



HACCP CERTIFICATION REGULATIONS 2006

Article 1

These certification regulations apply to accredited certification bodies that have subscribed to the (Dutch) National Board of Experts HACCP (NBE-HACCP).

In addition these regulations also apply to food processing businesses that receive assessment by these certification bodies in order to be granted a HACCP certificate.

Certification bodies that are particularly accredited for this purpose issue HACCP certificates.

The certificate provides buyers, consumers and other parties with justified assurance that the management and control of the safety of the food product meet the Requirements for a HACCP based Food Safety System and, in by doing so, the legislative/regulatory requirements with respect to HACCP.

The overall basic requirements for hygiene, the GMP requirements, form part of these certification criteria. In most cases, these GMP requirements are mandatory by national legislation.

Article 2

The NBE-HACCP is authorised to decide on admitting certification bodies that are recognised by other accreditation bodies then the Dutch Council for Accreditation.

Before admission is granted proof must be provided that this accreditation is comparable to the accreditation by the Dutch Council for Accreditation, at the discretion of the NBE-HACCP.

Article 3

The certification bodies are responsible for the full application of the certification scheme and have to observe the regulations and directives issued by the NBE-HACCP.

Article 4

Where these regulations do not stipulate any other requirements with respect to the HACCP certification process, the certification bodies have to apply the procedures set in force for the certification of quality systems, that are accredited on the basis of EN 45012 or ISO/IEC Guide 62, excepting article 3.3. of ISO/IEC Guide 62. This article is replaced by article 5.3 of ISO/IEC Guide 66:1998.

With the information/application phase of the certification process, these regulations have to be submitted by the certification body to anyone requesting HACCP certification in accordance with clause 3.1.1.1 of EN 45012:1998 and ISO/IEC Guide 62:1996.



Article 5

The certification bodies are obliged to apply the HACCP certification scheme as established by the NBE-HACCP. The scheme contains the certification criteria, methods of examination, the requirements for certification bodies with respect to the scope of activities, expertise and certification personnel (e.g. auditors and decision makers) and the procedures with regards to audits and their frequency.

With regards to non conformities revealed, certification bodies are required to establish and maintain criteria for application of critical and non-critical non conformities, in accordance with the specifications in the EA and/or IAF guidelines pertaining to EN 45012 or ISO/IEC Guide 62.

Only food operating businesses where no critical non conformities have been revealed in their HACCP system, can qualify for granting the HACCP certificate.

HACCP certificates may only be issued on the basis of the actual status of the HACCP system of the food operating business and not on the basis of proposed or expected measures.

Article 6

The certification bodies must employ proven expertise and experience at three levels:

1 audit team:

The requirements required in respect of auditors and the audit team are stipulated in the document *Requirements for Certification Bodies concerning scope, expertise and certification personnel*.

2 staff:

The certification body is required to appoint at least one officer who is assigned the following duties:

- conduct of the contract review
- selection, training and informing/instruction (briefing) of audit teams
- participation in Harmonisation Committee discussions carried out by certification bodies
- central point of contact for the NBE-HACCP.

The (collective) requirements demanded of this officer are that he/she must:

- be employed by the certification body (no on-the-job contracting; not necessarily full-time)
- meet the requirements with respect to 'lead auditor', as specified in the aforementioned *Requirements for Certification Bodies concerning scope, expertise and certification personnel*.
- have a minimum of five years' working experience in the relevant sector in one or more of the following 'sensitive' sectors:
 - primary animal products
 - cattle breeding
 - other primary sectors
 - egg-production and egg products
 - chopped fruit and vegetables
 - meat and meat products (unpacked and refrigerated)
 - fish and shellfish
 - dairy products.

For certification bodies which have only been accredited for 'other primary sectors', only the first three 'sensitive' sectors apply. In this case, other 'sensitive' sectors are not taken into consideration.



3 decision maker(s):

The decision maker(s), responsible for granting, maintaining, extending, suspending and withdrawing HACCP certificates is/are required to satisfy each of the following criteria:

- be employed by the certification body (no on-the-job contracting) or be an independent panel of (wholly or partially external) experts, which is an integral part of the organisational structure of the certifying body.
- meet the requirements for 'lead auditor', as specified in the aforementioned
- have a minimum of five years' working experience in the relevant sector in one or more of the following 'sensitive' sectors:
 - primary animal products
 - cattle breeding
 - other primary sectors
 - egg-production and egg products
 - chopped fruit and vegetables
 - meat and meat products (unpacked and refrigerated)
 - fish and shellfish
 - dairy products.

