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# EA Policy

# For the Accreditation of

# Organic Production Certification

## *PURPOSE*

This document outlines the EA policy for accreditation bodies when processing accreditation to control bodies in the field of organic production.

*Authorship*
The publication has been prepared by a task force of the EA Certification Committee in cooperation with the scheme owner, the organic farming unit of DG Agriculture and Rural Development.

*Official language*
The text may be translated into other languages as required. The English language version remains the definitive version.



*Further information*
For further information about this publication, contact your national member of EA. Please check our website for up-to-date information http://www.european-accreditation.org

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|---|---|
| **Category:** | Members' Procedural Documents<br>**EA-3/12 is a mandatory document.** |
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## *CONTENTS*

# *1 DEFINITIONS*

Control body: In these guidelines the term Control Body and its abbreviation CB is used to cover any independent body certifying organic production in the European Union which has been delegated these control tasks by a Member State in accordance Article 27 of Regulation (EC) Nº 834/2007 and any independent body which certifies organic production for the purpose of equivalence in third countries in accordance with Article 33 (3) of that Regulation. CB is synonym of Conformity Assessment Body (CAB), in this document is used CB in accordance with the EU regulation.

Accreditation cycle: In these guidelines, the length of the accreditation cycle should be no less than 4 years and no more than 5 years.

Critical location: Location as defined under point 2.2 of IAF-guide GD 3:2003.

Equivalence: Equivalence is the capability of different inspection and certification systems to meet the same objectives of the production standards and the control measures contained in Titles III, IV and V of Regulation (EC) Nº 834/2007 and associated implementing rules contained in Regulation (EC) Nº 889/2008.

Control visit: Activity performed by an AB whereby it conducts a post-audit review at the CB client premises, with the CB audit team or CB representatives being interviewed. Direct questioning to the CB client by the AB assessors should not occur, except where it was previously agreed with all parties concerned. Nevertheless, a guided visit through the CB client premises may be necessary.

Suspension: Temporary invalidation of the statement of conformity for all or part of the specified scope of attestation. During the suspension period a control body cannot issue new certificates.

**LIST OF ABBREVIATIONS**

| | |
|---|---|
| CB: | Control Body |
| AB: | Accreditation Body |
| CV: | Control Visit |

# *2 REQUIREMENTS FOR ACCREDITATION BODIES EVALUATING CONTROL BODIES FOR THEIR OPERATIONS IN THE EUROPEAN UNION*

## 2.1 Technical Assessor and Experts qualifications and training requirements

ISO/IEC 17011 requires the accreditation body to establish procedures for selecting, training and formally approving assessors and experts. This section specifies the formal qualifications, experience and competence required for the scope “Organic Production”.

Technical assessors and experts should have a degree in a discipline related to the scope of accreditation (e.g. agronomist, food scientist), in case of assessors without a degree, additional

professional experience has to be required. A minimum of two years professional experience in organic agriculture, aquaculture, food processing or in trade with products from organic production is required. Additionally, a minimum of two years professional activity with surveillance and/or assessment tasks in those technical areas where the assessor is assigned. Assessors and experts shall have adequate knowledge of the EU Regulations on Organic Production. Assessors and experts shall observe the relevant requirements for impartiality and occupational aptitude.

The initial and on-going training for assessors and experts shall cover the specific application of quality management systems according to ISO/IEC Guide 65 / ISO/IEC 17065 in a Control body certifying products from organic production as well as training in practical evaluations for the scope organic production.

## 2.2 References

When assessing CB's operating in the EU, AB's shall take into account at least the following documents:

- Regulation (EC) Nº 834/2007 and associated implementing rules contained in Regulation (EC) Nº 889/2008, Regulation (EC) Nº 1235/2008 and subsequent amendments.
- Working document of the Commission services on official controls in the organic sector dated 8 July 2011 (http://ec.europa.eu/agriculture/organic/files/eu-policy/data-statistics/control_guidelines_version_08072011_en.pdf).
- Other applicable documentation published by the European Commission regarding Regulation (EC) Nº 834/2007.

