

	Guidance on transition Regulation (EU) 2018/848 for control activities in third countries (compliance)		Revised: 29.04.2022
			Revision: 1.0
			Page: 1/8

Contents:

1	Purpose	2
2	Scope.....	2
3	Procedure.....	3
3.1	Applications to DAkkS.....	3
3.2	Required assessment activities.....	3
3.2.1	Submission of required documents and document review	4
3.2.2	Witness audits (WA)	4
3.2.3	On-site office assessment.....	4
3.3	Notice of accreditation and certificate.....	4
3.4	Planned time schedule	6
4	Contact persons at DAkkS	6
5	References.....	6
	Annex I	7

	Guidance on transition Regulation (EU) 2018/848 for control activities in third countries (compliance)		Revised: 29.04.2022
			Revision: 1.0
			Page: 2/8

1 Purpose

This guidance is addressed to control bodies that are currently recognised or listed in the list of recognised control bodies and control authorities referred to in Article 32(2) of Regulation (EC) No 834/2007.

With the implementation of Regulation (EU) 2018/848 as of 1 January 2022, such control bodies are required to submit a request for recognition of control activities for organic production in third countries in due time in accordance with Article 46(4) of Regulation (EU) 2018/848 in order to be able to carry out control activities in third countries in the future on the basis of the new Regulation. For this purpose, the European Commission has adopted delegated legal acts that define the criteria that are required to achieve successful recognition. Among other things, this requires confirmation of competence in the form of successful accreditation as set out in point (d) of Article 46(2) of Regulation (EU) 2018/848. This guidance has been drawn up for this purpose.

2 Scope

This guidance concretes or complements the requirements of document EA 3/12:2022 of the *European co-operation for Accreditation (EA)* for the transition from Regulation (EU) 834/2007 to Regulation (EU) 2018/848 for control activities of organic production in third countries.

Its goal is to ensure an efficient transition for certification bodies for organic production in third countries that are already accredited within the defined transition period. This period ends with effect from 31 August 2023 in order to allow control bodies to submit a timely request for recognition in accordance with Article 46(4) of Regulation (EU) 2018/848.

Pursuant to Article 57, the recognition of control authorities and control bodies granted under Article 33(3) of Regulation (EC) No 834/2007 shall expire by 31 December 2024 at the latest.

Audits/inspections on the basis of Regulation (EU) 2018/848 and the issuance of certificates to that effect can only be carried out after successful accreditation for the new Regulation and subsequent recognition by the European Commission.

This guidance reflects the status as of 15 April 2022. It will be adapted when new EA and/or IAF decisions are issued or when required by changes initiated by DG AGRI.

	Guidance on transition Regulation (EU) 2018/848 for control activities in third countries (compliance)		Revised: 29.04.2022
			Revision: 1.0
			Page: 3/8

3 Procedure

The procedure for the **transition of accreditation** to the new Regulation is as follows:

3.1 Applications to DAkkS

Applications for transition to the new Regulation are now being accepted.

To ensure a timely transition, allowing sufficient time to obtain the required recognition under Article 46(4) of Regulation (EU) 2018/848 by the European Commission, applications must be submitted in good time, but no later than 31 August 2022, as follows:

For control bodies legally established in Germany

Please send a regular “Application for change of scope” including the [Annex to the application for accreditation within the scope: Certification bodies for products, processes, services in the field of agriculture, food and sustainability](#), indicating the relevant **categories** and the respective **countries** in which your control body wishes to operate under the new Regulation, to DAkkS Central Application Processing – AS 3 – at DAkkS, Spittelmarkt 10, 10117 Berlin, Germany.

For control bodies legally established in third countries

Please send a separate informal letter (reference: DAkkS case number; subject: transition) by e-mail to your case manager with the [Annex to the application for accreditation within the scope: Certification bodies for products, processes, services in the field of agriculture, food and sustainability](#), indicating the relevant **categories** and the respective **countries** in which your control body wishes to operate under the new Regulation.

3.2 Required assessment activities

As a rule, the transition is based on the following assessment activities:

- Comprehensive document review on the basis of the documents submitted
- Conduct of witness audits and
- Assessment of the office on site

	Guidance on transition Regulation (EU) 2018/848 for control activities in third countries (compliance)		Revised: 29.04.2022
			Revision: 1.0
			Page: 4/8

3.2.1 Submission of required documents and document review

With confirmation of the application, the control body will receive a request to submit the list of documents set out in Annex 1 to this guidance document.

Please ensure that the requested documents are submitted to your case manager in due time and in full via MOVEit.

The estimated duration of the document review is approximately one day (8 hours), but may be longer depending on the categories and countries applied for and the quality and/or complexity of the documents submitted.

DAkkS would like to point out that the quality of the documents submitted for the document review is an essential prerequisite for the procedure described.

3.2.2 Witness audits (WA)

Regulation (EU) 2021/1698 sets out a number of requirements relating to the required witness audits that must be conducted, as well as requirements for the content of the resulting witness audit reports that must be submitted to the European Commission. The requirements for the number and type of witness audits to be conducted have also been adopted in EA 3/12:2022 (see 4.7).

In accordance with the requirements set out above, witness audits are planned and conducted to ensure sufficient coverage of the required WAs on the basis of the categories (including groups of companies) and countries requested by your control body. Please provide your case manager with the required details upon request.

