



GENERAL REGULATIONS FOR THE CERTIFICATION SCHEME HACCP

1	Scope	2
1.1	Field of application	2
2	Policy	2
2.1	General Conditions	3
2.1.1	Audit at subcontractors	4
3	Documents of reference	4
3.1	HACCP requirements	4
3.2	References of the certification scheme	4
4	General Regulations.....	4
4.1	Prices	4
4.2	Non Conformities	4
4.2.1	Criteria for classification	4
4.2.2	Closing Non conformities	5
4.3	Document Review	6
4.4	Preliminary Audit	6
4.5	Initial Audit	6
4.5.1	Concession And Use Of The Mark And Of The Certificate Of Conformity	6
4.5.2	Publication	6
4.6	Periodical audit	7
4.7	Periodical System re-assessment.....	7
5	Changes in product and/or processes characteristics	7
6	Changes in the certification scheme	8
7	Customers and consumers Complaints.....	8
8	Confidentiality and access to reports	8
9	Renunciation, suspension or withdrawal of the certification.....	8
10	Management of appeals, complaints and disputes	9

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No.:
ICP-3-4-i3-Food-i1-f5
Page:
1 of 9



1 SCOPE

This document constitutes the General Regulation for the "Certification Scheme for HACCP Systems in the food industry". It lays down the conditions and procedures applied by DNV Italia for certifying HACCP Systems in compliance with the Codex Alimentarius, used by organisations that supply products and/or services in the food sector.

1.1 Field of application

Generally, and by way of a guide, the following operating areas may be identified:

(1) – **Production and/or preparation:** The specific sectors, broken down in terms of degree of risk, include:

(1.1) – Raw meat and fish (Red meat, slaughtering, cutting up / Poultry, slaughtering and cutting up / Fish, refrigerated and frozen / Meat products and derivatives / Fish products and derivatives).

(1.2) – Fruit and vegetables (fresh and frozen)

(1.3) – Milk and cheese products (refrigerated and frozen). Eggs

(1.4) – Ready-to-eat products (refrigerated and frozen), included cooked meat and fish.

(1.5) – Packaged products, sealed and stable at room temperature

(1.6) – Other food products stable at room temperature (Drinks / Baked products / Desiccated - Dried / Confectionery / Snacks and Breakfast Cereals / Oils and Fats / Ingredients).

Products in each sector may also be combined with groups in the same risk category (e.g. raw minced cold meats).

(2) – **Animal Feed**

(3) – **Agricultural Companies**

(4) – **Wholesale distribution and sales (including transportation):** various categories can be identified, based on packaging (e.g. loose products) and perishability (e.g. fresh, frozen, and tinned products).

(5) – **Retail sales:** Various groups of products can be identified, based on their position in the food industry (e.g. fruit and vegetables) and the means of preservation used, perishability, and reciprocal compatibility (e.g. tinned foods, fresh meat, fruit and vegetables, frozen foods, dairy products, etc).

(6) – **Catering:** Various risk categories can be identified, based on the type of service (e.g. hot or cold, single or multi portion, etc.).

2 POLICY

DNV provides the service of management system certification according to the requirements of EN 45012 (ISO Guide 62), adopting non-discriminatory procedures, that is:

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No.:
ICP-3-4-i3-Food-i1-f5
Page:
2 of 9



- ❖ 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 management systems 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

Certification solely concerns conformity of the management system to reference standards and it does not concern fulfilment of laws in force, whose implementation responsibility exclusively belongs to the organisation concerned.

The Organisation is bound to:

- a) always conform to applicable dispositions of the certification scheme;
- b) abide by the local general legislation concerning food safety
- c) supply all necessary instructions to carry out the assessment, including dispositions for the review of documentation and access to every area, registration (including internal audit reports) and to the personnel for the evaluation, surveillance, supplementary evaluation and claims solutions;
- d) declare to be certified solely for those activities for which the certificate has been issued;
- e) make no use of the certification that could in any way discredit DNV; do not issue declaration about their certification that could be considered as deceitful or unauthorized by DNV;
- f) cease any use of advertising material including reference to certification in case the certificate is suspended or withdrew (status of Suspension or withdrawal of the Certificate);
- g) use certification only to show that Management System conforms to specific standards or other prescriptive documents and do not use certification to indicate that products or services are approved by DNV;
- h) guarantee that no document, mark or certification report – or any of their parts – is used in a deceitful way;
- i) conform to requirements provided by DNV when referring to the certification status on the media such as documents, illustrative or advertising material;
- j) regularly pay off the invoices issued according the signed contract

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No.:
ICP-3-4-i3-Food-i1-f5
Page:
3 of 9