For certification bodies which have only been accredited for 'other primary sector', only the first three 'sensitive' sectors apply. In this case, other 'sensitive' sectors are not considered.

NB: The decision maker(s) and the staff officer ('HACCP co-ordinator') may be one and the same person, but may not participate in the audit team that has carried out the assessment in question.

Article 7

The period of the contract between the certification body and the food-processing organisation shall last for 3 years. Reassessment, which takes place on expiration of these three years, is conducted in accordance with the initial assessment. By definition, during the initial certification period of three years a regime of semi-annual surveillance's will be in force. After three years the certifying body can transfer to a regime of annual surveillance's under the following conditions:

- there are no open non-conformities;
- no new non conformities have been revealed with the entire reassessment;
- adherence to the strict precondition of notification of changes in the HACCP system

During the first period of three years, changes in the system of semi-annual surveillance's may only be made under the following conditions:

- at least two semi-annual surveillance's have been conducted following the initial certification audit;
- all CCPs and PRP-requirements have been assessed;
- all production lines and all sites have been assessed;
- no new non conformities are revealed during the most recent audit and there are no open non conformities;
- the certification body documents the evaluation of above-mentioned conditions;
- the condition for notifications of any changes in the HACCP system, activities and
- locations by the food processing business is strictly adhered to.



Article 8

The certification body is required to apply the Calculation Model in the Rules for Time Allocation with respect to HACCP Audits, for determining the minimum auditor days for the initial certification audit, surveillance's and the re-assessment.

The Calculation Model is enclosed as Appendix I to these HACCP certification regulations

Article 9

- During the initial assessment, the certification body is required to assess whether all Critical Control Points (CCPs) have been identified and are being monitored.
A number of CCPs will be investigated with sufficient depth as much as possible at processes in action for implementation in practice.
- The initial investigation (on site certification audit) will be conducted in accordance with the two phase methodology as pointed out in ISO/IEC Guide 66/1998, article 5.3. Both phases are to be conducted at the company site.
- During Phase I the audit team will investigate the system documentation, especially the process, thoroughness and correctness of the hazard analysis and HACCP-analysis (risk), the HACCP-plan and the validation of this plan. The Phase I investigation will consist of a documentation investigation, a company survey and a planning of the Phase II investigation.

1) The audit team will examine whether – seen the activities of the organisation - all CCPs have been identified and whether all CCPs are being controlled as well as being monitored.

2) If the organisation has defined an inordinate number of CCPs, the certification body is required to make a precise assessment of the level of expertise within the organisation-
In the event of an inordinate number of CCPs being identified, the HACCP analysis has most likely been carried out with an insufficient level of expertise and a major non-conformity is to be revealed. Before the start of the certification audit at-site, the organisation is required to initiate a modified HACCP analysis with an acceptable number of CCPs and to make changes to the HACCP system (including the documentation).

3) After Phase I (if necessary, following any additional measures as indicated under 2), the audit team conducts a (risk) analysis of the CCPs identified by the organisation and selects those CCPs (nature and number) for which a more in-depth assessment is necessary on site. On the basis of this in-depth assessment of the CCPs, a sound judgement shall be provided with respect to the conformity of the organisation to the HACCP criteria.

4) As an integral part of the Phase I investigation the audit team will conduct an inspection at the site. During the on-site inspection the implementation of the 'Requirements' are assessed. Any non conformities with regard to GMP/GHP and or the prerequisite program are to be reported specifically. The report of the Phase I investigation must show which elements of the prerequisite program are assessed and to what extent the requirements are fulfilled.

5) Information or data of the hazard analysis and the HACCP-analysis, the validation and the companies HACCP-plan as well as the validation of the CCP's selected by the audit team are to be reported in a thorough and in-depth report.

During the following Phase-II-investigation the audit team will judge the implementation of the Food Safety System.



This assessment will also include a check if any non-conformities, reported in Phase I during the on-site inspection, are discontinued and arrangements to the Food Safety System to do so, are assessed. If necessary the HACCP analysis will be judged again whether it sufficiently encompasses the in practice occurring potential dangers.

During surveillance visits the implementation of the system and effective control of the processes/products will be reviewed by sampling. In the three year period ALL CCPs shall be assessed with full depth. However, by doing so, the certifying body must take into account new circumstances and new CCPs.

