Publication Reference **EA-3/12 M: 2020**

EA Policy for the Accreditation of Organic Production Certification

PURPOSE

This document outlines the EA policy for application of ISO/IEC 17011 when processing accreditation to control bodies in the field of organic production according to Regulation (EU) 2018/848.

Authorship
The publication has been written by a task force group 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 or the EA secretariat: secretariat@european-accreditation.org

Please check our website for up-to-date information: http://www.european-accreditation.org

Category:	Members' Procedural Documents EA-3/12 is a mandatory document.
Date of Approval:	25th June 2020
Date of implementation:	1st January 2021
Transition period:	Period of time between the approval and implementation dates. The equivalence procedure of EA-3/12 M:2013 in relation to the CBs own standard for recognition under Annex IV of Reg. (EC) No. 1235/2008 remains intact until 31 December 2023 (see clause 4.9).

CONTENTS

1 DEFINITIONS AND ABBREVIATIONS

1.1 Definitions

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

Control body: body as defined in point (56) of article 3 of Regulation (EU) 2018/848, in charge of performing conformity assessment services, object of this accreditation (the certification body as per definition of ISO/IEC 17000 and ISO/IEC 17065).

Location: Site where a control body performs at least one of the certification activities below:

- Competence management (qualification and monitoring) (ISO/IEC 17065 - clause 6);
- Application (ISO/IEC 17065 clause 7.2) and application review (ISO/IEC 17065 - clause 7.3);
- Plan and preparation of evaluation (ISO/IEC 17065 - clauses 7.4.1and 7.4.2);
- Review of evaluation results (ISO/IEC 17065 - clause 7.5);
- Decision making including issuing certificate or certificates of inspection [COI] (ISO/IEC 17065 – clauses 7.6, 7.7, and 7.11);
- Disputes with consequences for certification as complaints and appeals (ISO/IEC 17065 – clause 7.13);
- Development and approval of documents and policies (ISO/IEC 17065 – clauses 5.1.3 a), b), d), e) and 7.10).

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

1.2 Abbreviations

OF: Organic Farming (*generally symbolizing the area of certification, synonymous to Organic Production*)
CB: Control Body
NAB: National Accreditation Body
CA: Competent Authority
COM: European Commission represented by DG-AGRI
EU: European Union
TC: Third Countries outside EU
WA: Witness Audit performed by NAB
ICS: Internal Control System
COI: Certificate of Inspection
OFIS: Organic Farming Information System
MS: Member State of European Union

2 TECHNICAL ASSESSORS AND EXPERTS QUALIFICATIONS REQUIREMENTS

This section specifies the competence criteria for selecting, training and formally approving assessors and experts, required for the scope “Organic Production” in relation to clause 6.1.2 and table A.1 of ISO/IEC 17011.

Technical assessors and experts of NAB shall have a degree in a discipline related to the scope of accreditation (e.g. agronomist, food scientist). They shall have at least two years of working experience in the organic sector. In the exceptional case of assessors without an academic degree, a related profession in the food or agricultural sector is required including at least 5 years of professional experience within organic sector. Such experience can include scientific work, consultancy, production/operation, certification/inspection activities alike.

Assessors and experts of NAB shall have adequate knowledge of the requirements and practical implementation of the EU Regulation on Organic Production.

For the purpose of witnessing, assessors and experts shall have evident knowledge and/or experience in relation to the Regulation (EU) 2018/848 and the relevant delegated acts.

Additionally, for assessments and activities outside the EU, technical assessors and experts shall have adequate knowledge of Codex Alimentarius guidelines CAC/GL 32, and a proven track record of TC experience within the organic sector.

The initial and on-going training for assessors and experts shall cover the specific application of quality management systems according to ISO/IEC 17065 in a CB certifying products from organic production and shall permit exchange of accreditation practices, including for examples, group of operators, mass balance, traceability, etc. for the scope of organic production.

