All non-conforming products shall be handled or disposed of according to the nature of the problem and/or specific requirements of the customer.
- 1.7.5 There shall be a person responsible for ensuring that corrective action including the review of all records of incidents are taken together with preventative action.

1.8 TRACEABILITY

- 1.8.1 The company shall adequately identify all incoming materials and be able to trace work in progress and finished product at all stages during manufacture, storage, despatch and, where appropriate, distribution to the customer.
- 1.8.2 The storage times for the various production records shall be appropriate to the traceability requirements and the life time of the product.

PARA.	COMMENTS	+	-
1.6 SPECIFICATION			
1.6.1			
1.6.2			
1.6.3			
1.7 PRODUCT RECALL			
1.7.1			
1.7.2			
1.7.3			
1.7.4			
1.7.5			
1.8 TRACEABILITY			
1.8.1			
1.8.2			

1.9 SUPPLIER MONITORING (INCLUDING OUTSOURCING)

- 1.9.1 The Company shall operate procedures for the approval and monitoring of its suppliers. This shall include suppliers of materials, transport, warehousing and services to the Company, where appropriate, to the requirements of this Standard.
- 1.9.2 Where appropriate, suppliers of materials shall comply with a Standard that meets the same objectives as this standard.

1.10 INTERNAL AUDITS

- 1.10.1 The Company shall have an internal audit schedule and its scope and frequency shall be established in relation to the hazard inventory.
- 1.10.2 A record of all programmed internal audits and associated corrective actions shall be maintained. Corrective action shall be verified to ensure satisfactory completion.
- 1.10.3 Internal audits shall be carried out by competent auditors, who should be independent of the area of operation being assessed.
- 1.10.4 Results of the internal audits shall be monitored by senior management to see if the goals are achieved.

PARA.	COMMENTS	+	-
-------	----------	---	---

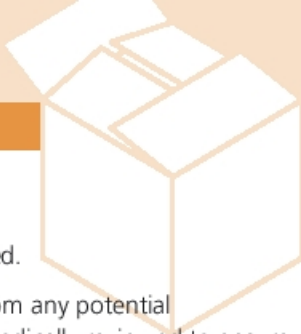
1.9 SUPPLIER MONITORING (INCLUDING OUTSOURCING)

1.9.1			
1.9.2			

1.10 INTERNAL AUDITS

1.10.1			
1.10.2			
1.10.3			
1.10.4			

FACTORY STANDARDS



2.1 SITE AND PREMISES

- 2.1.1 The site boundaries shall be clearly defined.
- 2.1.2 Measures necessary to protect the site from any potential contaminants should be in place and periodically reviewed to ensure they continue to be effective.
- 2.1.3 Both inside and outside the premises, sufficient space shall be left between walls, furniture, equipment and products to enable efficient cleaning.

2.2 FLOORS, WALLS, DOORS, WINDOWS AND CEILINGS

- 2.2.1 The doors, walls and ceilings should prevent entry of pests.
- 2.2.2 Walls, floors, ceilings and pipes shall be maintained in good condition and shall be capable of being kept clean.
- 2.2.3 Where windows are designed to be opened for ventilation purposes, they shall be adequately screened to prevent the access of pests.
- 2.2.4 During maintenance activities, those carrying them out shall take into consideration that dust, metal particles or other contaminating elements may be released.
- 2.2.5 Flaking or damaged spots shall be repainted or treated.
- 2.2.6 Doors providing access to production areas shall be kept shut when not in use.

2.3 GLASS AND LIGHTING

- 2.3.1 **(critical)** The company shall have in place a procedure for glass and hard clear plastic breakage. The procedure shall establish clear responsibilities and shall describe what actions shall be taken with the contaminated product.



PARA.	COMMENTS	+	-
2.1 SITE AND PREMISES			
2.1.1			
2.1.2			
2.1.3			
2.2 FLOORS, WALLS, DOORS, WINDOWS AND CEILINGS			
2.2.1			
2.2.2			
2.2.3			
2.2.4			
2.2.5			
2.2.6			
2.3 GLASS AND LIGHTING			
2.3.1			

- 2.3.2 Where applicable, adequate shatterproof lighting shall be installed.
- 2.3.3 The company shall remove all unnecessary glass and hard plastics from production areas.

