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

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Scope:

In accordance with Article 33 of Regulation (EC) No. 834/2007, organic products from third countries can be imported into the EU if the production rules and control measures are equivalent to those of the EU-Regulation on organic production and if these activities are inspected and certified by a certification body approved by the EU. Given the prerequisite of equivalence, there can be certain differences in the production rules and the control measures which shall be considered in the assessment. This rule summarises the assessment points which have been identified as essential for the surveillance of certification bodies recognised as equivalent.

Substantive changes in comparison to the previous issue of this rule are marked with a line on the right side or highlighted with a yellow background.

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1 Purpose and Scope

In accordance with Article 33 of Regulation (EC) No. 834/2007, organic products from third countries can be imported into the EU if the production rules and control measures are equivalent to those of the EU-Regulation on organic production and if these activities are inspected and certified by a certification body approved by the EU. Given the prerequisite of equivalence, there can be certain differences in the production rules and the control measures which shall be considered in the assessment. This rule summarises the assessment points which have been identified as essential for the surveillance of certification bodies recognised as equivalent.

2 Terminology

Not applicable

3 Description

3.1 Requirements for the certification body

Chapters 4 to 6 of the standard EN ISO/IEC 17065 define a series of requirements for certification bodies, for example in respect of organization, staff, independence and resources. For the inspection and certification in the context of equivalence the following aspects relating to the specific conditions in those countries in which the certification body actively inspects shall be defined by the certification body.

Due to the vast number of languages spoken in third countries, the certification body must ensure that a communication with the clients is established which guarantees mutual understanding (e.g. ensuring that the clients understand the standards and that the inspector understands information which the client provides).

3.1.1 Competence of inspectors

The inspections of group certification systems and particularly of high-risk operations shall be performed by competent staff with sufficient knowledge and experience in the respective area. The knowledge of possible sources of contamination and the procedure for sample taking are essential for the activities of certification bodies recognised as EU-equivalent. Training of the inspectors at regular intervals and information exchange concerning these topics, as well as the specifics of inspecting internal control systems shall be ensured by the certification body.

3.1.2 Rotation of inspectors

The certification body shall define a rotation of the inspectors in order to ensure objectivity.

3.2 Requirements for the certification programme and process

In order for the accreditation body to be able to assess the equivalence of the production and control requirements in accordance with the Regulation (EC) No. 1235/2008 (Chapter 2, Article 11 (3) c) as defined by the certification body, a number of specific aspects relating to its certification requirements shall be defined (within the equivalent certification programme). This specifically includes exceptional approvals. The following section describes the minimum of required aspects for the certification requirements which shall be de-fined and which shall be taken into account in relation to the inspection and certification of EU-equivalence.

3.2.1 Identifiability of plots and of premises

Agricultural plots (recognised organic, undergoing transition and, if relevant, also conventional) as well as premises for agriculture, processing, storage and/or marketing shall be unmistakably identifiable on maps. The inspector shall be able to find the plots and the premises by themselves with the aid of the maps. The use of officially recognised area drawings or GPS data is recommended. The maps shall be held by the certification body.

3.2.2 Conversion of plots

Beginning of conversion period

The conversion begins at the earliest with the signing of the control agreement between the certification body and the client and/or the documentation of new plots by the certification body.

Recognition of previous periods (cultivated or "fallow" land) as conversion period

If any retroactive recognition of time period as conversion is foreseen in the standard of the certification body, there shall be a corresponding documented process of recognition. This process shall define the conditions under which such recognition can be given. The retroactive recognition shall be justified by the expert opinion of the inspector in consideration of the standard provisions de-fined, recommended, and be plausibly supported with suitable, well documented proof. A mini-mum conversion time of one year is recommended.

3.2.3 Use of farm inputs

The certification body shall have a procedure for the determination of the equivalency of farm inputs. These inputs shall be clearly stated in the equivalent standard.

3.2.4 Harvest

Estimated harvest yield

The certification body shall have a procedure for estimating yields. This shall include year- and locality-specific key figures for the harvest yields of the respective crops. The determination of the result shall be documented. Larger deviations from the defined mean yield shall be justified and documented (e.g. extreme climatic conditions). The estimate shall be adjusted at least annually and, if necessary, at shorter intervals.

