



**INSTITUTE FOR ACCREDITATION OF THE
REPUBLIC OF MACEDONIA**

**Procedure for assessment and accreditation of
Organic Production Certification Bodies**

PR 05-12



CONTENTS

1. PURPOSE

Reference documents

Definitions

2. ASSESSMENT OF CERTIFICATION BODIES OPERATING IN COMPLIANCE WITH THE LAW ON ORGANIC AGRICULTURAL PRODUCTION IN R. MACEDONIA AND THE CONTROL MEASURES DESCRIBED IN THE ASSOCIATED IMPLEMENTING RULEBOOKS

2.1 Technical Assessor and Experts qualifications and training requirements

2.2 References

2.3 Documents to be submitted by certification bodies applying for accreditation

2.4 Description of the scope of accreditation

2.5 Initial assessment and re-assessment / re-accreditation

2.6 Duration of initial accreditation / re-accreditation

2.7 Extension of accreditation scope to additional product categories

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

2.9 Surveillance assessments

2.10 Witness assessments to be conducted during one accreditation cycle

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

2.12 Information Exchange between the IARM and the Ministry of Agriculture, Forestry and Water Economy

3. ASSESSMENT OF CERTIFICATION BODIES OPERATING IN COMPLIANCE WITH THE REFERENCE DOCUMENTS AND THE CONTROL MEASURES EQUIVALENT TO THE EU REGULATIONS

3.1 References

3.2 Technical Assessor and Experts qualifications

3.3 Documents to be submitted by certification bodies applying for accreditation

3.4 Description of the scope of accreditation

3.5 Granting of initial accreditation and re-accreditation

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

3.7 Extension of accreditation scope to an additional product category

3.8 Surveillance assessments

3.9 Witness assessments to be conducted during one accreditation cycle

3.10 Information Exchange between the IARM, the competent authority and the scheme owner

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



1. PURPOSE

This Procedure, issued by the Director of the IARM (Article 23 from the IARM's Statute), aims to describe the assessment and accreditation principles of organic production certification bodies.

Reference Documents

- MKC ISO/IEC 17011:2006, Conformity Assessment – General Requirements for accreditation bodies accrediting Conformity Assessment Bodies;
- MKC EN 17065:2012, Conformity Assessment – Requirements for Certification Bodies for Products, Processes and Services;
- EA-2/13 M:2012 - EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members;
- EA-3/12 M:2013 - EA Policy for the Accreditation of Organic Production Certification;
- IAF GD 3:2003 - IAF Guidance on Cross Frontier Accreditation

Definitions

Certification body: In these guidelines the term Certification Body (CB) is used to cover any independent body certifying organic production in the Republic of Macedonia which has been delegated these control tasks by the Ministry of Agriculture, Forestry and Water Economy in accordance Article 46 of the Law on Organic Agricultural Production (Official Gazette 146/2009) and any independent body which certifies organic production for the purpose of equivalence in third countries in accordance with Article 33 (3) of the Regulation (EC) N° 834/2007.

Accreditation cycle: The length of the accreditation cycle is 4 years.

Critical location: Location as defined under point 2.2 of IAF-guide GD 3:2003 (Guidance on Cross Frontier Accreditation).

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) N° 834/2007 and associated implementing rules contained in Regulation (EC) N° 889/2008.

Control visit: Activity performed by the IARM 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 IARM's 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 certification body cannot issue new certificates.

Third countries: Non-member countries of EU

OFIS – Organic Farming Information System (http://ec.europa.eu/agriculture/ofis_public/).

2. ASSESSMENT OF CERTIFICATION BODIES OPERATING IN COMPLIANCE WITH THE LAW ON ORGANIC AGRICULTURAL PRODUCTION IN R. MACEDONIAN AND THE CONTROL MEASURES DESCRIBED IN THE ASSOCIATED IMPLEMENTING RULEBOOKS

2.1 Technical Assessor and Experts qualifications and training requirements

The IARM has established procedures for selecting, training and formally approving assessors and experts. (PR 03-04, Selection, training and evaluation of assessors).

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). 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 RM and 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 MKC EN ISO / IEC 17065 for bodies certifying products from organic production as well as training in practical assessments for the scope organic production.

2.2 References

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

- Law on Organic Agricultural Production of RM (Official Gazette 146/2009) and Law on amending and modifying the Law on Organic Agricultural Production (Official Gazette of RM No.53/2011)
- Rulebook on the Manner and procedure for performing of professional control of the organic Agricultural Production (Official Gazette No.163/2010)



- Rulebook on the form and content of the certificate, the manner of its issuance, and the procedure for collecting, packaging, transport and storage of organic products (Official Gazette No. 163/2010)
- Rulebook on rules and procedures in organic crop production (Official Gazette No.163/2010)
- Rulebook on rules and Procedures in beekeeping (Official Gazette No. 163/2010)
- Rulebook on the procedure for breeding, minimum housing conditions for different type of animals and maximum density of animals per hectar (Official Gazette No. 162/2010)
- Rulebook on procedures for the production of organic processed food (Official Gazette No. 163/2010)
- Other applicable documentation published by the Ministry of Agriculture, Forestry and Water Economy of RM <http://www.mzsv.gov.mk>
- Other applicable documentation published by the IARM <http://www.iarm.gov.mk>

2.3 Documents to be submitted by certification bodies applying for accreditation

Concerning the documentation required under MKC EN ISO / IEC 17065 for accreditation of organic production certification, Certification bodies apart from the Application for accreditation OB 05-04-1, 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;
- general procedures the quality manual is reference to;
- a list of all relevant documents;
- all procedures/ guidelines for inspection/certification;
- certification plan for the current year;
- list of approved subcontractors;
- an overview indicating the responsibilities of the staff;
- 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.
- records of the most recent internal audit and the latest management review; ili records of the latest internal audit and management review.