2.4 EQUIPMENT AND MATERIAL

- 2.4.1 Maintenance equipment shall be cleared away after use and stored in designated areas or lockers.
- 2.4.2 A planned preventive maintenance programme for plant and machinery shall be in place and shall address the risks from contamination. Compressed air that comes into contact with the product should be filtered to prevent any contamination.
- 2.4.3 Production tools used shall be clean and shall be stored in a designated area.
- 2.4.4 Maintenance work shall be followed by a documented hygiene clearance procedure which demonstrates that contamination hazards have been removed from machinery and equipment where there is a risk of contamination to the product.
- 2.4.5 Where appropriate, food grade lubricants shall be used.
- 2.4.6 Hygiene and cleanliness should be taken into account when planning new equipment.
- 2.4.7 Where appropriate, equipment shall be available for the effective ventilation of odours, smoke and vapour.
- 2.4.8 Materials handling equipment that comes into direct contact with the product shall be kept in good condition.
- 2.4.9 Cutters with snap-off blades shall be prohibited.
- 2.4.10 Temporary «engineering and modifications» using adhesive tape, cardboard or similar materials shall not be permitted, except in emergencies.

PARA.	COMMENTS	+	-
2.3.2			
2.3.3			

2.4 EQUIPMENT AND MATERIAL

2.4.1			
2.4.2			
2.4.3			
2.4.4			
2.4.5			
2.4.6			
2.4.7			
2.4.8			
2.4.9			
2.4.10			

CONTAMINATION CONTROL

3.1 TIDYING AND CLEANING

- 3.1.1 **(critical)** The company shall have an effective cleaning procedure and schedules in place for all equipment, production and storage areas. **!**
- 3.1.2 Accumulated dust shall be removed on a regular basis (including corners and behind pallets and reels).
- 3.1.3 A high standard of cleanliness should be maintained at all stages of storage, processing and distribution. A «clean as you go» policy should be in operation.
- 3.1.4 Cleaning equipment and materials should be stored and maintained in a manner to prevent product contamination.
- 3.1.5 Production and other relevant staff shall be trained in cleaning.
- 3.1.6 Outside contractors shall be aware of and adhere to the Company hygiene procedures.
- 3.1.7 All cleaning agents and disinfectants used shall be suitable for their intended purpose and used in accordance with the operating instructions.
- 3.1.8 All glue, ink drainage and waste disposal devices shall be kept clean.

3.2 PEST CONTROL

- 3.2.1 **(critical)** Pest control procedures shall be documented and preferably be carried out by a competent company. Control records shall be maintained. **!**
- 3.2.2 Documentation shall detail the safe use and application of baits.
- 3.2.3 Pest control shall be in place in all areas of the premises. The control shall include birds.
- 3.2.4 Incoming materials, ancillary materials and finished products shall be stored so as to minimise the risk of infestation.
- 3.2.5 Baits, traps and electric fly killer units shall preferably be monitored at a minimum of four times a year. Records of checks shall also identify any actions taken.

PARA.	COMMENTS	+	-
3.1 TIDYING AND CLEANING			
3.1.1			
3.1.2			
3.1.3			
3.1.4			
3.1.5			
3.1.6			
3.1.7			
3.1.8			
3.2 PEST CONTROL			
3.2.1			
3.2.2			
3.2.3			
3.2.4			
3.2.5			

- 3.2.6 The location of all pest control measures shall be identified on a plan/diagram of the site. They shall not endanger the product by chemicals or dead pests.
- 3.2.7 For an effective operation, electric fly killer units shall be regularly maintained and cleaned. The tubes shall be replaced on failure and at least once a year.
- 3.2.8 Incoming materials that have a high risk of contamination by pests shall be examined to ensure that no pests are introduced.

3.3 WASTE CONTROL

- 3.3.1 Systems shall be in place to minimise the accumulation of waste in production areas.
- 3.3.2 A system for structural cleaning, emptying bins and waste collection shall be in place.

