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INSTRUCTION ON CRITERIA AND METHODS OF ACCREDITATION AND SUPERVISION OF CERTIFICATION BODIES FOR ORGANIC PRODUCTS UNDER REGULATION (EC) 2018/848 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL

List of amendments:

№	Date	Version, revision	Reason for amendment	Effective of/ Entry in to force:
1	07.11.2016	Version 1, revision 1	Addition of the instructions from the annex to EA-3/12	11.11.2016
2	05.08.2019	Version 1, revision 2	Add Privacy Release Statement	01.09.2019
3	16.01.2023	Version 1, revision 3	Update in relation to the requirements of Regulation (EU) 2018/848 of the European Parliament and of the Council and EA-3/12 M: 2022	09.03.2023
4	*14.01.2025*	*Version 1, revision 4*	*Update in connection with a changed name of the competent authority*	*15.01.2025*

CONTENTS

1. Definitions and Abbreviations

1. Definitions

Terms and definitions given in Regulation (EU) 2018/848 and ISO/IEC 17011:2017 apply;

Organic production certification body - Control body as defined in Article 3, point (56) of Regulation (EU) 2018/848, responsible for the performance of conformity assessment services subject to this accreditation (certification body as defined by ISO/IEC 17000 and ISO/IEC 17065).

Critical Findings: findings that compromise the reliability of certification results or the control body's ability to maintain the quality level of certification services.

Certification – the conformity assessment activities carried out by OCB in order to issue a certificate of conformity, according to Regulation (EU) 2018/848.

1.1 Abbreviations

OCB	Bodies for certification of organic production
BAS QR 2	Procedure for accreditation of EA BAS
EA BAS	Executive Agency "Bulgarian Accreditation Service"
OP	Organic production
Operator	any operator involved in activities at any stage of production, processing and distribution of biological products
MAF	*Ministry of Agriculture and Food*
CA	Competent authority
EU	European Union
EC	European Commission
DG-AGRI	General Directorate "Agriculture and Rural Development
NAB	National Accreditation Body
OFIS	Organic Farming Information System

2. Competence of technical assessors and experts participating in the process of accreditation of bodies for certification of organic production (OCB).

The competence criteria of leading assessors, technical assessors and experts included in OCB assessments are regulated in *Appendix 2 to BAS QR 7*.

Initial and ongoing training for assessors and experts covers the specific application of management systems according to ISO/IEC 17065 in an organic product certification body and to enable the exchange of accreditation practices, including for example group of operators, mass balance, traceability, etc. for the scope of organic production.

3. Requirements for the accreditation process of OCB operating within the European Union

3.1 Applicable Requirements:

- Regulation (EU) 2018/848 of the European Parliament and of the Council of May 30, 2018 on organic production and labeling of organic products and repealing Council Regulation (EC) No. 834/2007;
- The delegated and implementing acts and subsequent amendments related to Regulation (EU) 2018/848;
- Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities carried out to ensure the application of food and feed legislation, animal health and welfare rules, plant health and plant protection products, amending regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EC) No 1151/2012, (EC) No 652/2014, (EC) 2016/429 and (EC) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC of the Council, and to repeal of Regulations (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC of the Council and Decision 92/438/EEC of the Council (Regulation on official controls);
- Other applicable requirements published by the European Commission regarding Regulation (EU) 2018/848.

3.2 Application for accreditation

When submitting an application for accreditation/re-accreditation/extension of the scope of accreditation, OCBs must submit the documents described in BAS QF 2.3.

The following documents must be available on site and submitted to EA BAS upon request:

- A copy of the latest internal audit report, the CABs internal audit program and the latest management review;
- Curriculum vitae and evidence of competence and experience for all staff members and inspectors;
- Declarations of absence of conflict of interest from the staff and inspectors;
- Continuous training log for staff and inspectors, type of training, including dates, duration, evidence of successfully completed training.

3.3 Scope of Accreditation

The scope of accreditation is determined by the product categories, according to Article 35, paragraph 7 of Regulation (EU) 2018/848.

3.4 Assessment program

Upon initial accreditation or extension of the scope of the EA BAS performs:

- On-site assessment of the OCB main office;
- On-site assessment of each OCB office, if applicable;
- At least one monitoring of the activity on site (see item 3.7);
- EA BAS performs annual supervision assessments during the accreditation cycle, in which it assesses a sample of offices and conducts activity observations (see item 3.5 and item 3.7).