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



- 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 the Law on Organic Agricultural Production:

- Plants and plant products, including wild collection
- Livestock and livestock products, including beekeeping and beekeeping products
- Production and processing of plant and livestock products and foodstuffs composed of plant and livestock products, including trade of organic agricultural products
- Aquaculture
- Feed

2.5 Initial assessment and re-assessment / re-accreditation

The assessment of the certification body includes evaluation of the documentation, evaluation headquarters, evaluating 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

Duration of assessment of CB's office during initial accreditation and re-accreditation is at least 2 (two) days.

The following table illustrates the factors influencing the increase of man-days for CB's office audits.

Table 1: Factors influencing the increase of man-days for CB's office audits

Increase factors						
Critical findings	+ 1 ден					
Structural complexity (*)	Low /	Medium + 0,5 day		High + 1 day		
Product categories	2 or less /	3 + 0,5 day		4 + 1 day		
Number of operators	<100 /	101 – 1000 + 0,5 day	1001 – 3000 +1 day	3001 – 6000 + 1,5 days	6001 – 10000 + 2 days	>10000 + 2,5 days



(*) 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.

The number of witnessing for initial and reassessment is at least 1 (one) per each product category (combinations of product categories are also possible).

For critical findings additional witnessing/control visit can be carried out, when necessary.

Each critical location is 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, the IARM has to confirm the status of “not critical locations”, sampling a representative number of those locations.

2.7 Extension of accreditation scope to additional product categories

Before granting an extension of the accreditation scope to any additional product category, the IARM shall verify that the Certification body's inspectors have the necessary qualifications and shall perform at least one witness assessment in each additional product category for which the Certification 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 IARM shall refer to the requirements defined under point 3 for the granting of initial accreditation.

2.9 Surveillance assessments

The IARM 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 defined under point 2.6 herein.

2.10 Witness assessments to be conducted during one accreditation cycle

The IARM carry out witnessing of at least one physical inspection in each product category during an accreditation cycle for which the CB is accredited, not taking into account the



number of witness assessments conducted in the light of initial accreditation or reassessment. A single witness assessment could encompass different product categories if the activities of the witnessed operator and of the CB justify it.

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

The assessment team of the IARM selects the inspectors and operators for witnessing, 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 IARM takes into account the risk analysis conducted by the CB.

In the course of witnessing, the IARM also takes 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. traders).

It is preferable that the IARM 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 repeated witnessing shall be explained in the assessment report.

In order plan the witnessing, previous results on witnessing are taken into account.

2.12 Information Exchange between the IARM and the Ministry of Agriculture, Forestry and Water Economy

Ministry of Agriculture, Forestry and Water Economy as a competent authority delegating authority may provide the IARM with specific input for the assessment of CBs. The IARM shall consider the surveillance results provided by the competent Authorities.

If the IARM decides to suspend or withdrawn the accreditation of a CB, the IARM shall inform the Ministry of Agriculture, Forestry and Water Economy in a timely manner.

ASSESSMENT OF CERTIFICATION BODIES OPERATING IN COMPLIANCE WITH THE REFERENCE DOCUMENTS AND THE CONTROL MEASURES EQUIVALENT TO THE EU REGULATIONS

3.1 References

When assessing CB's for the purpose of verifying the fulfillment of equivalence with the above mentioned EU organic production standards and control measures, IARM'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 into 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) N° 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, certification 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) N° 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 CB is assessed whether it 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, the IARM shall not grant accreditation before having assessed the equivalence of the standard applied in the third country. The CB in third countries shall present a detailed description of its equivalent standard applied in third countries to the IARM. The CB shall ensure that those documents are up-to-date and cover all product categories for which the CB is seeking accreditation.

The equivalence assessment by the IARM shall be based on a side by side assessment prepared by the control body and verified by the IARM 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) N° 834/2007 and associated implementing rules in Regulation (EC) No 889/2008.

The assessment shall include an inventory of the substantial differences between the Certification body's production standard and control measures and the Titles III, IV and V of Regulation (EC) N° 834/2007 and associated implementing rules in Regulation (EC) N° 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 IARM 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, the IARM 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 certification 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 /		Medium + 0,5 day	High + 1 day		
Product categories	2 or less /		3-4 0,5 day	>4 1 day		
Countries of activities	1-2 /		3-4 +0,5 day	>4 -24 + 1 day		> 25 + 1,5 days
Operator numbers	< 100	101 – 1000	1001 – 3000	3001 – 6000	6001 - 10000	> 10000
	/	+0,5 day	+ 1 day	+ 1,5 days	+ 2 days	+ 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



Procedure for assessment and accreditation of Organic Production Certification Bodies

PR 05-12

		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, the IARM shall confirm the status of “not critical locations”, sampling a representative number of those locations.

IARM 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 IARM shall assess the equivalence of the organic production standard of the CB for the each 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 the IARM in a timely manner of technical changes in the equivalent standard(s).

3.9 Witness assessments to be conducted during one accreditation cycle

The IARM carries out witnessing 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 IARM selects 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 IARM, the competent authority and the scheme owner

The Commission Services, as the scheme owner may give the IARM specific input for the assessment of CBs operating in third countries, in particular about irregularities recorded in the OFIS-system. The IARM takes into account surveillance results by competent authorities of third countries and other accreditors.

If the IARM decides to suspend the accreditation of a CB operating in third countries, the IARM 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