3.4 TRANSPORT, STORAGE AND DISTRIBUTION

- 3.4.1 All transport shall be suitable for the purpose, well maintained and in a state of good hygiene.
- 3.4.2 Ongoing contractual arrangements with transport companies shall include requirements for hygiene and cleaning.
- 3.4.3 When the material transported is susceptible to weather damage, arrangements shall be made to protect the material.
- 3.4.4 The Company shall have a procedure for checking vehicles transporting finished products for cleanliness and water tightness.
- 3.4.5 Incoming and outgoing vehicles shall be registered and non-conformities recorded.
- 3.4.6 Contracted transport, storage and distribution shall be undertaken in such a way as to prevent raw materials or product being exposed to the risk of contamination, including taint or odour.
- 3.4.7 All pallets shall be sound, dry, clean and free from damage, visible infestation, taint and odour.
- 3.4.8 Storage including off site storage shall be controlled to ensure no cross contamination from any other material can occur.
- 3.4.9 No manufactured products shall come in direct contact with the floor.

PARA.	COMMENTS	+	-
3.2.6			
3.2.7			
3.2.8			
3.3 WASTE CONTROL			
3.3.1			
3.3.2			
3.4 TRANSPORT, STORAGE AND DISTRIBUTION			
3.4.1			
3.4.2			
3.4.3			
3.4.4			
3.4.5			
3.4.6			
3.4.7			
3.4.8			
3.4.9			

PERSONAL HYGIENE

4.1 STAFF PREMISES/TOILET FACILITIES

- 4.1.1 All personnel and contractors likely to enter production areas shall wash their hands after using the toilet and eating.
- 4.1.2 Adequate toilet areas shall be provided and kept clean on a regular basis.
- 4.1.3 Hand washing facilities shall be easily accessible and close to the production areas.
- 4.1.4 Wash basins should preferably be provided with non-scented liquid soap in dispensers. Dispensed disposable paper towels, with purpose made waste bins, provide the most hygienic way of drying hands. All towel bins shall be lined and should be emptied regularly in accordance with a schedule. Towels bins with lids should be foot operated.
- 4.1.5 The company shall have signs at all relevant entry points with an overview of the company rules with regard to hygiene.
- 4.1.6 The company shall provide adequate lockers.

4.2 PERSONNEL AND VISITORS

- 4.2.1 Staff shall have a copy of the rules on personal hygiene.
- 4.2.2 When visiting the company, every visitor is bound by the applicable hygiene regulations and the need for observing them. This also applies to external fitters or technicians.
- 4.2.3 Personal belongings shall not be taken into the production areas.
- 4.2.4 The company shall have a code of conduct for third parties (such as temporary employees, subcontractors, drivers).
- 4.2.5 Personnel shall report if they are suffering from, or have been in contact with, any disease likely to be transmitted through food, or from infected wounds, skin complaints or diarrhoea. All personnel suffering from any of the above shall be excluded from situations involving contact with food packaging for as long as the symptoms persist.

PARA.	COMMENTS	+	-
4.1 STAFF PREMISES/TOILET FACILITIES			
4.1.1			
4.1.2			
4.1.3			
4.1.4			
4.1.5			
4.1.6			
4.2 PERSONNEL AND VISITORS			
4.2.1			
4.2.2			
4.2.3			
4.2.4			
4.2.5			

- 4.2.6 Minor injuries such as cuts shall be covered with dressings that are easily visible and capable of detection in food processing operations.

4.3 FOOD AND DRINKS

- 4.3.1 **(critical)** Eating (including the eating of confectionery and chewing of gum) and drinking, shall only be allowed in designated areas that are indicated by signs in the production areas.



- 4.3.2 The company shall provide facilities for adequate storage of food and drink, including that brought from home. Drinking of water from purpose-made dispensers and/or by using only disposable cups may be allowed provided it is confined to a designated area away from equipment.

4.4 JEWELLERY

- 4.4.1 Jewellery shall not be worn, with the exception of one plain band finger ring and 'sleeper' earrings. Wristwatches are allowed. Rings and studs in other exposed parts of the body such as noses and eyebrows shall not be worn, or covered with dressings which are easily visible and capable of detection in food processing operations.