## 2.3 Documents to be submitted by control bodies applying for accreditation

Concerning the documentation required under ISO/IEC Guide 65 / ISO/IEC 17065 for accreditation of organic production certification, Control bodies need to submit at least the following:

- the complete list of offices, indicating for all, the certification activities carried out and countries covered;
- a copy of the CB's quality manual;
- an overview indicating the responsibilities of the staff;
- the standard control procedures [see art. 27 (6a) of Regulation (EC) Nº 834/2007] applied for all activities in the EU;
- list of qualified inspectors per product category;
- list of decision makers per product category.
- a current list of certified operators, including countries, locations and products certified.

The following documents shall be available on site and submitted on request:

- a copy of the most recent internal audit report, the control body's internal audit programme and the latest management review;
- curricula and supporting evidence of all Technical staff members and inspectors;
- declarations of absence of conflicts of interest for staff and inspectors;
- continuous training log indicating precisely for each staff member and inspector the nature of the training, dates, duration, attestations of successfully completed training received.

## 2.4 Description of the scope of accreditation

The accreditation scope shall be defined by the product categories as defined in Article 1 (2) of Regulation (EC) No. 834/2007.

## 2.5 Granting of initial accreditation / re-accreditation

Accreditation bodies shall not grant accreditation before having performed the following assessments: a head office assessment, an office assessment in each critical location and at least one witness assessment in each product category the control body has requested to be accredited for.

## 2.6 Office and witness/ control visit to be conducted for initial accreditation / re-accreditation

For initial accreditation and re-accreditation of control bodies operating exclusively in member states of the European Union, accreditation bodies shall foresee the minimum number of man-days for office audits and the minimum number of witness assessments (preferably) / control visit as defined in table 1:

### Table 1a: Minimum on-site times for office assessments

| | | | | | | | **Man-days on site** |
|---|---|---|---|---|---|---|---|
| | | | | | | | Standard minimum 2 days |
| Increase factors | | | | | | | |
| Critical findings | + 1 day | | | | | | |
| Structural complexity (*) | Low<br>No additional | | Medium<br>+ 0,5 day | | High<br>+ 1 day | | |
| Product categories | 2 or less<br>No additional | | 3<br>+ 0,5 day | | 4<br>+ 1 day | | |
| Members States of activity | 1-2<br>No additional | | 3-4<br>+ 0,5 day | | >4-10<br>+ 1 day | >10<br>+ 1,5 days | |
| Number of operators | <100<br>No additional | 101 – 1000<br>+ 0,5 day | 1001 – 3000<br>+1 day | 3001 – 6000<br>+ 1,5 days | 6001 - 10000<br>+ 2 days | > 10000<br>+ 2,5 days | |
| | | | | | | | **Total** |

(*) elements to be considered for structural complexity are for example, number of inspectors, number of offices, CBs managing different product certification schemes, different accreditation scheme, outsourcing, decentralization of decision making, etc.

**Table 1b: Minimum numbers of witness / control visit**

| | | At least 1 |
|---|---|---|
| **Increase factors** | | |
| Critical findings | If necessary: additional WA/CV | |
| Product categories | 1 per category (combinations of product categories is possible) | |
| Countries of activities / operators | + 1 per each 10 countries with > 20 operators | |
| | | **Total** |

Each critical location shall be evaluated prior to initial accreditation. The days required, never less than half day, of this are to be added additionally to the minimum office assessment man-days as defined in table 1. Further, in the initial assessment, ABs have to confirm the status of “not critical locations”, sampling those offices in a representative number.

## 2.7 Extension of accreditation scope to additional product categories

Before granting an extension of the accreditation scope to any additional product category, the Accreditation body shall verify that the Control body's inspectors have the necessary qualifications and shall perform at least one witness assessment in each additional product category for which the Control body requests to be accredited.