In case of re-accreditation, EA BAS performs the following assessments:

- On-site assessment of the OCB main office;
- On-site assessment of a sample of offices (see item 3.5);
- Observations of the activity, according to point (see item 3.7).

3.5 Office Assessment.

EA BAS determines the number of assessment offices based on a risk analysis, taking into account the following factors:

- Experience in certification activities under office accreditation;
- Information about the performance of the office from previous assessments;
- The number of countries covered by the office;
- Irregularities reflected in the OFIS (Organic Production Information System) database and transmitted by the MAF;
- The number of certificates with which the office works;
- Availability of information about possible fraudulent actions of the OCB.

3.6 Duration of On-Site Assessments

In case of initial accreditation, extension of the scope and re-accreditation of the OCB operating only in an EU member state, EA BAS determines the duration of on-site assessments of the offices, according to Application *4*.

Application *3* allows calculation of the degree of risk for OCB. Application *4* shows the minimum duration of each assessment, relative to a given degree of risk (result from Application *3*) and the minimum number of operator files to check.
Preparation and report preparation time are added to the total duration. When combining with another certification scheme, the duration specified in Application 4 is added to the duration calculated for the other scheme.
The minimum duration of surveillance assessments and operator records for verification is at least 50% of the minimum calculated using Applications *3* and *4*.

The minimum duration for an on-site assessment of one office is not less than half a day, which must be added to the duration of the on-site assessment determined according to Applications *3* and *4*.

3.7 Witness audits of OCB.

3.7.1 Determination of the number of witness assessments.

For initial accreditation or extension of the scope of accreditation of OCB, EA BAS performs at least:

- One witness assessment for each product category;
- one witness assessment for the certification of a group of operators.

If the OCB operates in more than one EU Member State, the activity in other Member States will be covered by the witnessing schedule.

A single witness assessment can cover different product categories of the observed operator.

For 4 years (one accreditation cycle), during the annual surveillance, EA BAS will perform at least the following witness assessments:

- One witness assessment for each product category referred to in Article 35 (7) of Regulation EU 2018/848), without taking into account the number of witness assessments carried out during initial accreditation;
- One witness assessment for each group of operators, if applicable and
- Additional number of witness assessments determined by risk analysis based on the listed factors: Number of inspectors; Number of controlled operators; Type of activities performed by the operators; The number of witness assessments carried out by the Competent Authority; Irregularities regarding OCB; The number of certified producer groups and their size; The significant non-conformities for OCB, or for designated inspector/s, and Application for recognition for a new Member State.

3.7.2 Criteria for selecting inspectors and operators to be witnessed

EA BAS assessment teams determine inspectors and operators, selecting operators with a higher risk of deviations from organic production requirements.

The following factors are taken into account when selecting operators:

- the complexity of the activities performed by the operators,
- in particular traders or brokers for export or import,
- the size of the group of operators,
- the list of high-risk products taken from the OFIS database or other information such as speculative food supply, etc.
- a list of high-risk countries taken from the OFIS database pursuant to Article 8 of Regulation (EU) 2021/1698),
- the amount of products certified for a certain operator,
- the derogations granted by OCB (for example: retroactive recognition of transition/conversion),
- the irregularities related to OCB,
- the witness assessments made by the Competent Authority,
- the result of previous witness assessments.

EA BAS seeks to avoid witness assessments of the same operators/inspectors, unless there are significant risks or specific indicators for that operator or inspector.

EA BAS must document cases where witness assessments is repeated due to a limited number of certified operators or inspectors available.

3.7 Extension of Accreditation

When applying to extend the scope of accreditation, according to BAS QR 2, with a new category of products, EA BAS performs at least a review of the documents listed in point 3.2 and witnessing of the activity for the given category.

When applying for an extension of the scope of accreditation with a new office, EA BAS conducts a document review to determine whether the office needs to be assessed on site based on the risk analysis defined in point 3.5 and whether witnessing of the activity is required in relation to point 3.7.