4.5 SMOKING

- 4.5.1 **(critical)** Smoking shall not be allowed in the production areas. If it is impractical for personnel to leave their work area, local controlled facilities shall be provided. *



- 4.5.2 Designated, enclosed and controlled smoking areas shall be isolated from production areas to an extent that ensures smoke cannot reach the product. Sufficient extraction to the exterior of the building shall be ensured. Adequate arrangements for dealing with smokers waste shall also be provided at smoking facilities, both inside buildings and at exterior locations. Facilities shall be available, with adequate reminders, for hand washing after smoking.

* **Remark:** A National legislation on smoking may overrule this criticism of the GMP standard and becomes in such case leading.

PARA.	COMMENTS	+	-
4.2.6			
4.3 FOOD AND DRINKS			
4.3.1			
4.3.2			
4.4 JEWELLERY			
4.4.1			
4.5 SMOKING			
4.5.1			
4.5.2			

4.6 CLOTHING (INCLUDING SUBCONTRACTORS AND TEMPORARY EMPLOYEES)

- 4.6.1 Working clothes, as defined in the Company's procedures, shall be worn at all times in the production areas and shall not be worn outside the perimeter of the plant.
- 4.6.2 The company shall have arrangements for working clothes including laundering, for all production personnel as well as for cleanliness and proper use. Self-care shall be permitted provided adequate controls and appropriate guidelines are in place.
- 4.6.3 Visitors and non-production staff shall wear adequate protective clothing when entering production areas.
- 4.6.4 If necessary and where appropriate hair covering shall be worn for operators who come in direct contact with the products.

4.7 EDUCATION AND TRAINING

- 4.7.1 All new personnel shall receive induction training covering the company hygiene rules before starting work.
- 4.7.2 A programme of refresher hygiene training shall be in place and records shall be maintained for all staff that have been trained.

AUDIT PROTOCOL

For auditing against the

International Good Manufacturing Practice Standard
for Corrugated & Solid Board

AUDIT PROTOCOL

CONTENTS

1. Introduction
2. Contractual arrangements and selection of the audit body
3. Audit notification
4. Scope of the audit
5. Audit flow
6. Level determination
7. Implications of results on issuing the audit report and certificate
8. Audit frequency
9. The audit report
10. Distribution of the audit report
11. Appeal procedure
12. Complaints
13. Copyright

1. INTRODUCTION

This audit protocol provides the specific requirements for those organisations involved with evaluations to the International Good Manufacturing Practice Standard for Corrugated & Solid Board.

This protocol will:

- Reinforce the standards required for those organisations carrying out audits; specifically through accreditation against EN 45011,

and

- Clarify for those organisations being audited, procedures to follow, ensuring contractual agreements are met.

Only those audit bodies that have accreditation to EN 45011 shall carry out audits against the International Good Manufacturing Practice Standard for Corrugated & Solid Board and issue reports and certificates. Organisations shall comply with the requirements of the accreditation standard, which are provided by a recognised Accreditation Body.

2. CONTRACTUAL ARRANGEMENTS AND SELECTION OF THE AUDIT BODY

The auditee shall appoint an appropriate body to perform the audit against the International Good Manufacturing Practice Standard for Corrugated & Solid Board preferably working with auditors who speak the native language of the auditee.

The audit body shall demonstrate its competence by gaining accreditation to EN 45011 and the specific requirements that the Accreditation Body demands for auditing against the International Good Manufacturing Practice Standard for Corrugated & Solid Board.

Audit bodies that are in the process of becoming accredited are allowed to carry out audits prior to achieving accreditation status, where they can demonstrate all of the following:

- An active application for EN 45011 accreditation
- Accreditation status to be achieved within 12 months of the date of application
- Individual auditor experience and qualification to be in line with the demands of the International Good Manufacturing Practice Standard for Corrugated & Solid Board

It is the responsibility of the auditee to verify that these requirements are met, by either requesting a copy of the accreditation certificate (or acknowledgement of application) and scope, or contacting the Accreditation Body that is responsible for the accreditation process of the audit body.

A contract shall exist between the auditee and the audit body, detailing the scope of the audit.