The report with regard to any information or data of the hazard analysis and the HACCP-analysis which is drawn up during the initial investigation, as well as the CCPs assessed, has to be updated after every audit or assessment.

All sites of the certified legal entity shall be audited at least once during the three-year period, regardless of the absence of CCPs.

Article 10

During each assessment, the certification body is required to investigate the handling of complaints and any writings to relevant governmental inspection bodies that have been registered. Any complaints on the part of the authorities, related to the HACCP system can therefore provide a better insight into the functioning of the HACCP system.

Article 11

Organisations may not display the HACCP certification logo or mention possession of a HACCP certificate on their products.

Article 12

In the event of the relevant documents (certification scheme) being changed, organisations will be given 6 months' time of grace to adapt to the implementation of the new requirements, unless the legal regulations stipulate a different transition period.

Article 13

At least once per year, the certification bodies are obliged to provide the NBE-HACCP with all the information relating to the nature, the content and the functioning of the HACCP scheme. This information shall be made anonymous so that confidentiality with respect to organisations is assured. The information required by the NBE-HACCP pertaining to the preceding year is provided in written format no later than April 1st.

Article 14

The certification bodies are required to ensure that the regulations, which are decided by the NBE-HACCP and accepted by the certification bodies, are established, authorised and included in their existing system documentation within a period of 2 months.

Certification bodies are required to control these documents according to their own document control procedures.

Article 15

New information or changes with regards to the HACCP certification system are to be communicated by the certification bodies to those parties involved, such as certificate holders and HACCP auditors (auditors and experts) within a period of 2 months.



Article 16

If required by certification bodies or by organisations, the NBE-HACCP can be called to intervene in the event of different opinions in the interpretation of the certification scheme. The NBE-HACCP will however not make any judgements with regards to individual disputes or appeals. The appeal regulations of the certification body are applicable to these disputes or appeals.

Article 17

The audit report on the status of the HACCP system will comply with the extensive method which basics are set out in Appendix II. Application of this model is required for all assessments, including surveillance's. The report should show a faithful representation.

Article 18

The Dutch National Board of Experts HACCP approved these regulations on 15 June 2006.

Appendix 1: 'Rules for Time Allocation with respect to HACCP Audits'

Appendix II: Basics for the audit report



Appendix 1 to HACCP Certification Regulations 2006

Time allocation for HACCP Audits

The basis is formed by a table (Table 1) in which is indicated the minimum number of auditor-days, dependent on the total number of employees involved within the scope of the audit, together with four categories of activities of the company concerned. The total number of employees is the total number of employees on day shift plus the total number of employees in the largest shift (all expressed in full-time equivalents (FTEs)).

The number of auditor-days shown is applicable to initial audits. This basic table is applicable to the simple situation of a company with one group of products, one location and a low level of risk.

TABLE 1 - Minimum number of auditor-days

Number of employees (FTEs)	Initial audit - auditor-days			
	Category			
	A	B	C	D
1-19	2.5	2	1.5	1.5
20-29	3	2.5	2.0	1.5
30-59	4	3.5	2.5	2
60-100	5	4	3.5	3
100-250	6	5	4.5	4
250-500	8	7	6	5
500-1000	10	9	7	6

N.B. The time is shown in auditor-days; the minimum length of an auditor-day is 8 hours!



Explanation:

Jobs:

Calculated is the total number of employees that are involved within the scope of the audit of the organization.

Considered as employees are not only those employed permanently, but also hired-in/temporary employees. The largest number of employees is the determining factor, taking into account any possible seasonal work.

Company activities:

A = preparation, processing, handling, packaging, transport, distribution and retailing

B = preparation, processing, handling and packaging

C = transport, distribution and retailing of unpackaged foodstuffs

D = transport, distribution and retailing of packaged foodstuffs

The time indicated (auditor-days) is the estimated time for the phase 1 and phase 2 study, excluding preparation and reporting. Phase 1 and phase 2 study must be carried out on site.

Compensation should then be applied for exceptional circumstances, i.e. variations from the simple situation, for which the factors shown hereunder are to be used:

Outline risk level of the product and/or product group:

Distinction is made between high and low risk:

Used in calculating risk level are the product-inherent aspects, such as: number and origin of raw materials, microbiological-chemical-physical risks and technological aspects of production.

In order to be able to establish the risk level, is made use of a list of product categories. To this end, Table 2 is applied. In the case of multiple product groups, the highest level of risk of the various product groups is taken as the basis.