3.2.3 On-site office assessment

After successful completion of the document review (and closure of any nonconformities where applicable), an additional assessment of the office is required.

The on-site office assessment for the new Regulation can be carried out as part of the annual office assessment or as a separate office assessment. An additional four to eight hours are added to the general assessment planning for this purpose. The contents of this additional assessment include in particular verification of the effectiveness of the corrective action implemented as a result of the preceding document review and the conformity or arrangements of the control body with regard to Sections 9, 10 of Regulation (EU) 2021/1698, as well as all other contents set out in Annex I, Part A, 2.1.

3.3 Notice of accreditation and certificate

Following a positive accreditation decision, the accreditation body will issue a notice of accreditation and a new certificate including the certificate annex.

	Guidance on transition Regulation (EU) 2018/848 for control activities in third countries (compliance)		Revised: 29.04.2022
			Revision: 1.0
			Page: 5/8

The existing scope on the basis of Regulation (EC) 834/2007 remains in place and requires an application for reduction once all clients of the control body have been transferred to the new Regulation.

	Guidance on transition Regulation (EU) 2018/848 for control activities in third countries (compliance)		Revised: 29.04.2022
			Revision: 1.0
			Page: 6/8

3.4 Planned time schedule

With immediate effect: until 31 August 2022	<ul style="list-style-type: none"> • Application for change of scope by the certification body to DAkKS Central Application Processing (ZAB, Berlin) or by e-mail to your DAkKS case manager • Submission of the required documents and evidence upon request (or after confirmation of the application) • Completion of the document review • At the same time: planning and implementation of the required witness audits
From 01 January 2023	<ul style="list-style-type: none"> • Start of on-site office assessments • Continuation of parallel conduct of required witness audits
31 August 2023	<ul style="list-style-type: none"> • End of the planned conversion/transition phase
After recognition by the European Commission	<ul style="list-style-type: none"> • Review of implementation of the new Regulation as part of the subsequent office assessments
After conversion of all holdings to the new Regulation	<ul style="list-style-type: none"> • Submission of an application for reduction of the existing scope of Regulation (EC) 834/2007

4 Contact persons at DAkKS

- a) Applications – DAkKS Application Service: Phone: +49 30/670591-951;
E-mail: zab@dakks.de
- b) For all questions regarding the conversion to compliance, please contact your DAkKS case manager – Technical Unit 3.2 Food and Agriculture | Forestry and Wood | Textile and Clothing Industry
- c) General questions about the conversion: Ms Schulte: Phone: +49 30/670591-282;
E-mail: sandra.schulte@dakks.de

5 References

- Regulation (EU) 2018/848
- Regulation (EU) 2021/1698
- EA 3/12:2022

	Guidance on transition Regulation (EU) 2018/848 for control activities in third countries (compliance)		Revised: 29.04.2022
			Revision: 1.0
			Page: 7/8

Annex I

Documents and records required for the document review as set out in 3.2.1

Organisational structure

- Current overview of the structure and size of your control body, including country offices, branch offices and their tasks among each other
- Description of the type of activities undertaken by the control body, including subcontracting of activities other than inspections and sampling
- Description and overview of the IT management systems used for implementation, of data management and communication, including the interfaces to each other

Conversion plan:

- (Updated) transition plan for transition to the new Regulation including time schedule for the conversion, as well as internal analysis of changes and determination of the action needed to adapt the certification procedure

Information exchange systems

- Procedures for the exchange of information between the head office and any branch offices/country offices and laboratories operated by subcontractors, and
- Procedures for the exchange of information between the Commission, Member States, control authorities and other control bodies

Competence management

- Up-to-date list of personnel at your control body, indicating their roles in the certification process, including the employment status of the inspectors concerned and their contractual relationship with the control body
- Up-to-date analysis and assessment of control body personnel with regard to activities in the third countries applied for and the required language skills
- Evidence of the knowledge and qualifications of control body personnel in matters concerning the Commission's legislation on organic production and related controls
- Where applicable, evidence of training in specific skills and training required by the inspectors at the control body who inspect the system for internal controls of groups of operators
- Evidence of the experience and competence of personnel in relation to the category or categories of products referred to in Article 35(7) of Regulation (EU) 2018/848 that are subject to the controls
- Procedures and information for monitoring the performance of control body personnel and monitoring of competence by the control body

	Guidance on transition Regulation (EU) 2018/848 for control activities in third countries (compliance)		Revised: 29.04.2022
			Revision: 1.0
			Page: 8/8

Specific requirement documents:

- Procedures/specifications for language provisions for internal and external requirement documents, making allowance for all relevant languages in the third countries applied for and language skills of control body personnel
- All documents specific to a position (e.g. contract documents, procedural instruction(s), description of the certification procedure, checklists) with reference to the Regulation must be submitted for review in all relevant languages, in particular:
 - Procedure(s)/description(s) of the control systems to be put in place for each third country, where applicable including the specifics of controls for groups of operators
 - Internal procedures relating to the control and certification activities of operators and – where applicable – groups of operators

Certificate of inspection:

- Sample of certificate of inspection in accordance with specific requirements

Updated list of countries

- an updated list of countries covered by application, number of estimated operators including group(s) of operators, if any, per category and per country