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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	13 July 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2021) 5100 final - Annexes
Subject:	ANNEXES to the COMMISSION DELEGATED REGULATION (EU) 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

Delegations will find attached document C(2021) 5100 final - Annexes.

Encl.: C(2021) 5100 final - Annexes

EUROPEAN
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ANNEXES 1 to 4

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU)

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

ANNEX I

Content of the assessment report referred to in Article 1(2)(i)

PART A

An assessment report referred to in point (i) of Article 1(2) shall consist of a document and record review report, an on-site assessment report and a witness audit report, and may contain any other information deemed necessary by the accreditation body or competent authority.

1. Document and record review report

The document and record review report shall contain the following elements:

1.1. Assessment of the following:

(a) the structure and size;

(b) IT management system;

(c) branch offices;

(d) type of activities, including subcontracting activities other than inspection and sampling;

(e) organisational chart;

(f) quality management;

1.2. Assessment of the procedures for the exchanges of information between headquarter and branch offices, and subcontracted laboratories, as well as with the Commission, Member States, other control authorities and other control bodies;

1.3. Assessment of the knowledge and qualification of the staff as regards Union legislation on organic production rules and controls;

1.4. Verification that the language regime chosen and the documents issued by the control authority or control body are understandable for the contracted operators or groups of operators, in particular internal procedures for the staff involved in the certification process or in the controls;

1.5. Assessment of the continuous training programmes, and effective monitoring by the control authority or control body of the competencies acquired during the trainings;

1.6. Assessment of the experience and the competency of the staff on the category(ies) of products as set out in Article 35(7) of Regulation (EU) 2018/848 subject to the controls and in each third country covered by the recognition, including the employment status of inspectors concerned and their contractual relationship with the control body;

1.7. Assessment of the internal procedures related to the control activities in respect of operators and groups of operators, if any, and the specific skills and training required for the inspectors of the control authority or control body controlling the system for internal controls of groups of operators;

1.8. A description and an evaluation of the performance of the control system to be put in place for each third country, including where relevant, control specificities for groups of operators;

1.9. Any other information deemed necessary by the accreditation body.

2. On-site assessment report

An on-site assessment report by the accreditation body or, as appropriate, by the competent authority, shall contain the following elements:

2.1. An assessment report of the office(s) where certification decisions are taken, containing the following information:

(a) result of the checking of files of all categories of products as set out in Article 35(7) of Regulation (EU) 2018/848 for which recognition is requested, and confirmation that the control body has correctly implemented the requirements on controls in respect of operators and groups of operators as set out in Chapter III of this Regulation and in particular Articles 9 and 10;

(b) evaluation of the catalogue of measures to be taken in case of established non-compliance;

(c) evaluation of the risk analysis procedures for the purpose of the inspections, including inspections without prior notice;

(d) evaluation of the sampling strategy, procedure and methodology;

(e) evaluation of the communication with the Commission and other control authorities and other control bodies;

(f) conclusions from interviews with control and certification staff regarding their performance and competency on certification and control tasks;

(g) confirmation that the control authority or control body has the means to implement the control system in line with this Regulation in each third country for which it requests recognition, in particular sufficient inspectors to carry out any physical checks at any stage of production, preparation and distribution, as appropriate, based on their risk assessment, additional inspections or samplings and documents in languages that are understandable by the contracted operators, when these documents are intended for operators or groups of operators;

(h) confirmation of the capacity and competencies of the control authority or control body to perform its tasks for each third country for which it requests recognition, taking into account, in particular, the expected number of operators or members of the group of operators, volume of exported products, nature and origin of products, including evaluation of operators and inspectors files.