Dual certification: Information exchange with other certification bodies

If a client is certified by several certification bodies, these certification bodies shall exchange information on the total harvest yield of the incoming and outgoing goods pursuant to Article 92 (1) of Regulation (EC) No. 889/2008 in a suitable manner. This information shall always be exchanged according to the ongoing goods movement. The certification body may not issue a certificate of inspection after the estimated harvest yield has been reached, unless it is convinced that the surplus quantities have organic status. The previous harvest yields shall be examined. Reasons for deviations from the estimated harvest yield shall be documented before issuing further inspection certificates.

3.2.5 Prepared/processed Products

The certification body evaluates, that only such ingredients are used for prepared/processed products, which were exported from an EU-member state or were certified by a certification body within the framework and under conditions according to Annex II respectively Annex IV Reg. (EC) No. 1235/2008.

3.2.6 Mass balance

At least with the annual inspection, the certification body shall undertake risk-oriented, replicable mass balance calculations and traceability checks. The inspection personnel shall choose products and operating resources in a risk-oriented manner. Inspection personnel shall justify and document its decision. A sufficient period of time shall be defined. The period for which the investigation is performed shall be documented to the day, as well as the relevant product. The result of the mass balance calculation shall be verified, justified in respect of plausibility (e.g. taking account of processing losses) and documented.

Mass balance and traceability checks exclusively on the basis of tables, overviews or evaluations of the client, without access to and plausibility check of the underlying data are not permitted.

All raw data of every mass balance are always legally relevant documents (bills of delivery and invoices) for purchasing and sales, in addition to locally documented data, such as the warehouse inventory in silos, flat storage or trading units.

Information concerning the handling of goods during the inspection (shipping, unloading, packing) shall be considered in the plausibility evaluation.

3.2.7 Cross Checks

The certification body shall have a procedure for risk-oriented investigation of mass balance and farming input purchases, so-called cross checks, across operators. In so far as doubt exists about the origin and the organic status of a product, the certification body shall obtain information from the certification body of the supplier of its client. Cross Checks shall as well be performed to a certain extent on a risk-oriented basis.

3.2.8 Export of products

According to Annex V of Regulation (EC) No. 1235/2008, the certification body confirms the status of products intended for export by certificate of inspection. Risk-oriented on-site inspections of goods for export are carried out before exporting, in order to verify the information in the certificate of inspection. The packaging of goods shall ensure that unequivocal identification is possible and that confusing with other goods and any form of mixing are excluded. Containers, ships and railway wagons may be recognised as packaging/containers in so far as these fulfil the requirements of Article 34 of the Regulation (EC) No. 889/2008. The certificate of inspection shall include the relevant information about the marking.

3.2.9 Complaints

The certification body examines whether and to what extent complaints/pesticide findings/rejections/product recall due to suspected lack of integrity of the organic status and how the client company deals with the indications and the batches concerned. The certification body shall take specific action to temporarily prevent the continued marketing of the batches concerned as organic during which time the suspicion must be verified or otherwise. If the organic mark must be with-drawn, the certification body shall control the conventional marketing of batches.

3.2.10 Risk analysis

The result of the risk analysis for the client forms the basis for the intensity of announced and un-announced inspections, sampling and control of the mass balance. According to Article 65 (4) of Regulation (EC) No. 889/2008, the risk analysis shall consider at least the results of previous inspections and the quantity of relevant products together with the risk of exchange of these products. Furthermore, the following criteria can offer support to the risk analysis:

- market importance and market reach of the products;
- structure and complexity of the company;
- number of employees;

- number and structure of external suppliers;
- existence of sub-contractors;
- a change of the owner or the (top) management of the company;
- existence of suitable internal quality management systems;
- parallel production and treatment/processing of organic and non-organic products and the existence of producer associations;
- information and complaints of third parties.

3.2.11 Additional random inspections

Following their risk assessment, certification bodies shall ensure that additional random inspections are carried out, according to risk classification, in at least 10% of the client companies in third countries.

3.2.12 Unannounced inspections

Furthermore, the certification body shall perform at least 10% of their inspections in third countries unannounced. The unannounced inspections take place on the basis of the risk analysis and are planned according to the risk level.