The auditee shall be in possession of an original copy of the latest version of the International Good Manufacturing Practice Standard for Corrugated & Solid Board in its full integrity, this shall be checked by the auditing body during the audit process.

3. AUDIT NOTIFICATION

Preparation for the audit

Before the documentation audit the auditee is required to review the International Good Manufacturing Practice Standard for Corrugated & Solid Board. It is the responsibility of the auditee to have the latest version of the standard

Documentation audit

Before the initial visit on site, the audit body shall carry out an audit on the quality management documents, including the hazard inventory. The resulting report from this audit is for the internal use of the auditee. The audit body shall check the corrective actions that are identified by the auditee, when nonconformities are found during the initial audit. A documentation audit is only required before the initial audit.

Initial audit

The first audit by the audit body will take place on a mutually convenient date. The result of the audit will have an effect on the frequency of the repeat-audits.

Follow-up audits

Follow-up audits shall be carried out when the auditee did not comply with the demands of the standard during the initial audit. At the follow-up audit, the audit body shall focus on the nonconformities only. If the auditee shows that all the nonconformities have been dealt with, the audit body may issue the certificate.

Repeat audits

The frequency of the repeat audit is determined by the result that was achieved at the last audit. The due date for the repeat audit will be detailed in the audit report and on the certificate.

It is the responsibility of the auditee to contact the auditing body to ensure that a mutually convenient date for the repeat audit is arranged before the due date of that audit.

4. SCOPE OF THE AUDIT

The scope of the audit shall be defined between the auditee and the audit body. The scope shall be stated in the audit report and on the certificate. All relevant product groups that are produced at a selected location should be audited against the standard. The audit is specific to the location where the audit has taken place. This shall be clearly defined in the report.

5. AUDIT FLOW

To define the time that is necessary for the audit, the audit body shall use a system that ensures sufficient time is planned for the audit. The physical size of the site, the type of manufacturing process and the scope will determine the time required to carry out a full audit.

An audit on site shall consist of four elements:

- Opening meeting
- Documentation check on site
- Site assessment
- Closing meeting

During the audit interviews shall be carried out at both management level and operator level.

The auditor shall audit the operation using the specific criteria on all the subjects in the International Good Manufacturing Practice Standard for Corrugated & Solid Board.

In accordance with EN 45011, the auditor can only give a preliminary judgement on the status of the company. After the receipt of the corrective action plan from the auditee, a final judgement can be made, a formal audit report issued and when appropriate a certificate awarded. (See also Section 6 for an explanation of the level determination).

6. LEVEL DETERMINATION

In order to determine whether the requirements of a clause in the International Good Manufacturing Practice Standard for Corrugated & Solid Board has been met, the auditor shall check every item in the standard. The auditor shall rank his findings as follows:

- A: In full compliance with the criterion in the standard
- B: Only partly in compliance with the criterion in the standard
- C: Not in compliance with the criterion in the standard.

The auditor shall provide reasons for raising all B and C nonconformities in the audit report.

How to interpret minor's and majors.

After ranking the audit findings with an A, B or C, the auditor has to determine whether the B or C ranking is a critical, a major or stays a minor (B or C).

MINOR NONCONFORMITY

Every failure to meet a requirement in the Standard that is awarded a B or C ranking is seen as a minor non-conformity if:

1. The auditor **does not classify it as:** «a substantial failure to meet all full clauses of the standard and/or a failure that can lead directly to contamination of the product» (if the auditor does not classify it as a major non-conformity);
2. The number of non-conformities per chapter classified as a C does not exceed the limit that is prescribed (see major non-conformity).

MAJOR NONCONFORMITY

A substantial failure to meet all full clauses of the Standard and/or a failure that can lead directly to contamination of the product.

1. A full clause of the standard means the whole paragraph, for example clause 1.3 Quality Manual. In case all the sub clauses of this clause (so sub clause 1.3.1 to 1.3.3) are classified as C minors, the full clause will receive a major;
2. It is the role of the auditor to judge if a situation in the operation being audited, can directly lead to contamination of the product.

