



GENERAL REGULATIONS FOR THE CERTIFICATION SCHEME “GMP-FEFCO”

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1 SCOPE

This document constitutes the "general regulations" that set out the procedures that DNV applies in order to issue, maintain, and withdraw the certificate of conformity against the "International Good Manufacturing Practice Standard For Corrugated and Solid Board" (FEFCO GMP) for companies of the packaging sector.

2 POLICY

DNV provides the service of product certification according to the requirements of EN 45011 (ISO Guide 65), adopting non-discriminatory procedures, that is:

- ❖ All the organisations whose activities fall within the standard's field of application can access the certification service provided their commitment to abide by general regulation and the standard itself
- ❖ Undue financial and/or other conditions are not applied
- ❖ Access will not be conditional upon the size of the organisation or membership of any association or group
- ❖ Access will not be conditional upon the number of certificates already issued

The correct application of conditions and procedures is verified by the Certification Committee which includes all the parts interested to the certification activities without any predominance of single interest.

DNV policies, organisation and procedures distinguish between product certification and any other activities in which DNV is engaged. Specifically, DNV does not provide consultancy services for the implementation of food safety systems.

2.1 General Conditions

To get and maintain the certification, the organization shall:

- a – abide by the local general legislation concerning food safety
- b - abide by requirement of this general regulation
- c – abide by requirement to use certificate and certification mark
- d – regularly pay off the invoices issued according the signed contract

3 DOCUMENTS OF REFERENCE

3.1 FEFCO Requirements

The requirements to be met in order to obtain a conformity certification in compliance with FEFCO GMP are specified in the FEFCO "International Good Manufacturing Practice Standard For Corrugated and Solid Board" protocol, in the revision current at the date when the certification application is submitted (at the date of issue of this set of regulations the Ed.2, January 2006 is in force).

3.2 References in the certification scheme

The following documents have been taken into consideration by DNV on applying this scheme:

- ♦ FEFCO "International Good Manufacturing Practice Standard For Corrugated and Solid Board" Appendix : Audit Protocol

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4 GENERAL REGULATIONS

4.1 Prices

DNV draws up and forwards to all companies requiring a quotation, a specific offer, including any information concerning technical aspects and price, based on the following aspects: existing Certified Quality System, number of products to be certified, dimensions of production units; number and location of the production unit/units.

4.2 Conditions for FEFCO GMP conformity

The company undergoing certification shall undertake (by written declaration) to comply with the FEFCO GMP regulations and meet its requirements.

The organisation must meet all applicable requirements.

The organisation must keep an original copy of the technical standard. FEFCO doesn't allow, under any circumstance, the use of unauthorized copies infringing copyright rights.

4.3 Non Conformities

The auditor shall check all of the standard requirements, ranking his/her findings as:

- A: Full compliance
- B: Partial Compliance
- C: Not in compliance

All the B and C are classified as "Non Conformity" as per the following criteria

4.3.1 Critical NCs

When one out of the five pre defined critical criteria is judged as C, the audit is terminated, and the certificate can not be issued until effective corrective action is implemented. The follow up audit is a new "initial audit", covering all of the standard requirements. It shall be carried out within 6 months.

In case of B-ranking on a Critical criterion a certificate can be issued only after DNV has verified and approved the improvement plan and the implementation evidences submitted by the company (within 4 weeks after issue of NCs) for removal of the NC causes.

4.3.2 Major NCs

- Substantial failure to meet a full clause of the standard (e.g. if all the subclauses 1.3.1, 1.3.2 and 1.3.3 are classified as "C", the full clause 1.3 will receive a major) and/or a failure that can directly lead to a contamination of the product.
- A number of findings classed "C" exceeding the following limits:
 - o Chapter 1: > 15 Cs
 - o Chapter 2: > 10 Cs
 - o Chapter 3: > 11 Cs
 - o Chapter 4: > 10 Cs

When Major NC are found, a certificate cannot be issued. The causes which originated the NC must be removed through a proper corrective action, whose efficacy DNV will verify during an on site audit. It shall be carried out within 6 months.

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4.3.3 Minor NCs

All the findings classed B or C which are not categorized "Major Non Conformity"

If minor NCs are found, a certificate can be issued only after DNV has verified and approved the improvement plan and the implementation evidences submitted by the company (within 4 weeks after issue of NCs) for removal of the NC causes.

4.4 Certification procedure

After the DNV offer is accepted, the organisation will send a formal request of certification and agrees with DNV upon the scheduling of certification steps, which are listed below.