## 2.8 Extension of accreditation scope to organic product certification for the purpose of equivalence in third countries

Organic product certification for the purpose of equivalence in third countries shall be regarded as an extension of the accreditation scope. Before granting such an extension the Accreditation body shall refer to the requirements defined under point 3 for the granting of initial accreditation.

## 2.9 Surveillance assessments

Accreditation bodies shall conduct annual surveillance assessments during the accreditation cycle.

Each critical location shall be subject to at least one assessment in an accreditation cycle. Additional surveillance assessments shall be conducted at all critical locations where major non-conformities were identified during the previous assessment.

The minimum duration of a surveillance assessment shall be respectively at least 50% of the minimum calculated using table 1.

## 2.10 Witness assessments to be conducted during one accreditation cycle

Accreditation bodies have to witness at least one physical inspection in each product category during an accreditation cycle for which the control body is accredited, not taking into account the number of witness assessments conducted in the light of initial accreditation or reassessment. An additional witness audit has to be carried out for each ten countries. A single witness assessment could encompass different product categories if the activities of the witnessed operator and of the Control body justify it.

## 2.11 Witness assessments: criteria for the selection of operators to be witnessed

The Accreditation body should select the witnessed inspectors and operators on its own, ensuring that witnessed assessments are performed in operators with a higher risks for deviations of organic production requirements. To establish which operators could present a higher risk for deviations, the Accreditation body will take into account the risk analysis conducted by the CB in accordance with Article 27 (3) of Regulation (EC) Nº 834/2007.

When selecting a witnesses, Accreditation bodies shall also take into account the production cycles of each product, as relevant, in order to assure that products are present at the time. It is not adequate that witnessing covers exclusively activities that are essentially of an administrative nature (e.g. brokers, traders).

It is preferable that the Accreditation body witness CB inspector(s) that have not been witnessed previously in that particular field of competence. Witness assessments shall avoid the repeated witnessing of the same certification body client. Where repeat witnessing occurs because of the limited number of certified operators, the Accreditation body report shall indicate the repeat witnessing.

Accreditation bodies shall take into account previous results on witnessing to establish its witness strategy.

### 2.12 Information Exchange between the accreditation body, Member State's competent authority and the scheme owner

The Commission services as scheme owner and a Member State's Competent Authority as delegating authority may provide Accreditation bodies specific input for the assessment of CBs. accreditation bodies shall consider surveillance results provided by Competent Authorities.

The accreditation body report shall indicate whether the corrective measures requested during the previous assessment where implemented in a timely manner.

If the Accreditation body decides to suspend the accreditation of a CB operating in a member state, the Accreditation body shall inform in a timely manner the Competent Authority.

## *3 REQUIREMENTS FOR ACCREDITATION BODIES EVALUATING CONTROL BODIES FOR THEIR OPERATIONS IN THIRD COUNTRIES*

### 3.1 References

When assessing CB's operating in third countries for the purpose of verifying the fulfilment of equivalence with the above mentioned EU organic production standards and control measures, AB's shall take into account, at least, the following documents:

- Titles III, IV and V of Regulation (EC) No 834/2007 and associated implementing rules contained in Regulation (EC) No 889/2008.
- Regulation (EC) No 1235/2008.
- European Commission Guidelines on imports of organic products intro the European Union (http://ec.europa.eu/agriculture/organic/files/news/download-material/guidelines_for_imports_en.pdf).
- Working document of the Commission services on official controls in the organic sector dated 8 July 2011 (http://ec.europa.eu/agriculture/organic/files/eu-policy/data-statistics/control_guidelines_version_08072011_en.pdf).
- Other applicable documentation published by the European Commission regarding Regulation (EC) Nº 834/2007.
- *Codex Alimentarius* CAC/GL 32 Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods.