3. There is also a limit on the number of non-conformities classified as C per chapter. If the number of C's exceeds the limit which is given in the table, the total per chapter will turn into a major non-conformity:

Chapter 1 more than 15 C's

Chapter 2 more than 10 C's

Chapter 3 more than 11 C's

Chapter 4 more than 10 C's

CRITICAL CRITERIA

The 5 critical criteria have to be in full compliance (judged as A) or in part compliance (judged as B).

When an auditor finds a critical criterion which is not in compliance (judged as C), the audit is terminated, the auditee has to take effective corrective actions and a new audit has to be performed.

Note: Critical criteria are sometimes named «KNOCKOUT» or «KO» criteria.

7. AUDIT RESULTS AND ISSUING THE AUDIT REPORT AND CERTIFICATE

Level of found non-conformity	Status closing meeting	Corrective actions	Report	Certificate
C-ranking on a Critical	Unable to recommend certification	Auditee has to take corrective actions and a new audit is required to verify compliance	Report confirms status	Cannot be issued
B-ranking on a Critical	Recommended to certification provided an acceptable corrective action plan & evidence is received	Send in corrective action plan and objective evidence within 4 weeks of receiving preliminary report: major NC's shall be addressed in it	The report including a corrective action plan confirms the status.	Can only be issued in case the corrective action plan and objective evidence show solving of NC. In case corrective action plan and evidence are not adequate, certificate is not issued

Level of found non-conformity	Status closing meeting	Corrective actions	Report	Certificate
Major non-conformity at initial audit	Unable to recommend certification	Send in action plan within 4 weeks of receiving preliminary report: major NC's shall be addressed in it. A follow-up will take place within 6 months	Report including corrective action plan confirms status	Cannot be issued. Certificate of approval can only be awarded after satisfactory evidence during a follow-up audit that NC has been eliminated.
Major non-conformity at repeat audit	Recommended to certification provided an acceptable corrective action plan & evidence is received	Send in corrective action plan and objective evidence within 4 weeks of receiving preliminary report: major NC's shall be addressed in it	Report including corrective action plan confirms status	Can only be issued in case the corrective action plan and objective evidence show solving of NC. If case action plan and evidence are not adequate, certificate is not issued
Minor non-conformity	Recommended to certification provided an acceptable corrective action plan & evidence is received	Send in corrective action plan and objective evidence within 4 weeks of receiving preliminary report: minor NC's shall be addressed in it	Report including corrective action plan confirms status	Can only be issued in case the corrective action plan and objective evidence show solving of NC. If case corrective action plan and evidence are not adequate, certificate is not issued

The audit body shall send the auditee a preliminary report so that the auditee has sufficient time to write a corrective action plan.

The auditee shall always write a corrective action plan before a final report is issued. This corrective action plan is incorporated into the final report so that a reader of the report can see the actions that the auditee is going to take on the nonconformities found.

8. AUDIT FREQUENCY

The audit frequency depends on the result of the audit.

C-ranking on critical (KO)	A complete new audit has to be performed. Term in which this new audit is scheduled, depends on the time the auditee needs to take effective corrective action for solving C-ranking
B-ranking on critical (KO)	Follow-up audit within 6 months; after that 12 months
Major NC during initial audit	Follow-up audit within 6 months; after that 12 months
Major NC during repeat audit	12 months
Minor NC during initial or repeat audit	12 months

The repeat audit date shall be calculated from the date of the previous audit and not the date of certificate issue.

9. THE AUDIT REPORT

Following each audit a full written report shall be prepared in an agreed format.

The audit body is required to provide reasons for raising all critical, major and minor nonconformities. It is appreciated that sections of the report may be shortened or lengthened to meet specific reporting needs, but the overall format of the report shall remain unchanged and comply with specific requirements.

The audit report should provide transparency and trust for the reader. The auditee shall write a corrective action plan that is incorporated into the final report. In this way the reader of a report can see the nonconformities raised but also the corrective actions that the auditee is initiating.

The report shall contain the following sections:

- Audit summary with detailed description of the scope
- Summary and overview of nonconformities per chapter.
- Corrective action plan from the auditee with the actions on all nonconformities.
- Detailed listing of findings with reasons for critical, major and minor nonconformities.

