

Document name	Instruction on the criteria and methods of accreditation and surveillance of organic production certification bodies according to Regulation (EC) No 834/2007 and Regulation (EC) No 889/2008 of the Commission	Version:	1
		Revision:	2
Document code	BAS QI 19	Date:	01.09.2019
Approve	Executive Director of EA BAS: Eng. Irena Borislavova		

**INSTRUCTION  
ON  
THE CRITERIA AND METHODS OF ACCREDITATION AND SURVEILLANCE  
OF ORGANIC PRODUCTION CERTIFICATION BODIES  
ACCORDING TO REGULATION (EC) NO 834/2007  
AND REGULATION (EC) NO 889/2008 OF THE COMMISSION**

**List of amendments:**

Nº	Date of amendment	Version, revision	Reason for amendment	Entry into force:
1	07.11.2016	Version 1, revision 1	Adding of the instructions from the Annex to EA-3/12.	11.11.2016
2	05.08.2019	Version 1, revision 2	Adding a Privacy declaration of release confidentiality	01.09.2019

Uncontrolled copy after printing

## CONTENTS

Section		Page
1.	Purpose	4
2.	Description of the activity	4
2.1.	General provisions	4
2.2.	Competence of persons involved in the process of accreditation of Organic Production Certification Bodies (OPCB)	5
2.3.	Assessment	7
2.4.	Maintaining of accreditation	9
2.5.	Assessment of the OPCB on their activities in third countries	10
2.6.	Administrative measures	12
2.7.	Public register of the OPCB	12
2.8.	Exchange of information	12
2.9.	Consideration of complaints related to OPCB	13
3.	Applicable documents	13

Uncontrolled copy after printing

## 1. PURPOSE

This instruction is intended to clarify the methods and criteria of EA BAS for the accreditation of organic production certification bodies and to provide guidance to the bodies wishing to obtain accreditation in this field.

## 2. DESCRIPTION OF THE ACTIVITIES

### 2.1 General provisions

According to the Law on National Accreditation of Conformity Assessment Bodies, the Executive Agency "Bulgarian Accreditation Service" provides accreditation and performs surveillance of the Product Certification Bodies, including CBs for Organic Production and Organic Farming.

EA BAS provides accreditation only to legal entities, which have declared their willingness to be recognized as competent certification of organic production bodies, *who have signed a declaration of release confidentiality in accordance with Annex 4 to this instruction*

#### 2.1.1 Description of the scope of accreditation

The scope of accreditation granted by EA BAS to organic production certification bodies operating within the territory of the European Union is determined by the categories of agricultural products, including aquaculture, as set out in Article 1 (2) of Regulation (EC) No 834/2007:

- (a) live or unprocessed agricultural products;
- (b) processed agricultural products for use as food;
- (c) feed;
- (d) vegetative propagating material and seeds for cultivation.

The scope of accreditation granted by EA BAS to organic production certification bodies operating in third countries is determined by the product categories as set out in Annex II to 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 standards applied in third countries. EA BAS provides accreditation for a product category when it finds that the body certifies against a standard equivalent to Regulation (EC) No. 834/2007 and the rules for its implementation.

The procedure for performing accreditation of OPCB is according to BAS QR 2 and BAS QI 2, which are supplemented and applied in conjunction with this instruction.

#### 2.1.2 This instruction has been developed based on:

COUNCIL REGULATION (EC) NO 834/2007 of 28 June 2007 on organic production and labeling of organic products and repealing Regulation (EEC) No 2092/91;

COMMISSION REGULATION (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labeling of organic products with regard to organic production, labeling and control;

COMMISSION IMPLEMENTING REGULATION (EU) No 203/2012 of 8 March 2012 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards detailed rules on organic wine

COMMISSION REGULATION (EC) NO 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries

БДС EN ISO/IEC 17065 Conformity assessment - Requirements for bodies certifying products, processes and services;  
БДС EN ISO/IEC 17067 Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes.  
EA - 3/12 M (rev. 00)- EA Policy For the Accreditation of Organic Production Certification;

Other relevant documentation published by the European Commission in regard to Council Regulation (EC) No 834/2007

Codex Alimentarius CAC/GL 32 Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods.