4.4.1 Document review (DR)

It is to be carried out at the company's premises and, as a rule, on the dates scheduled for the certification audit.

The review concerns the documents relevant to the Quality Management System and Hygienic Management System, in order to ascertain their compliance to the standard requirements.

4.4.2 Initial Certification Audit (IA)

After the DR, an audit "in the field" is carried out involving a site inspection, observation of activities, informal interviews with the management and the staff and examination of records demonstrating the system conformity.

The latter must allow an evaluation of the systematic application of the normative regulations. The requirement is considered satisfied if records include at least the 3 months before the audit; otherwise, the audit team shall ascertain the presence of frequent and effective monitoring activities (e.g. targeted internal audits) that can guarantee correct execution of the activities still in start-up phase, it being understood that every activity provided for (e.g. management review, internal audits, etc...) is carried out correctly at least once

4.5 Evaluation report

At the end of the IA the company is provided a detailed Preliminary Evaluation Report.

The auditee shall always write a corrective action plan before a final report is issued.

The Final Evaluation Report shall include the organisation's Corrective Action Plan, and it shall be delivered within 15 working days from the Corrective Action Plan delivery to DNV.

4.6 Issue of the conformity certificate and authorization to use the certification logo

In case of a positive result of the initial audit and technical review of documents carried out by DNV, the certified company will be assigned a univocal and permanent registration number; DNV will also send to the company the conformity certificate.

International GMP certified companies are entitled to make use of the GMP logo of FEFCO/ ESBO. They are committed to strict compliance with conditions set by FEFCO/ ESBO.

The Organisation can communicate to the public the obtained certification, but it must take all the precautions needed to avoid any confusion between certified and non certified products.

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4.7 Summary of the Initial Audit results

Audit Result	Status at closing Meeting	Corrective Actions	Final report	Certificate
C- Critical NC	Unable to recommend certification.	Auditee has to take corrective actions and a new audit is required to verify compliance	Confirm Status	Cannot be issued before satisfactory new audit.
B-Critical NC	Recommended to certification provided an acceptable C.A. is implemented.	Send C.A. plan and objective evidence within 4 weeks	Includes corrective actions	Cannot be issued before C.A. approval.
Major NC	Unable to recommend certification. Preliminary report delivered.	Send C.A. plan within 4 weeks; follow up audit within 6 months	Includes C.A. plan, delivered within 15 working days	Cannot be issued before satisfactory follow up audit.
Minor NC	Certification Recommended after acceptable Corrective Action plan and evidence of implementation. Preliminary report delivered.	Send C.A. plan and evidence of implementation within 4 week	Includes C.A. plan, delivered within 15 working days	Can be issued depending on the acceptability of the C.A. plan and implementation
NO Nc	Certification Recommended. Final report delivered.	----	-----	Issued after technical review

4.8 Certification renewal (PA)

Periodical audits frequency depends on the results of the audit:

C-Critical NC: complete new audit

B-Critical NC: 12 months

Major NC (Initial Audit): follow up within 6 months, after that 12 months

Major NC (Periodical Audit): 12 months

Minor NC: 12 months

Intervals are to be calculated starting from the dates of audits and not from the date of issue of a certificate.

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PA procedures are the same described for IA, as well as the relevant preliminary and final evaluation report.

4.8.1 NC in the periodical audits

If C-ranking Critical NCs are found after a periodical audit, the certificate is suspended and effective corrective actions are to be implemented within 6 month . DNV shell verify on site C.A. efficacy.

If Major NCs or B ranking Critical NCs are found after a periodical audit, the auditee shall implement and verify efficacy of the appropriate C.A. within 4 weeks. If the C.A. implementation can not be verified on the document basis, DNV can carry out an on site follow up audit. If the implemented C.A. plan is not satisfactory, the clause 4.10 applies (certificate suspension).

If Minor NCs are found after a periodical audit, the auditee shall send C.A. plan and evidence of implementation within 4 weeks. If it is not sent, clause 4.10 applies (certificate suspension).

4.9 Combined audits ISO 9001:2000

Combined audits can be carried out for the ISO 9001:2000 and FEFCO GMP certifications. The standards are easy to integrate and of course complementary, although separate reports are required.

