FEFCO GMP

International Good Manufacturing Practice Standard for Corrugated Board



GMP CERTIFICATION STAMP





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Introduction

Corrugated Board is used for the packaging of a variety of goods. It offers unique properties making it ideal for, but not limited to, transit packaging. Corrugated Board is widely used in food packaging. Corrugated Board is not only used for food contact.

As the requirements for safe foodstuffs have gradually become more stringent, and although specific regulations are yet to be finalised, FEFCO, as the representative of the European Corrugated Board industry, realised that it was necessary to take action to anticipate their customer requirements.

The members of FEFCO took part creating a standard that created four different hygiene standards in the period 1997 to 2001 as follows:

- Guide for Good Manufacturing Practice of Paper and Board Articles Intended for Food Contact Use published by the Club MCAS (France).
- Hygiene Code for Dutch Corrugated Board Industry published by Vereniging Golfkarton (Netherlands).
- Technical Standard and Protocol for Companies Manufacturing and Supplying Food Packaging Materials for Retailer Branded Products published by BRCGS (IOP) (UK).
- French Professional Code of Hygiene and Cleanliness for the Manufacture of Corrugated Board Packaging» published by ONDEF (France).

To achieve a uniform approach FEFCO decided to form a working group that would use the best of the existing standards, taking into consideration other standards such as American Institute of Bakery (AIB International) to produce an International GMP standard for Corrugated Board.

Corrugated board is referred to as Board in the rest of this standard.

The responsible committee 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 corrugated product.

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

Scope of the Standard

To cover the manufacturing of packaging made of corrugated so as to satisfy policy and market requirements for Good Manufacturing Practice such as required by the manufacturing of food contact materials.

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. All potential hazards can be controlled by Good Manufacturing Practices, and the Board industry uses the terminology "Point of Attention" instead of "Critical Control Point" 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 a hazard analysis and risk assessment 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 are required to comply with the principles of the EU Regulation 1935/2004 and EC Regulation 2023/2006 on good manufacturing practices, 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.

The first edition of the FEFCO GMP Standard was issued in the year 2003, followed by a second edition in January 2006, and the third was published in November 2019.

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.

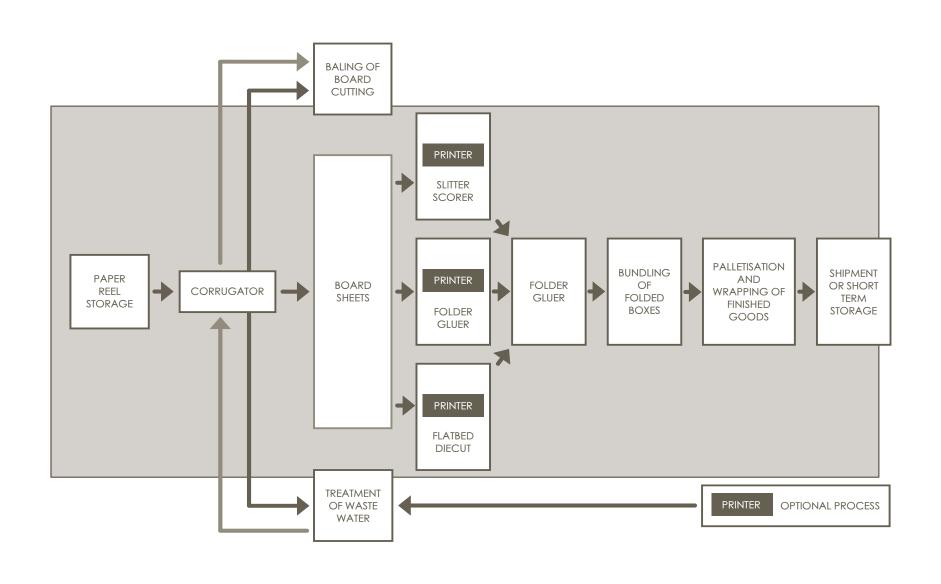
Converting Corrugated Board into Packaging

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 die cutting 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.

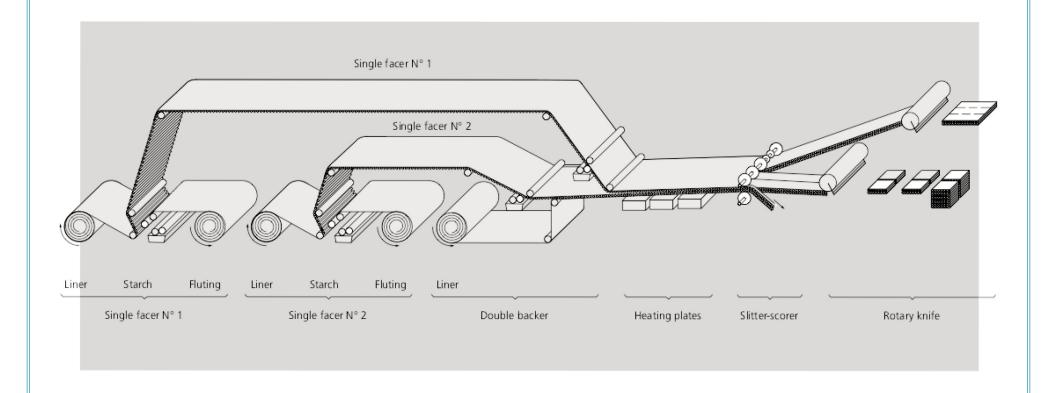
Die cut blanks may be supplied direct to customers or passed through a Folder Gluer for converting into a variety of Box/Packaging types. After folder gluing the product is collated, bundled and strapped prior to palletisation and wrapping where it is ready for dispatch.