4. ACCREDITATION PROCESS OF OCB OPERATING IN THIRD COUNTRIES

4.1 Applicable requirements used by EA BAS

When evaluating OCBs operating in third countries, EA BAS takes into account the following documents:

- Regulation (EU) No. 2018/848 of the European Parliament and the Council of May 30, 2018 on organic production and labeling of organic products and repealing Council Regulation (EU) No. 834/2007,
- The delegated and implementing acts related to Regulation (EU) No. 2018/848 and subsequent amendments and additions, as well as:

DELEGATED REGULATION (EU) 2021/1698 OF THE COMMISSION of 13 July 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with procedural requirements for the recognition of control and supervisory authorities competent to carry out control over operators and groups of operators, certified for organic production, and on organic products in third countries, and with rules for their supervision and for the control and other actions that must be carried out by these control and supervision authorities;

DELEGATED REGULATION (EU) 2021/1697 OF THE COMMISSION of 13 July 2021 amending Regulation (EU) 2018/848 of the European Parliament and of the Council regarding the criteria for the recognition of control and supervisory authorities competent to control organic products in third countries, and for the withdrawal of their recognition;

COMMISSION DELEGATED REGULATION (EU) 2021/1342 of 27 May 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the information to be sent by third countries, as well as by control and supervisory authorities, for the purposes of supervising their recognition pursuant to Article 33, paragraphs 2 and 3 of Council Regulation (EC) No. 834/2007 for imported organic products, and for the measures to be taken in the exercise of this supervision;

Other applicable documents published by the European Commission regarding Regulation (EU) No. 2018/848.

• Codex Alimentarius CAC/GL 32 Guide to the production, processing, labeling and marketing of organically produced foods.

4.2 Application for accreditation/re-accreditation of OCB

When submitting an application for accreditation/re-accreditation according to BAS QR 2, OCBs must submit the documents described in BAS QF 2.3.

4.3 Scope of accreditation

The scope of accreditation is determined by the product categories, according to Article 35, paragraph 7 of Regulation (EU) 2018/848.

4.4 Assessments program

The third country accreditation assessment program is based on the requirements described in point 3.4. The number of evaluated offices should be replaced with the requirements given in point 4.5, and the number of witnessing activities with the requirements given in point 4.7.

Assessment reports must contain at least the topics listed in the relevant delegated acts related to Regulation (EU) 2018/848, Regulation (EU) 2021/1698 (Annex I).

Point 3.8 also applies to accreditation in third countries.

4.5 Office assessment

Upon first application for recognition, EA BAS will conduct an on-site assessment of each office where a decision on certification is made. The assessment report of these offices must contain the information specified in Annex 1, Part A of Regulation (EU) 2021/1698.

Under OCB surveillance, each office where a certification decision is made must be assessed on site annually.

Assessments are carried out remotely only in cases of EU decision. For all other OCBs, on-site assessments are carried out

The annual assessment report of the office(s) where the certification decisions cover all

points listed in Annex II to Regulation (EU) 2021/1698.

4.6 Duration of on-site assessments

The method for calculating the duration of the assessment is specified in item 3.6, but annexes *3* and *4* have been replaced by annexes *5* and *6*. These annexes cover cases where the OCB operates only in third countries or in third countries and within the EU.

According to the experience of other NABs carrying out accreditation in third countries:

- The time to check one file per operator is on average 0.5 days (d);
- The time to verify the OCB with respect to clauses 4, 5, 6.2.2 and 8 of ISO/IEC 17065, is on average 3 days for BP only.

4.7 Witness assessments

4.7.1 Calculation of the number of witness assessments

When the OCB submits an application for accreditation (initial or extension of scope), EA BAS performs at least one witness assessment and adds another witness assessment further on:

• for each category of products, as specified in Article 35, paragraph 7 of Regulation (EU) 2018/848, for which recognition is requested;

• for each category of products in different third countries, if the OCB requires or is already recognized for more than one third country;

If the OCB certifies a group(s) of operators, it must cover at least one of the above witness assessments with a group of operators.

Where they operate in both an EU Member State and third countries, these witness assessments shall cover at least one EU Member State and one third country.

Witness assessment is carried out remotely only in cases where there is a decision of the EC. For all others, the witness assessments are carried out on site.

The witness assessment covers the entire activity of OCB, carried out physically and can only be carried out remotely, if so decided by the EC.