During verification activities, DNV Italia auditors shall consider as their contact persons those representatives of the organisation specified in the organisation chart of the auditing management system. In case the organisation wishes other persons to participate in (e.g.: consultants), it is anyway obliged to assure that these persons' role is limited to the one of "observers"

2.1.1 Audit at subcontractors

In order to verify the effectiveness of the organisation management system, DNV reserves the right to carry out audits at the organisation's subcontractors (inside the Initial Audit and/or the Maintenance Periodical Audits); this mostly when, by the opinion of Lead Auditor, products / processes of the subcontractor are likely to significantly influence the conformity of the product and/or service of the organisation and the subcontractor is not HACCP certified .

3 DOCUMENTS OF REFERENCE

3.1 HACCP requirements

The reference documents used for HACCP certification are as follows:

CAC/RCP 1-1969, Rev. 4 (2003) FAO/WHO - Codex Alimentarius Commission, Food Hygiene Basic Texts: Recommended International Code of Practice General Principles of Food Hygiene.

Annex to CAC/RCP 1-1969, Rev. 4 (2003) Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its application

3.2 References of the certification scheme

The following documents have been considered by DNV within the application of this scheme:

- ❖ UNI 10854: Guidelines to design and apply a system for the prevention of hazards based on HACCP method.
- ❖ ISO 9001: Quality Management Systems - Requirements

4 GENERAL REGULATIONS

4.1 Prices

DNV prepares and issues any applicant Company with a quotation, which is specific and complete, with full information on technical aspects and cost, based on the following aspects: Combined Quality System – HACCP certification procedure, the presence or lack of a Certified Quality System, number of production units, geographic location of such production unit(s), and the number and characteristics of the products and/or production processes involved.

4.2 Non Conformities

4.2.1 Criteria for classification

The criteria to issue nonconformities (NC) i.e. major anomalies are given below:

- ◆ Not all the CCPs have been identified.
- ◆ The hazard analysis is incorrect and incomplete.

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No.:
ICP-3-4-i3-Food-i1-f5
Page:
4 of 9



- ♦ A CCP has not been monitored (total absence of any records).
- ♦ The mandatory requirements have not been satisfied (e.g. EEC seal)
- ♦ Failure to meet management system requirements so as to arouse doubts concerning the system capability to grant the required safety level;
- ♦ Faulty handling of claims and contentious;
- ♦ Improper use of mark and certificate.

The following criteria are related to observations (OBS), i.e. minor anomalies:

- ♦ The case when product requirements which do not concern law, safety and/or wholesomeness requirements are not met;
- ♦ The case when management system requirements which are not met do not stir doubts concerning the system capability to grant the required safety level.

As for the OBS, if any, the organization defines proper Corrective Actions and undertakes to perform them within the following maintenance audit.

4.2.2 Closing Non conformities

DNV shall verify and close NCs (major anomalie) being able to judge the system as in compliance with requirements and recommend the issue of relevant certificate and/or consider an already issued certificate as valid, i.e. closing of NCs consists of the following phases:

- the organisation sets out the Corrective Actions to solve the NCs;
- DNV verifies the proposed Corrective Actions;
- the Company implements the Corrective Actions and notifies their completion of implementation to DNV;
- DNV verifies, when due and at the organisation's premises, the implementation and the effectiveness of the Corrective Actions during a Close-out Audit whose extent depends on the type of NCs .

Maximum available time for the organisation to implement the Corrective Actions and give notification in writing to DNV Italia is:

- 13 weeks for non-conformities issued during initial audits and audits for modification of the scope;
- 6 weeks for non-conformities issued during maintenance and/or system re-assessment audits;

The Close-out Audit is generally carried out at the expected expiry time of completion of the corrective action; in case the company is not able to observe such a term it could become necessary to fully repeat the Audit during which the non-conformities were issued.

Observations which are not corrected within the defined terms can turn into Non conformities.

The conformity certificate will not be issued until the Non conformities found during the initial audit activities are properly solved.

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No.:
ICP-3-4-i3-Food-i1-f5
Page:
5 of 9



4.3 Document Review

The documentation is examined for conformity to the criteria that apply to the HACCP system.

The identification of hazards, risk analysis, control measures, and CCPs are assessed in terms of their technical merit.

4.4 Preliminary Audit

The Preliminary Audit is intended to assess the degree of implementation of the system, checking its effective application "in the field", without judging its conformity (this aspect is looked at in the Initial Audit).

4.5 Initial Audit

After the document review, 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

All the groups of products and all the CCPs for each group are audited SYSTEMATICALLY.