3 REQUIREMENTS FOR ACCREDITATION PROCESS FOR CONTROL BODIES OPERATING IN THE EUROPEAN UNION

3.1 References

When assessing CB’s operating in the EU, NABs shall consider the following documents:

- Regulation (EU) Nº 2018/848 of the European Parliament and of the council of 30May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) N°834/2007;
- And its associated delegated and implementing acts related with Regulation (EU)N°2018/848, and subsequent amendments;
- Regulation (EU) N°2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products**,** [links with Regulation (EU) N°2018/848explained in chapter VI of Regulation (EU) N°2018/848];

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

3.2 CB's application for accreditation

NAB shall require CBs to submit as a minimum:

a) a description of CB's organization;
b) the complete list of locations, indicating for every location the certification activities carried out and countries covered;
c) the standard control procedures [see art. 40.1.a.ii) of Regulation (EU) Nº 2018/848] applied for all activities concerned by the application;
d) an overview indicating the responsibilities of staff;
e) list of qualified inspectors per product category;
f) list of reviewers and decision makers per product category.

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

a) a copy of the most recent internal audit report, the CB's internal audit program and the latest management review;
b) curricula and supporting evidence of all technical staff members and inspectors;
c) declarations of absence of conflicts of interest for staff and inspectors;
d) continuous training log, indicating precisely for each staff member and inspector the nature of the training, including dates, duration, attestations of successfully completed training.

3.3 Scope of accreditation

The accreditation scope shall be defined by the product categories as defined in Article 35 (7) of Regulation (EU) Nº 2018/848.
If the CA requires a specific national scoping, including a list of activities of operators (see Annex VI box 4), the accreditation scope shall clearly give the link with the product categories listed in Article 35.7 of Regulation (EU) Nº 2018/848.

Concerning the newly added category of product (clause g) of article 35.7 of Regulation (EU) Nº 2018/848), the scope of accreditation shall specifically include each of the products indicated in Annex I and covered by accreditation or treated as flexible scope in conformity with the document EA-2/15.

If applicable, certification of group of operators shall be explicitly and unambiguously listed on the accreditation scope.

3.4 Assessment program

For the first application for accreditation for organic farming (initial or extension), the NAB shall not grant accreditation before having performed the following assessments:

a) an onsite assessment of the registered legal entity of the CB, (often the head office of the CB);

b) an onsite assessment in each location of the CB, if applicable;
c) at least one witness assessment, as defined in clause 3.7 below.

Before performing assessments, the NAB shall examine by document review the set of documents listed in clause 3.2.

Concerning the surveillance of accreditation, the NAB shall conduct annual surveillance assessments during the accreditation cycle, shall assess a sample of locations and perform witness audits as defined respectively in clause 3.5 and clause 3.7 below.

For the purpose of reassessment (re-accreditation), the NAB shall not renew accreditation before having performed the following assessments:
a) an onsite assessment of the registered legal entity, (often the head office of the CB);
b) an onsite assessment in sampled locations as defined in clause 3.5;
c) at least witness audits as defined in clause 3.7.

3.5 Assessments of locations

The NAB shall calculate the number of locations to assess, based on risk analysis with, at least, the factors below:
a) the experience gained by the location for certification activities under accreditation;
b) the previous performance of the location;
c) the number of countries covered by the location;
d) irregularities registered in OFIS data base and transmitted by CA;
e) the number of certificates managed by the location.

This sample of locations shall be increased if the NAB is informed of suspicions of fraudulent activities by CB.

3.6 Duration of onsite assessments

For the first assessment for OF (initial or extension) and reassessment of the legally registered entity of a CB operating exclusively in MS, the NAB shall foresee the minimum number of days (d) for the team for an on-site assessment (head office and other locations defined in clauses 3.4 and 3.5).

Table A below permits to calculate a risk score per CB. Table B below shows the minimum duration for each assessment, based on the given risk score (result of table A) and the minimum number of operator files to check.