2.2. A witness audit report, resulting from a witness audit carried out in accordance with Part B, containing the following elements:

(a) the name of the operator, the audited inspector and the accreditation body's assessor;

(b) general information about the witness audit such as venue, time, audit plan or parties, and the operator's or group of operators' experience with regard to organic production rules;

(c) scope of inspection;

(d) inspector preparation and knowledge, such as planning of work, working instructions, documents and material made available to the inspector, knowledge of the inspector on the relevant category of products, evaluation of

the robustness of the organic system plan of the operator or the system of internal control of the group of operators, checking of conflicts of interest, knowledge on Regulation (EU) 2018/848, knowledge of the internal procedures of its control body as regard the functioning or the implementation of the control system and certification process;

(e) inspector performance, such as relevance of the duration of the inspection, evaluation of the interview, verification of previous non-compliances, collection of relevant information, authority and analytical skills, conversation and questioning technique, effective language skills, knowledge of the local agricultural conditions and agricultural practices, processing practices in that country and social skills;

(f) quality of the physical inspection of the facility/holding/unit such as methodology and quality of the inspection check list used, information provided by the operator in the organic system plan, robustness of the mass balance and traceability checks, the methodology used for the sampling and the inspection of critical areas;

(g) findings, status of the non-compliances detected and corrective measures applied;

(h) evaluation of the non-compliances identified by the accreditation body's assessor but not detected by the inspector;

(i) quality and completeness of the exit interview conducted;

(j) overall assessment of the effectiveness of the inspection;

(k) list of non-compliances detected, description and time line for the corrective measures to be carried out by the control authority or control body to solve them;

(l) in the case of a group of operators, a specific section providing a description and evaluation of the effectiveness of the system for internal controls; and

(m) an overall assessment of the capacity and reliability of the control authority or control body for performing the certification activities, taking into account the outcome of the assessment performed in accordance with section 2.1. Any other information deemed necessary by the accreditation body or competent authority, including for instance, reports and conclusions of additional witness audits.

PART B

1. The witness audit referred to in point 2.2 of Part A shall be:

(a) carried out by the accreditation body or, as appropriate, the competent authority;

(b) based on a risk analysis and shall document the whole activity under witness;

(c) carried out physically and may only be carried out remotely if so decided by the Commission.

2. In addition to Section 1, the witness audit shall be carried out:

(a) for each category of products as set out in Article 35(7) of Regulation (EU) 2018/848 for which the recognition is requested. All non-compliances detected

by the accreditation body or competent authority shall be fully addressed by the control authority or control body respectively, and confirmed by the accreditation body or competent authority;

(b) for each category of products in a different third country, if the control authority or control body requests or is already recognised for more than one third country; and

(c) as a matter of priority in groups of operators, in case the control authority or control body certifies groups of operators.

3. For a control authority or control body recognised under Article 33(3) of Council Regulation (EC) No 834/2007[1] and included in the list established in accordance with Article 57(2) of Regulation (EU) No 2018/848, the information referred to in point 2.2 of Part A of this Annex shall result from witness audits carried out:

(a) during the last 2 years by their accreditation body or competent authority for the purpose of their recognition under Regulation (EC) No 834/2007 for each category of products for which the control authority or control body requests recognition in accordance with Article 46 of Regulation (EU) 2018/848; and

(b) in a third country for which the control authority or control body is recognised under Article 33(3) of Regulation (EC) No 834/2007.

However, for each of these witness audits, the accreditation body or competent authority shall confirm that all non-compliances have been fully addressed by the control authority or control body.

[1] Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

ANNEX II
General and specific requirements for the annual report referred to in Article 4

1. The annual report shall update all the elements contained in the technical dossier as set out in Article 1(2).

2. The annual report shall contain the information of the control authority or control body to be updated for the purpose of the annual report and shall include the name and code number of the control authority or control body, mailing address, telephone number, email contact point and website address, which shall include a direct link, with an easy access from the home webpage, to the up-to-date list of operators or groups of operators.