### 2.1.3 Used abbreviations and definitions

OPCB	Organic Production Certification Bodies
BAS QR 2	Accreditation Procedure of EA BAS
EA BAS	Executive Agency "Bulgarian Accreditation Service"
Operator	Any operator involved in activities at each stage of the production, processing and distribution of organic products
CA	Competent Authority for Republic of Bulgaria - Ministry of Agriculture and Foods
NAB	National Accreditation Body

Definitions:

**Organic production certification body** - a legal entity or other legal subject carrying out inspection and certification activities in the field of organic production in accordance with the provisions laid down in Regulation (EC) No 834/2007. This definition includes a third country organic production certification body or relevant body operating in a third country.

**Certification** - Conformity assessment activities carried out by a verification body for the purpose of issuing a certificate of conformity according to Regulation (EC) No 834/2007.

## 2.2 COMPETENCE OF PERSONS INVOLVED IN THE PROCESS OF ACCREDITATION OF ORGANIC PRODUCTION CERTIFICATION BODIES.

### 2.2.1 General Criteria for Competence of Lead Assessors, Technical Assessors and Experts in the accreditation area Organic Production Certification Bodies according to Regulation (EC) No 834/2007

The general criteria for competence of lead assessors, technical assessors and experts involved in assessments of OPCB is specified in p 4.2 of BAS QR 7.

The area of competence of the Technical Assessors / Experts is determined in accordance with Annex 1 to this instruction (Annex 1 to BAS QI 19).

### 2.2.2 Specific Criteria for Qualification of Lead Assessors, Technical Assessors and Experts in the accreditation area Organic Production Certification Bodies according to Regulation (EC) No 834/2007

The following qualification criteria are supplements and amendments to the general criteria set out in p. 4.3 of BAS QR 7

Lead assessors of OPCB - no change.

Technical assessors and experts of OPCB:

- shall have a higher degree in specialty related to the scope of accreditation (eg veterinarian, zoo engineer, agronomist, food technology);
- in case of assessors / experts without the required level of education - at least two years of professional experience in organic farming, aquaculture, agri-food industry or in the field of trade in organic products. In addition, at least two years of professional activity related to monitoring and / or assessment tasks in those technical areas in which the assessor is appointed;
- training on the specific application of management systems in accordance with ISO / IEC 17065 in OPCB;
- training in practical assessment for the scope of organic production.

Additionally to the qualifications and training requirements defined under point 2.2.2, the technical assessors and experts involved in assessment teams for assessment of OPCB, operating in third countries, 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.

The specific qualification criteria for technical assessors / experts are set out in Annex 1 to this instruction (Annex 1 to BAS QI 19).

**Team composition:**

The assessment team of OPCB includes a lead assessor and, where appropriate, an appropriate number of technical assessors and / or technical experts for the specific scope of accreditation. If necessary, technical experts may be included in the team to provide in-depth knowledge and expertise on specific issues needed to assist the lead assessor or other assessor in conducting of the assessment activities. The technical expert performs specific tasks under the guidance and full responsibility of the lead assessor or other assessor from the relevant assessment team.

**2.2.3. Competence of controlling persons and those who take decisions in relation to the provision and maintenance of accreditation**

**Controlling persons and those who take decisions shall:**

- (a) comply with the requirements of ISO 17011;
- (b) have knowledge of Regulation (EC) No 834/2007, Regulation (EC) No 889/2008, ISO / IEC 17065 and other relevant legislation as well as the applicable guidelines listed in the ПpBAS QR 2-ОСП;

In addition to the above requirements, controlling persons and those who take decisions in relation to the provision and maintenance of accreditation have sufficient knowledge and experience to evaluate the accreditation process.

Controlling persons should, in addition to the above requirements:

- are independent;
- have the competence to analyze the information and to confirm the completeness and integrity of the information;
- can judge the lack or contradiction in the information;
- can track the information to assess whether the assessment has been conducted in sufficient depth to make a decision.

The order of assessment of lead assessors / technical assessors and experts is described in BAS QR 7, using the Evaluation Card of the Lead Assessor / Technical Assessor / Technical Expert in the area "Certification Bodies" BAS QF 7.3 (OPCB).