Table A - Risk score calculation for onsite assessment (for EU MS)

	Risk Level			Score
	Low (score =1)	Medium (score=2)	High (score=3)	
Presence of a Critical Finding at the previous assessment	no	/	yes	
Group Certification	no	/	yes	
Number of Locations	1	2 - 5	>5	
Number of Product Categories	1 - 2	3 - 4	>4	
Number of Members States covered	1 - 2	3 – 4	>4	
Number of operators certified	<1000	1001 - 6000	>6000	
			Total Risk score	

Relating to experience of NAB in the sector:

- the time to check one operator file is on average 0,25 days (d);
- the time to check the organization of a CB, regarding clauses 4, 5, 6.2.2 and 8 of ISO/IEC 17065, is on average 2d for a CB assessed only for OF.

Table B - Minimum duration for assessment (for EU MS)

Days (d) Calculation			
Total Risk Score, result of table A above	6-9	10-15	16-18
Number of operator files to check (A)	4	6	8
Total duration for only OF scheme = (A)x0,25d + 2d	3	3.5	4
Total duration for OF if other schemes applied = (A)x0,25d+1d	2	2.5	3

Preparation and reporting times shall be added to the total duration calculated above.
In case of combination with another certification scheme, the duration resulting from table B is added to the duration calculated for the other scheme.

The minimum duration of a surveillance assessment shall be at least 50% of the minimum calculated using tables A and B.

The minimum duration of an on-site assessment of one location shall never be less than half day, which is to be added to onsite assessment duration as defined in tables A and B.

3.7 Witness audits

3.7.1 Number of witness audits (WA)

For the first application for OF accreditation (initial or extension) the NAB shall perform at least,

a) one WA per product category (7 listed on art. 35(7) of Regulation EU 2018/848);
b) and one WA of a certification of a group of operators, if the CB provides that service.

In exceptional cases, the WA can be postponed as condition to accreditation if business activities inevitably relate to recognition by the national CA. If more than one MS is covered by the CBs activity, these need to be considered within the witnessing schedule.

A single witness audit may encompass different product categories if the activities of the witnessed operator and of the CB justify it.

The WA shall cover the whole activity under witness.

During 5 years, the NAB shall witness at least,

a) one WA per product category (7 listed on art. 35(7) of Regulation EU 2018/848), not considering the number of WA conducted for the first application, and
b) one WA of a group of operators if CB certifies groups of operators, and
c) an additional number of WA determined by risk analysis based at least on the factors below:
    - the number of inspectors;
    - the number of operators controlled;
    - the type of activities performed by the operators;
    - the number of WA performed by CA;
    - the irregularities concerning the CB;
    - the number of certified producer groups and the size of them;
    - the critical findings for either the CB or the specific inspector(s);
    - the application of recognition for a new MS.

For selecting inspections/control visits to be witnessed, see the clause 3.7.2 below.

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

The NAB shall select the witnessed inspectors and operators on its own, ensuring that witnessed assessments are performed with operators with a higher risk for deviations of organic production requirements. To establish which operators could present a higher risk for deviations, the NAB will consider the factors below:

a) the complexity of activities performed by the operators;
b) in particular traders or intermediates for exports or imports;
c) the size of group of operators;
d) the list of high risk products, extracted from OFIS database or other information like speculative supply chain, etc.;
e) the list of high risk countries, extracted from OFIS database or website of corruption (e.g.: Transparency International);
f) the volume of products certified for a given operator;
g) the derogations granted by the CB (e.g.: retroactive recognition of conversion);
h) the irregularities concerning the CB;
i) the WA performed by the CA;
j) the result of previous WAs.

Repeated witnessing of the same operator/inspector should be avoided, unless there are significant risks or specific indications for this operator or inspector.

Where repeated WAs occur because of a limited number of certified operators or availability of inspectors, the NAB report shall document this fact.
The NAB shall consider previous results on WAs to establish its witness strategy.

