**INFORMATIVE CIRCULAR** Ref. DC2021SPM119 **DATE** Milan, 19-11-2021

To all accredited and applicant certification bodies – PRD scheme

To the associations of conformity assessment bodies

To all assessors/experts DC

Loro sedi

**SUBJECT** **Certification and Inspection Department**

**This Information Circular DC N°47/2021 replaces the previous Circular N°42/2021 – Rules concerning the transition of accreditation according to the new Reg. (EU) 2018/848 of Certification Bodies performing certifications in accordance with the Organic certification scheme**

## Introduction

In 2018, the Regulation (EU) 2018/848 relating to organic production and labeling of organic products was published, repealing Regulation (EC) 834/2007 of the Council and it is applicable from January 1, 2022;

The new Regulation sets out the principles of organic production and establishes the requirements relating to organic production, to the related certification and to the use of indications referring to organic production in labeling and in advertising, as well as the rules relating to additional controls with respect to those set out in Regulation (EU) 2017/625;

The approach adopted in the standard provides that the body of the text of Reg. (EU) 2018/848 can be integrated or modified with the issuance of appropriate delegated provisions regulation by the European Commission;

For some aspects of implementation, the Regulation provides for the possibility that the European Commission may issue further executive provisions;

All these complementary Regulations can be grouped into 3 macro areas: Control, Production and Trade (activities in third countries).

To date, the following Regulations have been published:

**CONTROL**

Regulation (EU) 2021/715 – Commission Delegated Regulation (EU) 2021/715 of 20 January 2021 amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the requirements for groups of operators;

Regulation (EU) 2021/771 – Commission Delegated Regulation (EU) 2021/771 of 21 January 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council by laying down specific criteria and conditions for the checks of documentary accounts in the framework of official controls in organic production and the official controls of groups of operators.;

Regulation (EU) 2021/279 – Commission Implementing Regulation (EU) 2021/279 of 22 February 2021 laying down detailed rules for the implementation of Regulation (EU) 2018/848 of the European Parliament and of the Council on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products;

Regulation (EU) 2021/1006 – Commission Delegated Regulation (EU) 2021/1006 of 12 April 2021 amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the model of the certificate attesting compliance with the rules on organic production.

**PRODUCTION**

Regulation (EU) 2020/2146 – Commission Delegated Regulation (EU) 2020/2146 of 24 September 2020 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards exceptional production rules in organic production;

Regulation (EU) 2020/1794 – Commission Delegated Regulation (EU) 2020/1794 of 16 September 2020 amending Part I of Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the use of in-conversion and non-organic plant reproductive material;

Regulation (EU) 2021/1189 – Commission Delegated Regulation (EU) 2021/1189 of 7 May 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species;

Regulation (EU) 2020/427 – Commission Delegated Regulation (EU) 2020/427 of 13 January 2020 amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards certain detailed production rules for organic products;

Regulation (EU) 2021/642 – Commission Delegated Regulation (EU) 2021/642 of 30 October 2020 amending Annex III to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards certain information to be provided on the labelling of organic products;

Regulation (EU) 2021/1165 – Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists;

Regulation (EU) 2020/464 – Commission Implementing Regulation (EU) 2020/464 of 26 March 2020 laying down certain rules for the application of Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the documents needed for the retroactive recognition of periods for the purpose of conversion, the production of organic products and information to be provided by Member States;

Regulation (EU) 2021/716 – Commission Delegated Regulation (EU) 2021/716 of 9 February 2021 amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards organic production rules on sprouted seeds and chicory heads, on feed for certain aquaculture animals and on aquaculture parasite treatments;

Regulation (EU) 2021/1691 - Commission Delegated Regulation (EU) 2021/1691 of 12 July 2021 amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the requirements for record-keeping for operators in organic production;

**TRADE**

Regulation (EU) 2021/1342 – 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 and by control authorities and control bodies for the purpose of supervision of their recognition under Article 33(2) and (3) of Council Regulation (EC) No 834/2007 for imported organic products and the measures to be taken in the exercise of that supervision;

Regulation (EU) 2021/1378 – Commission Implementing Regulation (EU) 2021/1378 of 19 August 2021 laying down certain rules concerning the certificate issued to operators, groups of operators and exporters in third countries involved in the imports of organic and in-conversion products into the Union and establishing the list of recognised control authorities and control bodies in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council;

Regulation (EU) 2021/1697 - Commission Delegated Regulation (EU) 2021/1697 of 13 July 2021 amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the criteria for the recognition of control authorities and control bodies that are competent to carry out controls on organic products in third countries, and for the withdrawal of their recognition;

Regulation (EU) 2021/1698 - Commission Delegated Regulation (EU) 2021/1698 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 authorities and control bodies that are competent to carry out controls on operators and groups of operators certified organic and on organic products in third countries and with rules on their supervision and the controls and other actions to be performed by those control authorities and control bodies.