### **2.3. ASSESSMENT**

The order for the assessment of OPCB is written in the Accreditation Procedure BAS QR 2 and Instruction BAS QI 2 (Table 2.2 and 3.2 of BAS QI 2) and the following additions and amendments:

2.3.1 Preliminary study - no additional instructions

2.3.2 On-site assessment

2.3.2.1 Planning of the on-site assessments

In preparing, planning and organizing the assessment of Organic Production Certification Bodies, BAS QI 2 follows the general rules, taking into account the following factors:

- the complexity of the scope as well as the management system,
- procedures and information for the processes
- the geographic areas in which the applicant performs or plans to carry out the certification activity

2.3.2.2 On-site assessment

#### **Initial accreditation and re-accreditation:**

Prior to re-accreditation, EA BAS performs office assessment of the head office, office assessment of each critical location and at least one witness in each product category that the applicant has requested for accreditation. In the initial assessment, EA BAS confirms the status of "non-critical locations" by random sampling.

#### **office assessment**

The objective is to assess the implementation of the documented certification procedures and the WSSD management system. In addition, when reviewing documents and assessing the office, the team should pay special attention to the following issues:

- Participation of stakeholders and ensuring independence and impartiality;
- Competence of ODBP;
- contractual obligations, including assessment of the risks associated with the conduct of certification procedures;
- Planning the time for on-site inspections, the use of the necessary competency, defining the team of ODS;
- verification procedures and records for their implementation.

The on-site assessment shall be carried out at the main office (registered office) where records of activity, procedures and documents from the management system are kept, as well as any other place where key activities are carried out.

The key activities includes:

- Mechanisms to ensure impartiality and independence of OPCB and its personnel;
- processes of providing competence to the personnel which include training and continuous monitoring;
- the process of reviewing the request and the ability to execute it;
- planning of certification activities;
- the process of selecting the team performing the on-site inspections;
- an independent review of the process.

In the case of initial accreditation and re-accreditation of OPCB operating exclusively in the Member States of the European Union, the minimum number of man-days for office assessment are defined according to Table 1a:

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

Increase factors							<b>Man-days on site</b>
							Standard minimum 2 days
Critical findings	+ 1 day						
Structural complexity (*)	Low -	Medium + 0,5 day		High + 1 day			
Product categories	2 or less -		3 + 0,5 day	4 + 1 day			
Members States of activity	1-2 -		3-4 + 0,5 day		>4-10 + 1 day	>10 + 1,5 days	
Number of operators	<100	101 – 1000	1001 – 3000	3001 – 6000	6001 - 10000	> 10000	
	-	+ 0,5 day	+1 day	+ 1,5 days	+ 2 days	+ 2,5 days	
<b>Total</b>							

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

The days required to assess critical locations (not less than half a day) are added to the minimum man-days for office assessment as defined in Table 1.

Witness assessment - The objective of the witness is to assess the practical application and the efficiency of the certification procedures.

The witness assessment shall review and assess the preparation, implementation, follow-up reporting as well as the competence of the personnel performing review and decision-making.

At least one witness is performed in each product category that the applicant has requested for accreditation.

In the case of initial accreditation and re-accreditation of OPCBs operating exclusively in the Member States of the European Union, the minimum number of witnesses is defined according to Table 1b:

**Table 1b: Minimum numbers of witness**

Increase factors		<b>At least 1</b>
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	
<b>Total</b>		

**Extension of accreditation scope to additional product categories**



Before granting an extension of the accreditation scope to any additional product category, EA BAS assess the OPCBs competence for each product category and perform at least one witness assessment in each additional product category for which the OPCB requests for extension.

**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 by EA BAS as an extension of the accreditation scope. Before granting such an extension the EA BAS shall refer to the requirements defined under point 2.5.2 for the granting of initial accreditation to OPCBs operating in third countries.

**2.4 MAINTENANCE OF THE ACCREDITATION, supplement to point 5.1 of BAS QR 2**

The maintenance of accreditation shall be carried out for the entire duration of the accreditation granted, through annual surveillances, in order to verify the maintenance and implementation of the certification procedures.