3.8 Extending accreditation

If the CB applies for accreditation of a new product category, the NAB shall at least perform a document review of the documents listed in clause 3.2 and a WA for the given category.

If the CB applies for accreditation of a new location, the NAB shall perform a document review to determine if the location shall be assessed on site, based on risk analysis defined in clause 3.5 and if a WA is necessary in regard to clause 3.7.

3.9 Information Exchange between NAB, Member State's CA and COM

The COM services as scheme owner and a MS's CA as delegating authority may provide the NAB specific inputs for the assessment of CBs. The NAB shall consider surveillance results provided by CA. The NAB report shall indicate whether the corrective measures requested during the previous assessment of CA where implemented in a timely manner.

If the NAB decides to suspend or withdraw the accreditation of a CB operating in a member state, the NAB shall inform the relevant CA in a timely manner.

3.10 Suspending, withdrawing or reducing accreditation

If a CB has got no client for a given product category during 3 consecutive calendar years, the NAB should suspend the category concerned from the accreditation scope. Reasons not to suspend part of the accreditation scope need to be justified and documented. Such reasons can include positive business outlook (gaining new clients in due course) or specific evidence of substituting competence management despite a lack of clients.
Such a suspension may be lifted after a successful WA on the given category was performed.

If the CB has got no clients for a given category for 4 consecutive years, the procedure for withdrawal of the respective accreditation scope shall be initiated.

4 ACCREDITATION PROCESS FOR CB OPERATING IN THIRD COUNTRIES (TC)

4.1 References

When assessing CBs operating in third countries, the NAB shall consider, at least, the following documents:

a) Regulation (EU) Nº 2018/848 of the European Parliament and of the council of 30 May 2018 on organic production and labelling of organic products and repealing

Council Regulation (EC) n°834/2007;
b) Associated delegated acts and implementing acts related with Regulation (EU) N°2018/848, and subsequent amendments;
c) Other applicable documentation published by the European Commission regarding Regulation (EU) Nº 2018/848;
d) Codex Alimentarius CAC/GL 32 Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods.

4.2 CB's application for accreditation

Additionally to the documents defined under point 3.2, CBs need to submit at least the following:

a) a description of their production standard, control measures adapted for TC, and the standard control procedures implemented for all activities in TC, or the documents required on the technical dossier (art 46.4 of Regulation EC 2018/848) by the COM;
b) an updated list of countries covered by the application, number of estimate operators per category and per country;
c) a draft/copy of the application for recognition by the COM.

4.3 Scope of accreditation

The accreditation scope shall be defined as in clause 3.3 above.

4.4 Assessment program

The assessment program for accreditation in TC is based on the same requirements defined in clause 3.4. The number of locations assessed shall be replaced by the requirements of clause 4.5 below. The number of WA shall be replaced by the requirements given in clause 4.7 below.

The assessments reports shall contain at least the topics listed in the respective secondary acts of Regulation (EU) 2018/848.

Clause 3.8 applies as well for TC accreditations. If a CB already accredited for OF within the EU applies for OF in TC, the NAB shall perform a document review to determine the number of onsite assessments and the extra number of WA needed in regards with 4.5 and 4.7 below.

Clause 3.10 applies as well for TC accreditations.

4.5 Assessments of locations

The location performing activities in high risk countries shall be assessed on-site at least every 2 years by the NAB. The list of high risk countries is provided each year by COM,

based on the analysis of the OFIS data base.

Additionally, the NAB shall calculate the number of locations to be assessed, on the basis of risk analysis with, at least, the factors below:

a) the experience gained by the location for certification activities under accreditation;
b) the previous performance of the location;
c) the number of countries covered by the location and the risk of country, (list transmitted by COM based on OFIS database);
d) irregularities registered in OFIS data base and transmitted by COM;
e) the number of certificates managed by the location;
f) the accreditation of the location granted for local organic law being in force.

The number of assessed locations shall be increased if the NAB is informed of suspicions of fraudulent activities by CB.