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

PROCESS FLOW CHART: FLOW CHART OF A TYPICAL INTEGRATED CORRUGATED BOARD PLANT



CORRUGATOR MACHINE: PROCESS FLOW OF THE CORRUGATOR



GMP STANDARD REQUIREMENTS



1. QUALITY MANAGEMENT

1.1 Hazard Analysis and Risk Assessment

- 1.1.1 The Company shall have a documented hazard analysis and risks assessment for every stage in the process from procurement to delivery of the product. It shall include all reasonably foreseeable risks that can affect consumer safety and product integrity.
- 1.1.2 The scope of the hazard analysis and risk assessment shall be based on the range and the intended use of the products that are manufactured.
- 1.1.3 The Company shall be able to demonstrate that appropriate controls and preventive measures for the identified hazards and risks are established. Important controls and preventive measures should be managed as a "Preventive Program" (PRP).
- 1.1.4 A review of hazard analysis and risk assessment shall be carried out at least once per year or when process changes, or after management reviews.

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 analysis and risk assessment shall have Senior Management commitment and shall be implemented through the Company's documented management systems.
- 1.2.3 The company shall appoint a person who is responsible for maintaining the whole GMP system including the hazard analysis and risk assessment.
- 1.2.4 The company shall have a management review that includes a periodical review of customer complaints, claims, audit results and corrective actions.
- 1.2.5 The company shall implement a system for continuous improvement.
- 1.2.6 The Quality and Hygiene policy shall be regularly reviewed by the company.
- 1.2.7 The company shall include duties related to this standard in the job descriptions of the staff.

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 at least 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. Record keeping should be in line with shelf-life of the product. In the absence of reliable data, a minimum period of five¹ years for documents is recommended.
- 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 of time.
- 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.

 $^{^1}$ DG SANTE – Standing Committee on the food chain law and animal health – Guidance on the implementation of articles 11, 12, 16, 17, 18, 19 and 20 of regulation (EC) N^0 178/2002 on general food law.

1.6 Specification

- 1.6.1 The Company shall ensure that appropriate specifications and documentation [for example Declaration of Compliance (DoC)] 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 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, dispatch and distribution to the customer.
- 1.8.2 The storage times for the various production records shall be appropriate to the traceability requirements and the lifetime of the product.

1.9 Monitoring of suppliers and subcontractors

- 1.9.1 The Company shall operate procedures for the approval and monitoring of its suppliers. This shall include subcontractors, 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 and subcontractors 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 analysis and risk assessment.
- 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.

2. FACTORY STANDARDS

2.1 Site and Premises

- 2.1.1 The site boundaries shall be clearly documented so that the extent of the responsibilities of the company are clearly defined.
- 2.1.2 Measures necessary to protect the site from any potential source of contamination 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 corrective and preventive actions shall be taken with the contaminated product.
- 2.3.2 Shatterproof lighting shall be installed if the hazard analysis and risk assessment indicates the necessity.
- 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 easy access for cleaning 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.

3. 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 to minimise the risk of infestation.
- 3.2.5 Baits, traps and electric fly killer units shall be monitored at a minimum of four times a year. A pest infestation shall be handled immediately when it occurs. Records of checks shall also identify any actions taken.
- 3.2.6 The location of all pest control measures shall be identified on a plan/diagram of the site. Baits, traps and electric fly killer units shall not contaminate 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.

4. PERSONAL HYGIENE

4.1 Staff Premises/Toilet Facilities

- 4.1.1 All personnel and contractors likely to enter production areas shall wash their hands before entering the production area.
- 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. Towel 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 regarding 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 Every third party (visitors, subcontractors, ...) is bound by the applicable hygiene regulations and the need for observing them.
- 4.2.3 Personal belongings shall not be taken into the production areas and storage areas. A list of authorised personal belongings should be given.
- 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.
- 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 at the machines is allowed when there is no contamination risk to the product. Hard plastic and glass shall not be used.