Reports shall be prepared and despatched to the auditee within an agreed timescale.

Prescribed report format of FEFCO / ESBO

FEFCO / ESBO have developed a format for writing the audit report. It's obliged to use this format.

10. DISTRIBUTION OF THE AUDIT REPORT

Audit reports shall remain the property of the auditee and shall not be released, in whole or part, to a third party unless the auditee has given prior consent (unless otherwise required by law)

This consent for distribution can only be in written form and can exist between the auditee and the audit body and between the auditee and a customer. The audit body shall retain a copy of the audit report. The audit report shall be stored safely and securely for a period of five years.

11. APPEAL PROCEDURE

The audit body shall have documented procedures for the consideration and resolution of appeals against the results of audits. Procedures shall be independent of the individual auditor and shall be considered by the top management of the audit body. Appeals shall be finalised within 4 weeks of receiving information from the auditee.

12. COMPLAINTS

The audit body shall have a documented procedure for dealing with complaints received from the auditee and other relevant parties. An initial response will be given within 2 weeks of receipt of the complaint. A full written response will be given after the completion of thorough investigation into a complaint.

13. CERTIFICATE

FEFCO will issue a unique number for each certificate. This number can be used to trace the information of the auditee on the FEFCO website www.fefco.org.

If the certification body has issued a certificate to a certified firm, they are required to inform FEFCO. This will be done by sending or faxing the issued certificate to FEFCO.

14. COPYRIGHT

The copyright of the International Good Manufacturing Practice Standard for Corrugated & Solid Board is under full ownership of FEFCO. If unauthorised use of the standard and its protocol should occur, FEFCO will take the appropriate actions.

GLOSSARY OF TERMS

Audit	A systematic examination to substantiate whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Consumer	The end user of an item, commodity or service.
Contractor / Supplier	A person or organisation providing services or materials.
Control	a) To manage the conditions of an operation to maintain compliance with established criteria, and/or, b) The state wherein correct procedures are being followed and criteria are being met.
Corrective action	Procedure to be followed when a system requirement is not met.
Customer	A person or organisation that acquires, or is intended to acquire, ownership of the product <i>and/or service</i> .
Good Manufacturing Practice	The combination of manufacturing and quality control procedures aimed at ensuring that products are consistently manufactured to their specifications.
Hazard	The potential to cause harm; can be a biological, chemical or physical entity.
Hazard inventory	An inventory of all <i>relevant</i> hazards.
Hygiene	All measures necessary to ensure the wholesomeness, quality and safety of an entity that might otherwise be hazardous.
Incident	An incident is any event that may potentially compromise the hygiene standard of the product.
Incoming materials / raw materials	Any base material or semi-finished material used by the organisation for manufacture of a product.
Non-conformities	The non-fulfilment of a specified product safety, legal or quality requirement or of a specified system requirement.
Preventive measure	Any factor or activity that can be used to prevent an identified hazard.
Procedure	Description of a particular course of action.
Product recall	Procedure to ensure the immediate return from the entire supply chain, including the consumer, of all products identified as potentially having a non-conformity, which could present a hazard.

Quality manual	Document specifying the quality management system of an organization.
Quality system	A management system to direct and control an organization with regard to quality.
Record	Written or otherwise permanently recorded account of a fact or event.
Specification	An explicit or detailed description of a material, product or service.
Traceability	Ability to trace the history, application or location of that which is under consideration.
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.
Pest	<p>Any living organism (excluding human beings) with the potential to cause physical or biological contamination within a manufacturing operation.</p> <p>Note: the organisms specifically requiring attention in board manufacturing and converting operations are rodents, birds and flying and crawling insects including those with the potential to cause infestations such as psocids.</p>



GMP Certification Stamp

ISBN 90-77-505-06-7

*Published by: FEFCO (European Federation of Corrugated board manufacturers)
In cooperation with ESBO and ISA*

250, avenue Louise - B-1050 Brussels

*Telephone: + 32 2 646 40 70 - Fax: + 32 2 646 64 60
e-mail: information@fefco.org - Web site: www.fefco.org*

*Copyright FEFCO
January 2006 Second Edition*