4.6 Duration of onsite assessments

The method for calculating the duration of assessment applies as given in clause 3.6, except that the tables A and B are replaced by table C, and D.
These tables cover cases where a CB operate in TC only or in TC and within the EU.

Tables C - Risk score calculation for onsite assessment for TC

	Risk Level			
	Low (score=1)	Medium (score=2)	High (score=3)	Score
Operators in TC and within the EU	No	/	Yes	
Group Certification	No	/	Yes	
Presence of a critical finding at the previous assessment	No	/	Yes	
Number of Locations	None	1 - 5	>5	
Number of Product Categories	1	2 - 4	>4	
Number of Countries covered	1 - 2	3 - 10	>10	
Number of operators certified	<1000	1001 - 6000	>6000	
			Total Risk score	

Relating to experience of NAB in the sector:

- the time to check one operator file is on average 0,5 days (d);
- the time to check the organization of a CB, regarding clauses 4, 5, 6.2.2 and 8 of ISO/IEC 17065, is on average 3d for a CB assessed only for OF.

Table D - Minimum duration for assessment for TC

Days (d) Calculation			
Total Risk Score, result of table C above	7-9	10-13	14-21
Number of operator files to check (A)	4	6	8
Total duration for only OF scheme = (A)x0,5d + 3d	5	6	7
Total duration for OF if other schemes applied = (A)x0,5d+2d	4	5	6

4.7 Witness audits

4.7.1 Calculation the number of WA

For the first application for OF accreditation (initial or extension), the NAB shall perform at least,

a) one WA per product category (7 listed on art. 35(7) of Regulation EU 2018/848), and
b) one WA of a certification of a group of operators, if the CB provides that service.

When active in both MS as well as in TC, these WA shall cover at least one MS and one TC. In exceptional cases, WA can be postponed as condition to accreditation if business activities inevitably relate to recognition by the national CA. If more than one country is covered by the CBs activity, these need to be considered within the witnessing schedule.

A single witness audit may encompass different product categories if the activities of the witnessed operator and of the CB justify it.

The WA shall cover the whole activity under witness.

During 5 years, the NAB shall witness at least,

a) one WA per product category (7 listed on art. 35(7) of Regulation EU 2018/848), not considering the number of WA conducted for the first application;
b) one WA if CB certifies groups of operators;
c) one WA per high risk country every 2 years;
d) one WA per 10 countries active;

The specific number of WAs is further determined by risk analysis at least based on:

- the number of inspectors;
- the number of operators controlled;
- the type of activities performed by the operators;
- the irregularities concerning the CB;
- the feedbacks of COM following the annual report of the CB;
- the number of certified producer groups and their size;
- the critical findings for either the CB or the specific inspector(s).

For selecting inspections/control visits to be witnessed, see the clause 4.7.2 below.

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

The NAB shall select the inspectors and operators to be witnessed on its own, ensuring that WA are performed with operators with a higher risk for deviations from organic production requirements. To establish which operators could present a higher risk for deviations, the NAB will consider the factors below:

a) the complexity of activities performed by the operators;
b) particularly traders or intermediates for exports;
c) the size of the group of operators;
d) the list of high risk products, extracted from OFIS database or from guidelines of COM;
e) the list of high risk countries, extracted from OFIS database or website of corruption (e.g.: Transparency International);
f) the volume of products certified for a given operator;
g) the derogations granted by the CB (e.g.: retroactive recognition of conversion);
h) the irregularities concerning the CB;
i) the feedbacks of COM following the annual report of the CB;
j) results of the previous WA, etc.

Repeated witnessing of the same operator/inspector should be avoided, unless there are significant risks or specific indications for this operator or inspector.
Where repeated WA occur because of a limited number of certified operators or availability of inspectors, the NAB report shall document this fact.
The NAB shall consider previous results on WAs to establish its witness strategy.