The first planning surveillance of OPCB is carried out no later than 12 months after the date on which the accreditation certificate was issued.

During one accreditation cycle, the OPCB has to provide records or ensure the performance of witness of categories of products in the accredited scope. In the event that the OPCB cannot provide such records or provide witness of the activity for any of the activities, EA BAS shall reduce the scope of accreditation.

When OPCB accredited by EA BAS performs certification in another Member State, the Agency may assign the performance of surveillance to the National Accreditation Body of the Member State where the certification is carried out. In this case, EA BAS is responsible.

EA BAS may make extraordinary assessments of its accredited OPCB at any time to ensure that they meet the requirements of EN ISO / IEC 17065.

**Surveillance assessments**

EA BAS conduct annual surveillance assessments during the accreditation cycle which include office and witness assessment. Each critical location is subject to at least one surveillance assessment in an accreditation cycle. Additional surveillance assessments are 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.

**Witness assessment**

EA BAS performing a witness of at least one physical inspection in each product category during an accreditation cycle for which the OBCB 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 of EU in which the OPCB is operating. A single witness assessment could encompass different product categories if the activities of the witnessed operator and of the OPCB justify it.

During the witness of the activity, all the documents of the operators and of the OPCB should be available to the assessment team of EA BAS.

**Criteria for the selection of operators to be witnessed:**

EA BAS 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, based on the risk analysis conducted by the CB in accordance with Article 27 (3) of Regulation (EC) N° 834/2007.

- taking into account the production cycles of each product, in order to assure that products are present at the time.
- avoiding the repeated witnessing of the same certification body client.
- taking into account previous results on witnessing

## 2.5 EVALUATION OF OPCBS FOR THEIR OPERATIONS IN THIRD COUNTRIES

### 2.5.1 Description of the scope of accreditation

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

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

Before granting accreditation to OPCB for a given product category the EA BAS finds out that the OPCB certifies against a standard that is equivalent to the Regulation (EC) No. 834/2007 and its implementing rules

### 2.5.2 Initial accreditation and re-accreditation

Additionally to the requirements defined under point 2.4, EA BAS assess the equivalence of the standard for production and control measures applied in the third country. EA BAS requires from OPCBs in third countries to present a detailed description of its equivalent standard and comparative table with Regulation (EC) N° 834/2007 and associated implementing rules in Regulation (EC) No 889/2008.

#### 2.5.2.1 Office and witness assessment for initial accreditation re-accreditation

For initial accreditation and re-accreditation, EA BAS foresee the minimum number of man-days for office audits and the minimum number of witness audits as defined in table 2.

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

Increase factors						Man-days on site
						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 No additional	Средна + 0,5 day	Висока + 1 day			
Product categories	2 or less No additional	3-4 0,5 дни	>4 1 day			
Countries of activities	1-2 No additional	3-4 +0,5 day	>4 -24 +1 day	> 25 + 1,5 days		
Operator numbers	<100 No addi.	101 – 1000 + 0,5 day	1001 – 3000 +1 day	3001 – 6000 + 1,5 day	6001 - 10000 + 2 days	> 10000 + 2,5 days
<b>Total</b>						

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

**Table 2b: Minimum numbers of witness**

<b>Increase factors</b>		Witnessed assessments / Control visit for initial assessment
Grower Group		<b>+1</b>
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	
		<b>Total</b>

Each critical location (area) 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 2. Additionally, in the initial assessment, ABs shall confirm the status of "not critical locations", sampling those offices in a representative number.

EA BAS 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.

**2.5.3 Extension of accreditation scope to an additional product category.**

Additionally to the requirements mentioned under point 2.3, EA BAS assess the equivalence of the organic production standard of the OPCB for the additional product category

**2.5.4 Maintenance of accreditation**

Additionally to the requirements under point 2.4, each critical location in a third country is subject to at least one assessment in an accreditation cycle. Additional surveillance assessments is 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 set out in table 2.

The CB shall inform EA BAS in a timely manner of technical changes in the equivalent standard.

Additionally to the requirements under point 2.4, EA BAS 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 are conducted in a third country for which the OPCB 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 OPCB justify it.