ACCREDIA believes that, for the purposes of the transition to the new Reg. (EU) 2018/848, the main Regulations relating to the certification activity by the Control Bodies have all been published.

It should therefore be noted that although some Regulations are still currently in draft form, it is possible to proceed with the start of the transition process, which shall be concluded not later than **December 31, 2021.**

**New applications for accreditation/extension of accreditation (for CABs already accredited to the standard UNI CEI EN ISO/IEC 17065)**

From the publication of this circular, ACCREDIA will only accept applications for accreditation under the new Reg. (EU) 2018/848.

The CAB, in addition to completing the modules DA-00 and DA-01, shall complete MD-08-20-DC indicating all the countries where it is operative, has operative sites and the related activities undertaken.

The accreditation process provides for the following steps:

1) *CABs requesting accreditation to operate in the EU:*
   - Document review of 1 man-day;
   - On-site assessment of 4 man-days;
   - Assessment of any branch offices at which at least one critical activity among those defined by ACCREDIA is performed (development and approval of processes including policy, approval of competences and monitoring of auditors/outsourced activities, review of the contract and decision) with a duration of at least 1 man-day for each site;
   - Granting of general accreditation without specification of the categories for the purpose of obtaining ministerial authorization to operate;
   - 1 witness assessment, following authorization, for each requested category;
   - 1 witness assessment on a group of operators, if such accreditation was required in the application.

2) *CABs requesting accreditation to operate in third countries which are in conformity:*
   - Document review of 1 man/day;
   - Onsite Assessment of the head office which is responsible for the management of the activities in third countries. For calculation of the number of man-days refer to paragraph 4.6 of EA 3/12:2020 (see the table below);
   - Assessment of any branch offices at which at least one critical activity among those defined by ACCREDIA is performed (development and approval of processes including policy, approval of competences and monitoring of auditors/outsourced activities, review of the contract and decision) with a duration of at least 1 man-day for each site;
   - 1 witness assessment for each requested category. If recognition is requested in several third countries at the same time, for each category the assessment shall be undertaken out in a different third country;
   - 1 witness assessment on a group of operators, if such accreditation was requested in the application.

**Accredited CABs – management of the transition**

*Third countries – passage from equivalence to conformity*

The CABs currently operating in equivalence as provided for by Reg. EC 1235/08 are required to complete the annex to this circular specifying whether they want to continue to operate in equivalence or if they want to make the transition to conformity.

It is emphasized that the two scopes of accreditation against Reg. EC 1235/08 and compliance to Reg. (EU) 2021/848 can both be valid until December 31, 2024

- *Maintenance of equivalence:*

  In this case, ACCREDIA will continue to issue annual assessment reports until 2024 or until further communication from the CAB and the scope of accreditation according to Reg. EC 1235/08 shall be maintained;

  All accreditations against EC Reg. 1235/08 will be withdrawn starting from **December 31, 2024.**

- *Passage to conformity:*
  The CAB may at any time request the passage to conformity, attaching to the request as follows:

  - the completed annex to this circular duy completed;
  - MD-08-20-DC completed indicating all the countries where the CAB is operative, the operative sites and relative activities performed;
  - the list of updated documents following the modifications introduced;
  - the list of documents shared with operators translated into the language of the third countries for which recognition is requested. Alternatively, a declaration by the CAB that the English language is understandable by the operators;
  - the procedures for the management of branch offices, laboratories, and for the exchange of information with the Commission, Member States and other CABs;
  - the certification procedures that describe in detail the functioning and implementation of the control measures to be established according to Reg. (EU) 2018/848, including, where appropriate, the control specification details for the group of operators;
  - the risk analysis procedure for establishing the frequency of controls;
  - a list of the measures to be taken in the event of ascertained non-conformity as required by the draft delegated act;
  - the qualification procedure for auditors;
  - the results of internal audits performed against chapter VII of Reg. (EU) 2018/848, including internal audits of the offices located in third countries, if any, and a list of the files sampled during the audit. The CAB shall provide evidence that it has sampled at least one file in each country in which it issued certificates;

- evidence of the training provided to all staff involved in the management of the certification process and evidence of the requalification of auditors regarding the new Regulation;

- communication to certified companies regarding the changes introduced by the new Regulation and the policy defined for the management of the transition.