4.8 Extending accreditation to specific areas of activity

Clause 3.8 applies for extensions of scope with the specifications added above for TC accreditations in the current chapter 4.

Additionally, accreditation is required by Regulation (EU) N°2018/848 (Art 45.b and 57) according to 4 options of recognitions for CBs providing certifications of organic products, imported into the EU coming from TC, which are:

a) complied with EU regulation (Compliance) (See art. 45.i and 46 of Regulation (EU) N°2018/848);
b) recognized under a trade agreement (Trade agreement) (See art. 45.ii and 47 of Regulation (EU) N°2018/848);
c) recognized and listed in annex III of Regulation (EC) 1235/2008 (See art. 45.iii and 48 of Regulation (EU) N°2018/848);
d) controlled by CB recognized in purpose of equivalency, listed in annex IV of regulation EC 1235/2008 (Equivalency) (See art. 57 of Regulation (EU) N°2018/848).

4.8.1 Option n°1 (Compliance)

The extension of accreditation is based on on-site assessments as defined in clause 4.

If the CB is already accredited for OF with equivalency option, the extension assessment for the new compliance option is based on document reviews at least. Onsite assessments may be added depending the results of risk analysis described in the clauses 4.4, 4.5 and 4.7.

4.8.2 *Option n°2 (Trade agreement)*

Accreditation may be requested by the local CA of the TC recognized by the EU under a trade agreement. The NAB shall contact the COM to establish the set of requirements covered by the trade agreement and the contact of the local CA. The local CA may require specific accreditation programs. Where applicable, clause 4 applies by default.

4.8.3 Option n°3 (TC recognized)

That recognition will expire on 31 December 2025 according to article 48 of the regulation (EU) n°2018/848.

Accreditation may be requested by the local CA of the TC recognized by the EU under Regulation (EC) 1235/2008. The NAB shall contact the COM to establish the set of requirements covered by that recognition and the contact of the local CA. The local CA may require specific accreditation programs. Where applicable, clause 4 applies by default.

4.8.4 Option n°4 (Equivalency)

This recognition of CBs will expire on 31st December 2023 according to article 57 of Regulation (EU) n°2018/848. During the transition period starting on 01st January 2021, clause 4 of this document is implemented for this case.

Additionally to the requirements defined under point 4.2, the NAB shall not grant accreditation before having assessed the equivalence of the standard applied in TC. The CB shall present a detailed description of its equivalent standard applied in TC to the NAB. 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 NAB shall be based on a side by side assessment prepared by the CB and verified by the NAB that demonstrates the equivalence of the production standard for each product category with the regulation (CE) 1235/2008 and associated acts. The assessment shall include an inventory of the substantial differences between the CB's production standard and control measures and the Regulation (CE) Nº 889/2008 and associated acts and provide a description of how the differences are resolved, taking into account the Codex Alimentarius Guidelines CAC/GL 32. The assessment shall include a confirmation by the NAB 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 the Regulation (CE) No 1235/2008 and associated acts as applied in TC.

4.9 Information exchanged between the AB and COM

Additionally, to the requirements under point 3.10, the COM Services may give the NAB specific input for the assessment of CBs operating in TC, about irregularities recorded in the OFIS-system. The NAB shall consider surveillance results provided by COM or CA in TC and other NABs, if and when available.

In case an accreditation of a CB operating in TC is suspended or withdrawn, the NAB shall inform the COM services in a timely manner, including the reasons.

4.10 Suspending, withdrawing or reducing accreditation

If a CB has got no client for a given product category during 3 consecutive calendar years, the NAB should suspend the category concerned from the accreditation scope. Reasons not to suspend part of the accreditation scope need to be justified and documented. Such reasons can include positive business outlook (gaining new clients in due course) or specific evidence of substituting competence management despite a lack of clients.
Such a suspension may be lifted after a successful WA on the given category was performed.

If the CB has got no clients for a given category for 4 consecutive years, the procedure for withdrawal of the respective accreditation scope shall be initiated.