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Accreditation of organic certifiers (EA and DAkkS)

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I. Accreditation and Notification

II. Common rules of EA (EA 3/12)

III. What about the risks?

IV. Further Experience

I. Accreditation and Notification

Accreditation – Proof of professional ability (competence)

Notification - Proof of the legal permission (authorization)

Regulation (EC) No. 834/2007

Within the EU:

- National accreditation
- National “notification”

Outside the EU:

- “equivalence”
  Reg. 1235/2008
  Annex 3 and Annex 4
- Accreditation by several (N)AB
- Notification by the EU

Regulation (EC) No. 834/2007

Within the EU:

- Supervision by competent authorities

- Germany…
  16 federal states
  - Office assessments
  - Witnessing (high numbers)

Outside the EU:

- Supervision by the EU COM
  - annual reports by CB
  - sampling/Audits by DG Sante

- Heavy reliance on Accreditation
  - witnessing and office reports

II. Common rules of EA (EA 3/12)

EA ?

> European Cooperation for Accreditation

> Peer Evaluation of its members
(mandate by Reg. (EC) 765/2008)

> Harmonizing rules / common approach, where possible

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II - EA

EA 3/12

EA Policy for the Accreditation of Organic Production Certification

(European Cooperation for Accreditation)

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EA 3/12

Purpose:

Harmonization of assessment scope and requirements for the accreditation of control bodies for Organic Production

Developed in cooperation with DG Agri (EU Commission)

As well, the process included an informative exchange with US and Canadian authorities and IOAS.

Mandatory within EA from 01. Januar 2014

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EA 3/12

- Applicable within the EU and Third Countries (location and activities)

  (Regulations (EC) No. 834/2007, 889/2008, **1235/2008**)
- Requirements regarding assessor/competence
- List of necessary documents
- Clarification of scope for the accreditation certificate
- **Process of equivalence assessment**
- **Requirements on assessment scope / man day calculation (OA/WA)**

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EA 3/12

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 addi.		Medium + 0,5 day	High + 1 day		
Product categories	2 or less No additional		3-4 0,5 day	>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
						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.

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EA 3/12

Table 2b: Minimum numbers of witness / control visit

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

- **Global Application, multiple sources/regulations**
- **EC wants IAF membership as prerequisite…**
- **Revision of European Regulation**
- **Experience**

Revision

Move to IAF level?

III. What about the risks?

ISO/IEC 17011 (new version 2017)
-> 20 x „risk“ / 4 x in direct relation to the assessment process

risk based **assessment principles** (6.1.2.4)

In selecting the **activities to be assessed** the accreditation body shall consider the **risk** associated with the activities, locations and personnel covered by the scope of accreditation. (7.6.4)

The assessment programme shall ensure that the requirements of the international standards and other normative documents containing requirements for conformity assessment bodies and the **scope of accreditation shall be assessed** taking **risk** into consideration […] 7.9.4

EA 3/12

referring to minimum mandays and witnessing

EA 3/12, 2.11 Witness assessments: criteria for the selection

The Accreditation body [ensures]witnessed assessments are **performed in operators with a higher risks** for deviations of organic production requirements. To establish […] **take into account the risk analysis conducted by the CB** in accordance with Article 27 (3) of Regulation (EC) Nº 834/2007. […]

It is **not adequate** that witnessing covers exclusively activities that are essentially of an administrative nature (e.g. brokers, traders). […]

Witness assessments **shall avoid the repeated witnessing** of the same certification body client. […]

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

EA 3/12, 3.6 Office and witness/review audits to be conducted for initial accreditation / re-accreditation

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

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

EA 3/12, 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.
[…]

EA 3/12, 2.12 Information Exchange between the accreditation body, Member State's competent authority and the scheme owner

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

ISO/IEC 17011 > principle of the use of third party information

The assessment team shall analyse **all relevant information** and objective evidence gathered **prior to and during** the assessment to determine the extent of competence and conformance of the conformity assessment body with the requirements for accreditation.

IV. (Further) Experience

Several years of experience within the system

„Development“ in equivalence assessments (CB>AB>EC)

Delay in active exchange of information between AB and authorities (but increasing now)

Letters by DG AGRI addressed to the CB > reaction by the AB required

increasingly risk oriented witnessing, based on external information and planned samples (costs attached…)

DAkkS 71 SD 6 055

Requirements for certification bodies which certify organic products in third countries according to production rules and control measures recognized as equivalent to Regulation (EC) No. 834/2007 and it's implementing rules

71 SD 6 042

Resolutions of the Sector Committee Agriculture/Food/ Sustainability

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