## **2.6 ADMINISTRATIVE MEASURES – in accordance to p. 5.4. of BAS QR 2**

## **2.7 Public register of OPCBs - in accordance to p. 8.3 f) of BAS QR 2**

## **2.8 INFORMATION EXCHANGE**

### **2.8.1 Information Exchange between EA BAS, Member State's competent authority and the scheme owner.**

#### **2.8.1.1 For OPCB in regard to certification activities on the territory of the European Union**

EA BAS evaluates any information provided by the Directorate General Agriculture and Rural Development to the EC as the owner of the scheme and the Competent Authority of the Member State for the Organic Production Control Body.

EA BAS reviews the results of witnesses provided by the Competent Authority.

The evaluation reports of EA BAS indicate whether the corrective actions requested in a previous assessment have been completed in a timely manner.

In the event of suspension, withdrawal, reducing of the scope of accreditation of the OPCB, EA BAS shall inform the Competent Authority of the Member State in due time.

#### **2.8.1.2 For OPCB in regard to certification activities in third countries:**

Additionally to the requirements in p. 2.8.1.1, EA BAS evaluates any information provided by the Directorate General Agriculture and Rural Development to the EC, in particular – for irregularities in the Management system.

EA BAS take into account surveillance results by Competent authorities of third countries and other accreditation bodies.

In the event of suspension, withdrawal, reducing of the scope of accreditation of the OPCB, EA BAS shall inform Directorate General Agriculture and Rural Development to the EC in due time.

### **2.8.2 Information Exchange between EU member-states NABs.**

#### **2.8.2.1 Information Exchange with respect to the witness carried out by EA BAS**

In case when NAB of a Member State assign to EA BAS to carry out witness activities on an accredited body for biological production certification operating on the territory of the Republic of Bulgaria EA BAS reports the results of the NAB of the Member State, if there is no other agreement between the EA BAS and the NAB of the member state

The NAB which granted accreditation by this OPCB is required to provide information to EA BAS in relation to:

- the actions taken related to the findings in the EA BAS report;
- the actions taken by the OPCB related to the non-conformities identified;
- administrative procedures that NAB has undertaken.

#### **2.8.2.2 Information Exchange with respect to the surveillance carried out by NAB of another Member-state**

Where an OPCB accredited by EA BCA carries out certification activities in another Member State, EA BAS may assign the National Accreditation Body of that State to carry out witness activities on behalf of EA BAS.

The National Accreditation Body, which EA BAS has commissioned to witness BAS-accredited OPCB, operating in the territory of the Member State, reports its findings to EA BAS.

Depending on the results, EA BAS shall take appropriate action and inform the National Accreditation Body that carried out the witness.

## **2.9 REVIEW OF COMPLAINTS RELATED TO OPCB**

When EA BAS receives a complaint about accredited Organic Production Certification Bodies, the Agency takes action according to point 4.3.3 of BAS QR 25, Procedure on resolution of complaints with an amendment to the time limits for consideration, namely: The Agency shall notify the persons concerned within three months of receipt of the signal.

For complainant is considered also the information received by EA "BAS" from CA for founded non-conformities with the requirements of the OPCB accredited by the Agency. The Agency takes action according to point 4.3.3 of BAS QR 25, Complaint Procedure as within three months of receipt of the information notifies the CA of the action taken and, as the case may be, of the administrative measures imposed on the CAB.

### **3. Applicable documents:**

BAS QR 2	Accreditation procedure
BAS QR 25	Procedure on resolution of complaints
BAS QI 2	Instruction on determination of the duration of on-site assessments. Factors of influence
Annex 1	Criteria for Competence of Technical Assessors/Experts
Annex 2	Justification of the duration of on-site assessments of OPCBs
Annex 3	<i>Internal instructions for conducting an office assessment and witness of the activities of the OPCBs by EA BAS teams</i>
Annex 4	<u>Privacy declaration of release confidentiality</u>

- ❖ *This document translation has been prepared for the needs of activities related to the accreditation, based on the official document of EA BAS.*  
*In case of discrepancies and differences between the Bulgarian document and its translation, the original document in Bulgarian shall be considered as leading.*