### 3.2 Technical Assessor and Experts qualifications

Additionally to the qualifications and training requirements defined under point 2.1, technical assessors and experts shall have adequate knowledge of *Codex Alimentarius* guidelines CAC/GL

32, the equivalent(s) standard(s) applied and experience with surveillance and/or assessment tasks in third countries.

### 3.3 Documents to be submitted by control bodies applying for accreditation

Additionally to the documents defined under point 2.3, control bodies need to submit at least the following:

- a description of their equivalent production standard and control measures; the standard control procedures applied for all activities in third countries;

- side by side comparison between the production standard and control measures of the CB and the EU regulation;

- inventory of substantial differences of the equivalent production standard and the control measures;

- an updated list of operators and of products certified as organic as foreseen by art. 12 (d) of Reg. (EC) Nº 1235/2008.

### 3.4 Description of the scope of accreditation

The accreditation scope is defined by the following product categories as set out in Annex II of Regulation (EC) No 508/2012.

A: Unprocessed plant products

B: Live animals or unprocessed animal products

C: Aquaculture products and seaweeds

D: Processed agricultural products for use as food

E: Processed agricultural products for use as feed

F: Vegetative propagating material and seeds for cultivation

The accreditation scope shall identify the standard(s) applied in third countries.

In order to grant accreditation for a given product category the Accreditation body shall assess that the Control body certifies against a standard that is equivalent to the Regulation (EC) No. 834/2007 and its implementing rules.

### 3.5 Granting of initial accreditation and re-accreditation

Additionally to the requirements defined under point 2.5, Accreditation bodies shall not grant accreditation before having assessed the equivalence of the standard applied in the third country. The Control body in third countries shall present a detailed description of its equivalent standard applied in third countries to the Accreditation body. The Control body shall ensure that those documents are up-to-date and cover all product categories for which the control body is seeking accreditation.

The equivalence assessment by the Accreditation body shall be based on a side by side assessment prepared by the control body and verified by the accreditation body that demonstrates the equivalence of the production standard for each product category and of the control measures

with Titles III, IV and V of Regulation (EC) Nº 834/2007 and associated implementing rules in Regulation (EC) No 889/2008.

The assessment shall include an inventory of the substantial differences between the control body's production standard and control measures and the Titles III, IV and V of Regulation (EC) Nº 834/2007 and associated implementing rules in Regulation (EC) Nº 889/2008 and provide a description of how the differences are resolved, taking into account the Codex Alimentarius Guidelines CAC/GL 32. The assessment should include a confirmation by the accreditation body of the equivalence of the production standard and the control measures.

An equivalence table should be used for the side by side assessment for production standard and control measures with Titles III, IV and V of Regulation (EC) No 834/2007 and associated implementing rules in Reg. 889/2008 as applied in third countries.

## 3.6 Office and witness/review audits to be conducted for initial accreditation / re-accreditation

For initial accreditation and re-accreditation, Accreditation bodies shall foresee the minimum number of man-days for office audits and the minimum number of witness/review audits as defined in table 2. For control bodies operating within the EU and in third countries, the following table applies:

### Table 2a: Minimum on-site times for office assessments

| | | | | | | | **Man-days on site** |
|---|---|---|---|---|---|---|---|
| **Increase factors** | | | | | | | Standard minimum 2 days |
| Operators in the EU and in third countries | + 1 day | | | | | | |
| Group Certification | + 1 day | | | | | | |
| Critical findings | + 1 day | | | | | | |
| Structural complexity (*) | Low<br>No addi. | | Medium<br>+ 0,5 day | | High<br>+ 1 day | | |
| Product categories | 2 or less<br>No additional | | 3-4<br>0,5 day | | >4<br>1 day | | |
| Countries of activities | 1-2<br>No additional | | 3-4<br>+ 0,5 day | | >4 -24<br>+ 1 day | > 25<br>+ 1,5 days | |
| Operator numbers | < 100<br>No addi. | 101 – 1000<br>+ 0,5 day | 1001 –3000<br>+1 day | 3001 – 6000<br>+ 1,5 day | 6001 - 10000<br>+ 2 days | > 10000<br>+ 2,5 days | |
| | | | | | | | **Total** |

(*) elements to be considered for structural complexity are for example, number of inspectors, number of offices, CBs managing different product certification schemes, different accreditation scheme, outsourcing, decentralization of decision making, etc.