3.2.13 Inspection of sub-contractors (without own agreement)

A classification as sub-contractor is possible only when the sub-contracted party is paid for its activity as a service by the client subject to inspection, but not when the sub-contractor sells organic product to or purchases organic product from the client. The certification body shall suitably control which orders of its client are assigned to sub-contractors and which facilities and storage locations are used. The certification body shall document the plan, describing how the delegated activities of the sub-contractor are inspected and shall provide proof of the implementation of this plan. The frequency of inspections shall be defined risk-oriented in accordance with Sections 3.2.10 and 3.2.11.

Regarding the control arrangements according to Article 86 of Regulation (EC) No. 889/2008, a full description of the unit shall be available for each sub-contractor, as well as a written consent that the operation is subject to the control regime and its activities are appropriately considered in the inspection. The sub-contractor shall be obliged to ensure that sufficient care is taken in order to prevent contamination with substances which are not permitted.

Multi-level sub-contractor constructions, in which sub-contractors delegate further sub-contractors are not permitted. In a number of third countries, sources of contamination have been found with service providers which did not carry out the necessary decontamination process following the use of substances permitted in conventional agriculture. Means of transportation can also constitute a

cause of contamination when these are not adequately cleaned. Such risk shall be excluded by employing suitable preventive measures. These sub-contractors and service providers shall also be subjected to risk-oriented control measures.

3.2.14 Sampling and analytics

Sampling

The certification body shall have a documented sampling procedure. This procedure shall include amongst other provisions a description of sample handling, representative and a risk-oriented sample taking, identification of the samples in order to exclude the possibility of confusing these with others (sealing the samples), documentation, storage, transport, shipping and interpretation of the analytical results.

Analytical spectrum

The request for analysis shall be in accordance with the risk for the presence of specific substances. The certification body shall be up to date about the most important risks of contamination in respect of pesticides and contamination with GMO in the respective crops, farming input and storage facilities commonly found in the relevant country.

Laboratory

The laboratories assigned for such analysis shall be evidently competent; meaning they have to be accredited according to ISO/IEC 17025. In relation to (new) methods of analysis, where there are no accredited laboratories available, the fulfilment of the requirements of ISO/IEC 17025 shall be evident.

Scope of sampling

In third countries the number of samples to be taken and analysed annually shall correspond to at least 5% of the companies under control agreement. Which companies require sampling depends upon the risk analysis carried out by the certification body (see Section 3.2.10).

3.2.15 Multiple certification and change of control body

The certification of a client by different certification bodies for the same certification category occurs relatively often in third countries. As well, a change of the control body is common practice. In application of Article 92 (1) Regulation (EC) No. 889/2008, as soon as the certification body is made aware of the fact that a certificate holder and/or its sub-contractors are partly or completely de-certified by another certification body or in case of a change of the control body it shall exchange the complete information about the results of the evaluation, review and certification. The exchange of infor-

mation shall be ensured before a decision about certification is made. In the event of a change to another certification body the relevant documentation shall be made available to the certification body which continues the certification process.

3.2.16 Producer groups

The certification body shall enforce the requirements of the "*EU - Guidelines on imports of organic products into the European Union*". The group which performs the activities under certification shall have a legal entity concluding a contractual (certification) agreement with the certification body. The individual producers have agreements with the group which shall include at least a declaration of commitment for observing the production rules and the acceptance of control measures, as well as consenting to both internal and external inspections.

List of producers

At the location at which the review and certification decision for the relevant producer group take place, the certification body shall have a list of all producers belonging to the group. The list shall contain at least the following information:

- name and address of the group and documentation of its legal entity
- a list of the names of the registered producers and the allocation of these producers to the group, if possible according to an identification number
- a list of all parcels for each producer
- size of the parcels with organic crops and, if applicable, the size of conventional parcels and the size of the overall parcels
- crop rotation for each parcel: preculture and current crop of the parcel(s) to be certified, for permanent crops the population density and the total plant inventory
- crop yields for the previous year, except for the first inspection, and the estimated yields for the current year at the producer level, as well as the overall yield for the group
- date for the beginning of conversion of the parcels and the last use of agents not permitted with organic crops
- certification status of the parcels and the crops yielded (updated annually by the certification body)
- date of the last internal control of each producer
- date of the last external inspection of each producer
- deviations found / corrective measures at the producer level and the organisation level.