As an example, the following equivalence table can be considered:

ISO 9001:2000		FEFCO GMP	
Requirement		Requirement	
Quality manual	4.2.2	1.3	Quality Manual
Control of documents	4.2.3	1.4	Document control
Control of records	4.2.4	1.4	Document control
Management responsibility	5		
Management commitment	5.1	1.2	Management responsibility
Quality policy	5.3	1.2	Management responsibility
Responsibility, authority and communication	5.5	1.2	Management responsibility
Management review	5.6	1.2	Management responsibility
Resource management	6		

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Competence, awareness and training	6.2.2	4.7	Education and training
Infrastructure	6.3	2 4	Factory standards Personel hygiene
Work environment	6.4	3 4	Contamination control Personel hygiene
Product realization	7		
Planning of product realization	7.1	1.1 1.6	Hazard inventory Specification
Design and development	7.3	1.1	Hazard inventory
Purchasing	7.4	1.9	Supplier monitoring
Identification and traceability	7.5.3	1.8	Traceability
Product conservation	7.5.5	3.4	Transport, storage and distribution
Measurement, analysis and improvement	8		
Internal audit	8.2.2	1.10	Internal audits
Control of Non conforming products	8.3	1.7	Product recall
Corrective actions	8.5.2	1.5	Complaint handling

4.10 Sanction system

After issue of certificate, whenever the conditions below described occur, DNV will take the following steps.

4.10.1 Certificate temporary suspension

Use of certificate is suspended for a maximum period of 6 months when:

- ◆ C-ranking Critical NCs are found
- ◆ No corrective actions are carried out after finding of B-ranking Critical NC or major/minor NCs;
- ◆ Changes which have been officially announced by FEFCO have not been carried out.

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4.10.2 Certificate withdrawal

Use of certificate is totally forbidden once and for all whenever the following conditions occur:

- ♦ The reasons for suspension are not removed within 6 months;
- ♦ Company bankruptcy.

5 CHANGES IN PRODUCT AND/OR PROCESSES CHARACTERISTICS

The issued certification is valid only for the products and processes which were evaluated in conformity with the organisation's relevant technical documents.

The organisation shall timely and in writing inform DNV of any change to products and/or processes able to influence the product conformity. DNV will decide if:

- a – the changes implemented do not influence substantially the conditions for certification, and they will be verified at the next periodical audit
- b – the changes implemented affect the conditions for certification, and further evaluation is needed. In this case a specific quotation will be issued by DNV to the company.
- c – the changes implemented need a new certification

6 CHANGES IN THE CERTIFICATION SCHEME

In the case of substantial changes in the regulation and/or in the relevant standard, DNV will:

- ❖ Inform the concerned companies
- ❖ Specify the actual enforcement date for the new rules.

The company can renounce to the certification if it deems to not implement the needed changes. Written communication shall be sent to DNV at least 3 months in advance to any scheduled activity.

7 CUSTOMERS AND CONSUMERS COMPLAINTS

The organisation shall:

- ❖ record all the customers and consumers complaints connected to the certified products, and make them available to DNV when requested
- ❖ take and document appropriate actions with respect such complaints.

8 CONFIDENTIALITY

DNV guarantees full confidentiality about all the information gained during certification activities, with the exception of possible different legal requirements.

DNV employee and subcontractors undersign and shall commit themselves to not disclose to third parties any information collected during auditing activities, unless authorised in writing by the company itself.

9 RENUNCIATION, SUSPENSION OR WITHDRAWAL OF THE CERTIFICATION

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The certified company can renounce to the certification at any time, informing DNV by means of registered letter at least 30 days in advance. DNV is authorised to invoice all the activities carried out before the renunciation.

DNV can suspend the certificate validity (or withdraw it) according to the FEFCO rules (see § 4.10) and the following

- ❖ Improper use of the certificate (e.g. equivocal communication to the public)
- ❖ Invoice outstanding
- ❖ Lack of information to DNV concerning substantial product and/or process changes
- ❖ According to specific agreement between DNV and the company due to any reason (e.g. production suspension)

10 MANAGEMENT OF APPEALS, COMPLAINTS AND DISPUTES

The organisation can set up written claims or appeals.

The complaints are connected to the organisation's un-satisfaction with the DNV administrative or technical performances. The Appeal is the organisation refuse of acceptance of decisions taken by DNV during verification and certification activities. The disputes come from the organisations refuse of acceptance of the DNV decision taken in case of appeals.

Complaints and Appeals are managed according the procedure C5-ce-3.19. An initial response will be given within ten working days of receipt of the complaints.

Appeals will be finalised within 30 working days of receipt of information.

In the event of an unsuccessful appeal, DNV has the right to charge costs for carrying out the appeal.

In case of dispute, a decision is taken by arbitration: one independent expert is appointed by DNV, one by the organisation, and one together by DNV and the organisation. If there is no agreement, the third expert is appointed by the Court of Justice competent in the area where the involved DNV office is located.

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