4.4 Jewellery

4.4.1 Jewellery, wristwatches and visible piercings shall not be worn unless they are appropriately controlled to minimise contamination. The company shall clearly define the type of jewellery allowed to be worn as determined by hazard analysis and risk assessment.

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.
- 4.5.3 Sufficient extraction to the exterior of the building shall be ensured.
- 4.5.4 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.

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 guidelines are in place.

^{*} Note: A National legislation on smoking may overrule this criterium of the GMP standard and becomes in such case leading.

- 4.6.3 Visitors and non-production staff shall wear adequate protective clothing when entering production area.
- 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.

5. APPENDIX: AUDIT PROTOCOL

- 1. Introduction
- 2. Contractual arrangements and selection of the audit body
- 3. Audit process
- 4. Scope of the audit
- 5. Audit flow
- 6. Level determination
- 7. Audit results
- 8. Audit frequency
- 9. The audit report
- 10. Distribution of the audit report
- 11. Appeal procedure
- 12. Complaints
- 13. Certificate
- 14. 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 Board.

Only those audit bodies that have accreditation to EN/ISO 17065:2013 and EN/ISO 17021:2015 shall carry out audits against the International Good Manufacturing Practice Standard for Corrugated 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 Board preferably working with auditors who speak the native language of the auditee.

The audit body shall demonstrate their accreditation to EN/ISO 17065:2013 and EN/ISO 17021:2015 with the scope of packaging.

It is the responsibility of the auditee to verify that that the selected body is accredited, by either requesting a copy of the accreditation certificate 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 Board in its full integrity, this shall be checked by the auditing body during the audit process.

3. Audit process

Preparation for the audit

Before the documentation audit the auditee is required to review the International Good Manufacturing Practice Standard for Corrugated 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 analysis and risk assessment. 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 non-conformities 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 influence 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 non-conformities only. If the auditee shows that all the non-conformities 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, checking every criteria mentioned in the International Good Manufacturing Practice Standard for Corrugated Board.

In accordance with EN/ISO 17065:2013 and EN/ISO 17021:2015, 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 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 has been met, the auditor shall check every criteria 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 write down his motivation for raising all B and C non-conformities in the audit report.

How to interpret minors 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 NON-CONFORMITY

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

- The auditor does not rank it as: «a substantial failure to meet a full clause 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 below).

MAJOR NON-CONFORMITY

A major non-conformity is given in the following situations:

- 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. If the auditor judges that a situation in the operation being audited can directly lead to contamination of the product.

- 3. 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

In the standard there are five pre-defined critical criteria. The five critical criteria have to be in full compliance (judged as A) or in part compliance (judged as B).

When an auditor finds a critical criteria, 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

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
Major non-conformity at initial audit	Unable to recommend certification	Send in corrective action plan within 4 weeks of receiving preliminarily 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 & objective 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. In 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 non-conformities 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 motivations for raising all critical, major and minor non-conformities. 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 non-conformities 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 non-conformities per chapter.
- Corrective action plan from the auditee with the actions on all non-conformities.
- Detailed listing of findings with reasons for critical, major and minor non-conformities.

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

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 a thorough investigation into a complaint.

13. Certificate

If the certification body has issued a certificate to a certified company, they are required to inform FEFCO. This will be done by sending the issued certificate to FEFCO via e-mail: info@fefco.org.

14. Copyright

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

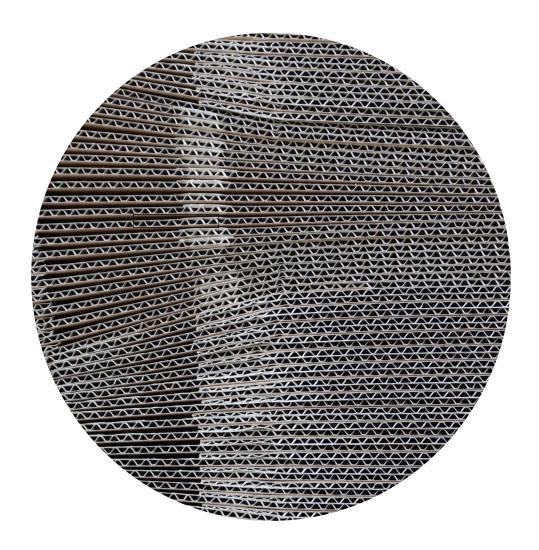
GLOSSARY OF TERMS USED

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 and/or service.
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 analysis	An evaluation of all relevant 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-fulfillment of a specified product safety, legal or quality requirement or of a specified system requirement

GLOSSARY OF TERMS USED

Pest	Any living organism (excluding human beings) with the potential to cause physical or biological contamination within a manufacturing operation. 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.
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 organisation
Quality system	A management system to direct and control an organisation regarding 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.





Published by: FEFCO - European Federation of Corrugated Board Manufacturers 250, Avenue Louise • 1050 Brussels Telephone: +32 2 646 40 70

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