The certified parcels of the individual group members and other (also conventional) related parcels and other operational sites shall be described in a regional survey map according to replicable area identification or on the basis of GPS data.

The list of producers shall document the current certification status of the producers and is reviewed in conjunction with certification. The certification body sends the list of producers to the group or organisation for their information and their surveillance/confirmation. The certificate makes reference to this list of producers. The organization shall continuously update the list of producers. A documented procedure shall describe, how the certification body is made aware of deviations, exclusions and new members between inspection visits.

Internal control system

The group of producers shall have a documented internal control system (ICS) and shall name a person who is primarily responsible for the implementation of the ICS and the coordination of the internal controls.

The internal control system (ICS) shall fulfil at least the following requirements:

- documentation of internal regulations and procedures;
- description of the basic principles of organic farming in the region of the crops cultivated;
- description of the group and its structure, with all levels and steps through which the cultivated product passes (production, storage, processing, packaging);
- this includes all relevant documents (list of producers, checklists for internal controls, etc.) or refers if necessary to the documents made available by the certification body;
- internal control reports shall contain pertinent information in relation to the conduct and the results of the internal control;
- A catalogue of sanctions with a definition of the application shall be in place;
- A definition of how to deal with deviations, e.g. expulsion proceedings against members shall be in place;
- documentation of the training, education, independence and objectivity of the internal inspectors;
- A process of how to deal with conflicts of interest of the internal inspectors is defined.

For every producer within a producer group the internal control shall be documented in detail in an internal control report and include information about the crop, crop sequencing (for changing/rotating crops), use of fertiliser, pesticides, yield quantities, the producer's own conventionally cultivated parcels if applicable and possible irregularities (including the classification of the irregularity, agreed corrective action, implementation of the corrective action, possible recurrences and, if applicable,

proof of having attended a training session). In addition, it shall be evident that the producer has sufficient knowledge of the production regulations and control measures and has read the report or, in the case of illiteracy, has had the contents of the report explained.

The certification body examines the effectiveness of the internal control system by assessing whether the inspector of the certification body reaches results similar to those of the internal control. In case the internal control system is evidently ineffective, certification is withdrawn for the complete producer group.

Risk classification of producer groups

For the risk classification of the group, the certification body shall consider at least the risk factors named in the "Guidelines on imports of organic products into the European Union" and further also the homogeneity of the group, the locations of the operations, the type of organic crops and, if applicable, the conventional crops. The certification body shall document the minimum number of inspections specified in the above "Guidelines" for the members of the group. The extent and object of the additional random inspections and sampling are defined according to the number of members and the risk level. The certification body shall (in the event of repeated deviations) increase the extent of additional random inspection and sampling. Furthermore, producers with a history of deviations and new producers shall be considered in choosing the random sample.

Documentation of the certification body

The documentation of the certification body shall clearly show

- which members of the producer group have been inspected externally in the past;
- which external inspector inspected which group member and when;
- for how long the external inspector was at the site of the individual member;
- which control activities were performed by the inspector at the individual member (e.g. verification of parcels, verification of yield quantities, sample taking, etc.);
- that the external inspector of the certification body was actually at the site in question (e.g. by signatures);
- the documentation of all activities within the scope of certification performed at the site of operation of the individual producer group member (description of the operation, inspection report, verification of areas, verification of yield quantities, use of seed material, deviations found, sample taking, etc.).

3.3 Requirements for the accreditation process

The specifications for the scope of accreditation, depth of assessment and competence of the accreditation body are described in the mandatory EA-rule 3/12. DAkkS implements the relevant text in Chapter 3 of EA 3/12.

4 Applicable documents

EA 3/12	EA Policy for the Accreditation of Organic Production Certification
71 SD 6 042	Resolutions of the Sector Committee Agriculture/Food/Sustainability

„Guidelines on imports of organic products into the European Union“, European Commission, Directorate-General for Agriculture and Rural Development, 15.12.2008