For the purposes of the annual report, the OCB ensures that the witness assessments are carried out in accordance with Sections 1 and 2 of Part C of Annex I to Regulation (EU) 2021/1698 and the following rules:

- the duration period between two (2) activity witness assessments must not exceed four (4) years;
- the number of activity witness assessments carried out after submitting an application for accreditation is not taken into account when calculating the total number of activity observations to be carried out in the 4 years;
- one additional witness assessment of the activity should be carried out:
  - every two (2) years in those third countries where high-risk products are manufactured or processed, as specified in Article 8;
  - for every 10th recognized third party. This additional monitoring shall be carried out within four (4) years;

  more witness assessments of the activity are carried out at the request of the EC or EA BAS based on risk analysis, in particular the following factors: the number of inspectors; the number of operators; the type of activities performed by the operators; the number of activity witness assessments carried out by EA BAS; the irregularities in relation to OCB; the number of certified groups of operators and their size; the critical findings for the OCB or the specific inspector or inspectors; the nature of the products and the risk of fraud; feedback from the EC based on the previous OCB annual report; suspected fraud on the part of the operators. the volume of products imported from third countries into the EU and the activity of OCB in recognized third countries.

4.7.2 Criteria for the selection of inspectors and operators to be witnessed

The surveillance sample is determined by the EA BAS teams so that witnessing is conducted at operators with the greatest risk of deviations from the requirements for organic production. When determining the operators with the highest risk of deviations, EA BAS considers the following factors:

- the complexity of the activities performed by the operators;

- traders or intermediaries in export;
- size of the group of operators;
- a list of high-risk products from the OFIS database or from DG AGRI manuals;
- a list of high-risk countries extracted from the OFIS database or a corruption website (eg: Transparency International);
- the volume of products certified for a given operator;
- the derogations granted by OCB;
- irregularities related to OCB;
- feedback from EC;
- results of previous witness assessments.

Repeat witness assessment of the same operator/inspector should be avoided unless significant risks or specific indicators for that operator or inspector are present.
EA BAS documents cases where witness assessment of an operator or inspector is repeated due to a limited number of certified operators or inspectors available.

4.8. Extension the scope of accreditation

When extending the scope for third parties according to BAS QR 2, the requirements of item 3.8 and additional requirements specified in item 4.1.
In addition, accreditation is required by Regulation (EU) 2018/848 (Art. 45.b and 57) according to 4 recognition options for certification bodies providing certificates for organic products imported into the EU coming from third countries, which are:

- in accordance with the EU Regulation (Conformity) (See Art. 45.i and 46 of Regulation (EU) 2018/848);
- recognized under a trade agreement (Trade Agreement) (See Article 45.ii and 47 of Regulation (EU) 2018/848);
- recognized and included in Annex III to Regulation (EC) No. 1235/2008 (see Article 45.iii and 48 of Regulation (EU) 2018/848);
  • controlled by OCB, recognized for the purpose of equivalence, listed in Annex IV to Regulation (EC) No. 1235/2008 (Equivalence) (See Article 57 of Regulation (EU) 2018/848).

5. Exchange of information
5.1

The European Commission, represented by DG Agriculture and Rural Development (DG-AGRI), as the owner of the scheme, and the Ministry of Agriculture and Food, as the delegating authority, can provide specific information to the EA BAS for the assessment of the OCB. EA BAS takes into account the results of surveillance provided by the Ministry of Health. The EA BAS report shall indicate whether the corrective actions requested in the previous surveillance of the MAF have been implemented in a timely manner.

EA BAS shall promptly notify the Competent Authority of the relevant EU Member State of the suspension or withdrawal of the accreditation of the OCB operating in the Member State.

5.2 Exchange of information between EA BAS and EC

In addition to the requirements under point 4.1, the EC may provide the EA BAS with information for the assessment of OCBs working in the TC regarding irregularities recorded in the OFIS-system. EA BSA considers the surveillance results provided by the EC or CA in a third country and other NABs when available.

In the event that the accreditation of an OCB operating in third countries is suspended or withdrawed, EA BSA promptly informs the services of the EC, including the reasons.

6. Applications:

Application 1	*Internal instructions for carrying out office assessment and witnessing of the activity of the OCB by teams of the EA BAS;*
Application 2	*Privacy Release Statement;*
Application 3	*Calculating the degree of risk for an on-site assessment for OCBs operating on the territory of EU Member States;*

Application 4	*Minimum duration of the assessment for OCBs operating on the territory of EU Member States;*
Application 5	*Calculating the degree of risk for on-site assessment for third parties;*
Application 6	*Minimum duration for assessment for TC*