When working with identical CCPs on the same site, a sampling method may be applied. In the case of multi-site companies, production sites are to be sampled according to the IAF rules, making sure that all product groups are covered by the sampling procedure.

As to the Catering sector, sampling of production sites and giving sites is done based on the various types of service (hot or cold links, single-multi portion(s), etc.).

The process involves critical evaluation of HACCP system validation and the routine verifications carried out by the company to confirm that the system is effective.

In the case of combined ISO 9000 – HACCP audits, separate reports are issued. The results are independent of one another and may differ (for example failure to identify a CCP may not invalidate a Quality System, while failure to approve suppliers may not affect the HACCP system).

4.5.1 Concession And Use Of The Mark And Of The Certificate Of Conformity

Following the positive results of the auditing process and the Certificate issue, the Organisation is authorised to the use of the System Certification Mark and Certificate of Conformity.

The Organisation has to use the Mark and/or the Certificate of Conformity according to the "**Regulations and Handbook relating to the Registered Mark Of DNV 's Certification System.**"

4.5.2 Publication

Information about organisations provided with certified management systems are registered in relevant "Registers of Certified Companies" managed by DNV Italia and in any similar publications

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issued by Det Norske Veritas group. Such Registers are available to the public and are updated at least every six months.

4.6 Periodical audit

Periodical Audits aim at verifying the continuous and correct system implementation and the effective solution of Observations if issued in the previous audits.

During periodical audits, the system is generally partially reviewed assuring anyway that the equivalent of a complete audit is carried out within the three year period.

The periodical audits frequency normally is 12 months.

Upon completion of the activities, an audit report is given to the organisation describing the audit results and any possible Non-Conformities and Observations issued. Any Non-Conformity shall be solved by appropriate Corrective Actions, as described in this standard, in order to keep the certificate valid.

Execution of planned Periodical Audits is subject to the condition that the organisation is up-to-date with its payments concerning activities already carried out. Failing this, DNV Italia will not execute the planned activities and will take steps to suspend the Certificate of Conformity.

4.7 Periodical System re-assessment

Periodical system re-assessment is carried out every three years and aims at verifying the complete and continuous effectiveness of the whole system. This activity assesses and considers the system performances during the former certification period and includes a complete document review and "on the field" audit equal or wider than a periodical maintenance audit that will assess:

- Effective interaction and connection among the system elements
- Complete effectiveness of the system considered as a whole and against operational changes
- Evidence of the engagement to maintain system effectiveness.

Upon completion of the audit, DNV gives the organisation the Report of the Audit in which the results of the verification are detailed and any possible Non-Conformities and/or Observations are specified. Non-Conformities have to be eliminated by proper Corrective Actions in order to maintain the certificate validity.

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.

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No.:
ICP-3-4-i3-Food-i1-f5
Page:
7 of 9



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 AND ACCESS TO REPORTS

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

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.

In case of serious and significant problems, DNV Italia is entitled to temporarily suspend the Certificate of Conformity; e.g. in case the organisation:

- does not implement within the stated terms the appropriate Corrective Actions relevant to any Non-Conformities;
- is not up-to-date with payments about the activities already carried out;
- does not fulfil the conditions specified in the applicable standards for certification;
- is not able to assure the regular performance of the scheduled verification activities;
- misuses the Certification Mark and/or the Certificate of Conformity
- does not correctly manage claims received;

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No.:
ICP-3-4-i3-Food-i1-f5
Page:
8 of 9



- does not inform DNV about substantial facts which can influence the effectiveness and reliability of the certified system.

DNV, in case of suspension, sends the official notification of suspension by registered letter or equivalent means, and also specifies time available for revocation of the suspension and reserves the right to make such a suspension public; publication of any withdrawn or cancelled certificate is carried out by registering it in the corresponding section of the register of the certified organisations.

Once DNV verifies that the organisation has effectively solved the situations resulted in the suspension, the latter is revoked, and the organisation concerned is informed accordingly (and in case of publication of the suspension its revocation is also publicised); failing this, DNV provides for the Withdrawal/Calcellation of the Certificate.

In case the conditions which led to its suspension are not solved within the term specified in the suspension notification, DNV Italia provides for the withdrawal of the certificate. The Certificate can also be withdrawn without any prior suspension phase in case of serious breaches by the organisation.

The certificate is cancelled / withdrawn if the organisation is not willing to go on with keeping the certification and if it confirms its will by a written communication.

The certificate cancellation / withdrawal is officially notified to the organisation by registered letter or by any equivalent means; the publication of any withdrawn or cancelled certificate is carried out by its registration in the relevant section of the register of the certified organisations

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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Page:
9 of 9