## Table 2b: Minimum numbers of witness / control visit

| | | Witnessed assessments / Control visit for initial assessment |
|---|---|---|
| | | **At least 1** |
| **Increase factors** | | |
| Grower Group | | **+1** |
| Critical findings | **If necessary: additional WA/CV** | |
| Product categories | **1 per category (combinations of product categories is possible)** | |
| Equivalent production standard | **1 per equivalent production standard** | |
| Countries of activities / operators | **+ 1 per each 10 countries with > 20 operators** | |
| | | **Total** |

Each critical location shall be evaluated prior to initial accreditation. The days required, never less than half day, of this are to be added additionally to the minimum office assessment man-days as defined in table 2. Additionally, in the initial assessment, ABs shall confirm the status of “not critical locations”, sampling those offices in a representative number.

The Accreditation body shall select the third countries where to conduct the witness assessments taking account of:

- relevance of countries and noticed products affected by irregularities in the past;
- the number of operators certified in the third countries;
- whether producer groups are being certified in the third country;
- equal geographical distribution of witnessing in all Third Countries where inspection activities are carried out has to be considered.

## 3.7 Extension of accreditation scope to an additional product category

Additionally to the requirements mentioned under point 2.7, the Accreditation body shall assess the equivalence of the organic production standard of the CB for the additional product category as defined previously.

## 3.8 Surveillance assessments

Additionally to the requirements under point 2.9, each critical location in a third country shall be subject to at least one assessment in an accreditation cycle. Additional surveillance assessments shall be conducted in countries where major non-conformities were identified during the previous assessment.

The minimum duration of a surveillance assessment shall be at least 50% of the minimum on the basis of the calculation method in table 2.

The CB’s shall inform AB’s in a timely manner of technical changes in the equivalent standard(s).

## 3.9 Witness assessments to be conducted during one accreditation cycle

Additionally to the requirements under point 2.10, Accreditation bodies shall witness at least one physical inspection in each product category during an accreditation cycle not taking into account the number of witness assessments conducted in the light of initial accreditation or reassessment. The witness assessments have to be conducted in a third country for which the control body is listed in annex IV of Regulation (EC) 1235/2008. A single witness assessment could encompass different product categories if the activities of the witnessed operator and of the Control body justify it.

The Accreditation body shall select the third countries where to conduct the witness assessments taking account of:

- where relevant, the countries and products concerned by irregularities in the past;
- the number of operators certified in the third countries;
- whether producer groups are being certified in the third country;
- equal geographical distribution of witnessing in all third countries where inspection activities are carried out has to be considered.

## 3.10 Information Exchange between the accreditation body, Member State's competent authority and the scheme owner

Additionally to the requirements under point 2.12, the Commission Services, as the scheme owner may give the Accreditation bodies specific input for the assessment of CBs operating in third countries, in particular about irregularities recorded in the OFIS-system. Accreditation bodies shall take into account surveillance results by Competent authorities of third countries and other accreditors.

If the Accreditation body decides to suspend the accreditation of a CB operating in third countries, the Accreditation body shall inform in a timely manner the Commission services as the suspended CB cannot issue certificates of inspection during the duration of the suspension.

## *ANNEX – CHECK LIST OF RECOMMENDED POINTS TO BE ADDRESSED DURING ASSESSMENTS*

**Initial assessment report and re-assessment report**

Equivalence Assessment (for CBs operating under equivalence in third countries)

- Verification availability to operators of up-to-date, complete description of equivalent production standard and control measures covering all product categories the control body has applied to be accredited for.
- Assessment of the completed, up-to-date side by side assessment of equivalence of CB production and control standard with measures with Titles III, IV and V of Reg. (EC) No 834/2007 and associated implementing rules in Regulation (EC) No 889/2008. A side by side assessment should not be limited to differences.
- Verification identification of substantial difference by CB and how they are resolved.
- Assessment of the statement on equivalence of CB's production and control standard.