TABLE 2 – Categorization of foodstuffs companies according to risk level

Product group	Risk level	
	Low	High
egg processing and egg products		X
dairy - chilled and frozen (dairy, milk products, ice cream and cheese (except hard cheese))		X
ready to eat or heat (chilled and frozen), including cooked meat and cooked fish products, salads, sandwiches.		X
restaurants, hotel catering, canteens, kitchens		X
Other food categories	X	

- **The number of different product groups:**

In general within the company, different product groups will follow different production processes; as a consequence, the amount of time required for auditing will increase.

As a definition is given that products belong to the same product group provided that there are no



(significant) differences in the risk analysis in relation to the entire production process. In this, consideration should be given to the process and production characteristics. In almost all cases this can be derived from the scope that the company is required to provide; if this is not the case, the number of product groups can be established in consultation with the company or the risk analysis can be submitted in advance.

The number of production lines is not taken into account further, as it is assumed that this is allowed for sufficiently by the number of employees.

- **Number of locations:**

In principle, each location of the company must be visited individually during all types of HACCP audit (initial assessment and follow-up audits). Each location is certified separately and receives its own certificate (a multi-site approach is not permitted). The table is applied to each location, and the total is the total sum of the days needed for all the individual locations.

In certain instances, (a well-founded and documented) reduction in the time can be given on the basis of the uniformity of multiple locations included in the study on the basis of proven uniformity, without the application of a multi-site approach. This cannot be covered in a table and will have to be substantiated on a case for case basis by the CB.

- **Time used for reporting:**

Typically, a minimum period of 4 hours will be necessary to cover making a report on an initial assessment or a reassessment, with 2 hours being necessary for a control audit. This time use should be added to the table.

The factors 'risk level' and 'number of product groups' have been incorporated in Table 3, in which is shown the number of days that would be added to the days in the basis table (Table 1) in a situation under consideration (Table 1).

TABLE 3 – Additional number of auditor-days

Number of product groups	Risk level	
	Low	High
1-2	0	1
3-4	0.5	1.5
5-7	1.5	3
8 or more	3	5

Follow-up audits and reassessments:

The above refers to initial audits. The following instructions are applicable to follow-up audits and reassessments:

- In the case of follow-up audits, ca. 30% of the time is used for classification in groups A and B and ca. 20% of the time is used for classification in groups C and D.
- Approximately 80% of the initial audit time will be calculated for a complete reassessment. This initial audit time is the time as it is calculated for the situation prevalent at the time of reassessment (this can vary from the initial audit carried out).



Appendix II: Basics for the audit report

General objectives

- The report should contain information that primarily concerns the audited company
- The Phase I and Phase II reports and the re-assessment report can differ
- All below mentioned elements can be taken up in the report or added as an appendix

Phase I Investigation

This report should at least contain the following elements:

- The requirements for a HACCP based Food Safety System, version 4, June 2006. Audit plan with date and place of execution. A description of the audited functions and processes
- Description of the company (name legal entity and address)
- Scope
- Description of the audit team members
- Description of the representatives of the auditee
- Conclusions (overview of agreed actions for Phase II investigation)
- Overview of Major and Minor NC's as well as remarks together with corresponding paragraph number and description
- Documentation with an emphasis on the risk-analysis (general overview and in-depth description)
- Description of CCP's related to every process step.
- The auditor decides during the phase I audit which CCP's will at least be investigated thoroughly and registers this.
- Validation (general view / depth).
- PRP (General overview of the company survey and its results as well as a short checklist of the aspects of the PRP).

Phase II Investigation

This report should at least contain the following elements

- The requirements for a HACCP based Food Safety System. Audit plan with date and place of execution. A description of the audited functions and processes
- The Audit plan with date and place of execution and functions and processes that have been audited
- Description of the company (name legal entity and address)
- Scope
- Description of the audit team member
- Description of the representatives of the auditee
- Summary including conclusions and recommendations on certification
- Overview of Major and Minor NC's as well as remarks together with corresponding paragraph number and description
- Overview of relevant changes to documentation, processes and products
- Description of CCP's reviewed. Indication of random sampling and result of this assessment.
- Verification (General overview / in-depth report)
- PRP (General overview of the company survey and its results as well as a short checklist of the aspects of the PRP).
- Registered complaints on Food Safety and reports to concerning government
- Results per area, function or process with a reproduction of all questions issued and (non-)compliances with the "Requirements" (which normative elements have been assessed in which area)