For the evaluation of the evidence received ACCREDIA shall conduct 1 assessment at the head office of the CAB which is responsible for the management of third countries. The duration will be calculated according to paragraph 4.6 of EA 3/12: 2020 (see table below).

By the completion of the annex to this circular, ACCREDIA will assign the Country and the new categories without additional assessment activities if the CAB demonstrates that it has already issued certificates to clients that are part of the new categories and in third countries.

**Groups of operators**

CABs that by completing the annex to this document request accreditation also for group certifications in the EU and/or third countries operating in conformity, in addition to the documents required for the transition, shall send the following evidence:

- implementation of the requirements of Reg. (EU) 2018/848 relating to the certification of groups of operators in the EU or in third countries;
- evidence of the training provided to all personnel involved in the management of the certification process and evidence of qualification of auditors for the certification of groups of operators.

For the evaluation of the evidence that are received, ACCREDIA will conduct a document review of **0.5 man-days** for the EU and **0.5 man-days** for third countries, reserving the right to carry out any further in-depth activities, if considered necessary.

ACCREDIA will subsequently perform a witness assessment relating to the certification of a group of operators in the EU and/or third countries in conformity for the issue of accreditation for group certifications.

This procedure also applies to CABs that already carry out group certifications in accordance with Reg. EC 1235/08.

**Modalities for assigning products coming under category G "other products listed in Annex I of this regulation or not included in the previous categories" of EU Regulation 2018/848.**

ACCREDIA will enter in category G a product from Annex I to EU Reg. 2018/848 only if the CAB is accredited **for all the categories** in which the product falls as indicated in Table A.

Examples:

- The MATE product will be assigned to all accredited CABs for categories A and D;
- The SALE product will be assigned to all accredited CABs for categories A, E, F;

**TABLE A**

| G) Other products listed in Annex I of this regulation or not included in the previous categories. | A) Unprocessed plants and plant products, including seeds and other plant reproductive material | B) Unprocessed animals and animal products | C) Unprocessed algae and aquaculture products | D) Processed agricultural products, including aquaculture products, intended for use as food | E) Feed | F) Wine |
|---|---|---|---|---|---|---|
| Yeasts used as food or feed | X | | | X | X | |
| Mate | X | | | X | | |
| Sweet corn | X | | | X | | |
| Vine leaves | X | | | X | | |
| Palm hearts | X | | | X | | |
| Hop shoots and other similar edible parts of plants and products obtained from them | X | | | X | | |
| Sea salt and other salts for food and feed | X | | | X | X | |
| Silkworm cocoons suitable for reeling | | X | | | | |
| Natural gums and resins | X | X | | X | | |
| Beeswax | | X | | X | | |
| Essential oils | X | | | X | | |
| Natural cork stoppers, not agglomerated, and without binders | X | | | X | | |
| Cotton, neither carded nor combed | X | | | | | |
| Wool, neither carded nor combed | | X | | | | |
| Raw and untreated leathers | | X | | X | | |
| Traditional herbal plant based preparations | | | | X | | |

**Assessment times applied by ACCREDIA in Third Countries**

For the completion of the above paragraphs, it is considered appropriate, with regard to accreditation/extension/transition to conformity for third countries, to report paragraph 4.6 of the document EA 3/12:2020 relating to the calculation of man/days for on-site assessments at CABs that intend to operate in third countries:

### 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 |

For all clarifications, please contact the reference Technical Officer Marco Zanardi (m.zanardi@accredia.it)

With kind regards.

**Dott.ssa Mariagrazia Lanzanova**

Vice Director Department
Certification and Inspection

Firmato digitalmente da: MARIAGRAZIA LANZANOVA
Data: 22/11/2021 11:47:21