**Office assessments (Head Office and Critical Location)**

Standards

- Verification and document that equivalent production and control standards are available and up-to-date during all office and witness-assessments

Assessment of the qualification of staff regarding certification for the purpose of equivalence

- Interview with the staff, in particular decision makers in combination with the local standards/countries/product categories.
- technical management and monitoring of the certification process.
- CVs of all inspectors and certifiers. Verification of selected CVs indicating criteria for sampling and number of files assessed.
- Absence of conflicts of interest for staff and inspectors.
- Continuous training log for inspectors and certifiers indicating precisely the nature of the training, dates, duration, attestations of training received (if sample, indicate criteria for sampling and number of files assessed).
- Linguistic abilities of CB inspectors and countries in which they carry out inspections.

Subcontracting to other control body

- Documented verification by subcontracting CB that subcontracted CB is recognised for equivalence by COM for the product category and the third country;
- Certification decision remains with subcontracting CB.

Procedures

- Check availability of information on determining unannounced and follow-up visit: procedure, risk assessment methodology;
- check availability of policy on sampling, to include detailed procedure for sampling and circumstances requiring sampling;
- verify presence and implementation of specific procedures for retroactive recognition of conversion period, separation and inspection of conventional production units, of parallel/split production, of group certification and of wild collection;
- verify presence and quality of procedures for handling non-conformities and documenting through objective evidence;
- verify presence of CB's procedures for handling requests for information from Member States' competent authorities and Commission services and reporting procedures to the Commission Services;
- verify availability of CB's procedures for exchange of information with other control bodies;

check that CB has procedures for documenting and following up on operators' notification of batch suspension and of product withdrawal, including documentation of information to the CBs of its operator's clients in case of batch suspension or in case of product withdrawal;
verify that control bodies have procedures for accepting operators from other control bodies assuring that all the relevant requirements have been met in order for certification/conversion period to be maintained and that no outstanding nonconformities noted by the previous control body are left unresolved;
verify publication of operators list by the control body.

Documentary file review

Indicate selection criteria for files subjected to documentary file review. The selected files should be representative of the CB's product categories and geographical scope;
indicate total number of documentary file reviews carried out;
for each file, indicate code and location of operator, product categories certified, date of last inspection report, risk category according to CB;
review to include files of operators in countries where the CB has no critical location;
status of conformity shall be indicated (completeness, up-to-date, orderly, verification of NC termination by CB documented, follow up to complaints documented, communication to other CBs, MS documented).

Information exchange

Verify and summarise documentation of swift information exchange with other CBs, with Member States competent authorities, with Commission services;
verify and summarise timeliness and completeness of follow-up to information requests received by CB from other CBs, Member States competent authorities and Commission services.

- **Witness assessments**

*Scope*

List name and address of operator, name of CB inspector, date and duration of inspection;
indicate product category(ies) witness assessment covers.

*Documentation*

List documents and materials available to the inspector at start of assessment and those made available during witness assessment.

*Description of witness assessment*

Summarise points raised in opening meeting;
describe verification of operator's follow-up to all the main previously noted NCs;
description of physical inspection including questions and findings raised by inspector during physical inspection;
description of sampling conducted and assessment of adequacy thereof;
description of documentary inspection conducted and adequacy of file selection and examination;
description of the main points raised in closing meeting;
description of inspector's preparedness, communication skills / linguistic ability (did operator understand observations made?), thoroughness, adequateness of handling operators, handling of difficult situations;
read written report and other documents that are prepared and verified (e.g. handling of nonconformities), as basis for decisions on certification.