3. For the purposes of the annual report, the technical dosser shall be completed with the following:

   (a) the control activities of the control authority or control body in the third country or third countries in the previous year, per category of products, as set out in Article 35(7) of Regulation (EU) 2018/848, including the information about the number of operators and groups of operators as well as the number of their members (including subcontractors, if the operators or groups of operators do not remain responsible for the subcontractors) which were subject to their controls on 31 December of the previous year, broken down by third country and category of products;

   (b) an undertaking that the control authority or control body has performed the required updates of the translation of the production rules according to Article 1(2)(e) of this Regulation or any other relevant documents required for the purposes of Article 46(2) of Regulation (EU) 2018/848 or this Regulation;

   (c) any update of the internal procedures, including the certification and control system set up by the control authority or control body in compliance with this Regulation;

   (d) a link to the website of the control authority or control body, with the information required in accordance with Article 17;

   (e) an annual assessment report of the office(s) where certification decisions are taken, as referred to in point 2.1 of Part A of Annex I:

      (i) ensuring that the control authority or control body has been satisfactorily assessed by the accreditation body or competent authority in the previous year on its ability to ensure that products imported from third countries comply with Regulation (EU) 2018/848;

      (ii) confirming that the control authority or control body still has the capacity and the competencies to implement the control requirements, conditions and measures set out in Article 46(2) and (6) of Regulation (EU) 2018/848 and in this Regulation, in each third country for which it is recognised;

      (iii) including any updated information of the annual assessment report as regards the results and an evaluation of:

         – the checks of the files of the operators or groups of operators;

- the list of non-compliances, as well as the number of non-compliances in relation to the number of certified operators or groups of operators;
- the handling of non-compliances and complaints, if any, with an explanation on the corrective measures implemented by the operators or groups of operators for the lasting closure of its non-compliances;
- the catalogue of measures and its implementation;
- the risk analysis procedure;
- the annual risk plan;
- the sampling strategy, procedure and methodology;
- the changes to any of the procedures;
- the exchange of information with other control authorities, control bodies and the Commission;
- the competence of the staff involved in the inspection and certification process;
- the training programmes;
- the knowledge and competence of new staff;
- the effectiveness and reliability of the activity witnessed and an overall assessment of the performance of the control authority or control body;
- other elements that the accreditation body or competent authority considers relevant for the purposes of Regulation (EU) 2018/848;

(iv) confirming as regards the extensions of the scope of recognition to additional third countries or categories of products in the previous year, the capacity and competencies of the control authority or control body to perform controls in accordance with this Regulation in each new third country or for each new category of products concerned, if there are active operators or groups of operators.

4. The annual report shall include the following information with regard to cases of non-compliance and the measures taken:

(a) the number of physical on-the-spot inspections with and without prior notice;

(b) the number of the samples collected in inspections with and without prior notice and where applicable, the actions taken;

(c) the number of samples collected due to suspicion, complaints or during an investigation as referred to point (a) of Article 22(1) notified through OFIS as referred to in Article 21(2) (OFIS case);

(d) the number of OFIS cases of suspected or established non-compliance;

(e) the number of non-compliances found, broken down into minor, major and critical according to the classifications of non-compliances of organic or in-conversion products laid down in Annex IV;

(f) measures referred to Annex IV taken in respect of operators or groups of operators in cases of non-compliances.

5. When the control authority or control body has certified operators or groups of operators from another control authority or control body, the annual report of the receiving control authority or control body shall indicate for each transferred operator or group of operators:

(a) the name of the operator or group of operators, its geographical location and its previous certificate number;

(b) the name of its previous control authority or control body;

(c) the date of transfer of the control file;

(d) the list and nature of open non-compliances and measures required by the previous control authority or control body, if any;

(e) the measures put in place by the operator or group of operators to ensure that the non-compliances will not occur again, and the date(s) of the inspection(s) carried out by the new control authority or control body to verify that corrective measures have been correctly implemented;

(f) the indication whether the operator or group of operators was involved in any OFIS case.

6. Concerning high-risk products referred to in Article 8, the following information shall be provided:

(a) the list of the operators or groups of operators responsible for the high-risk products;

(b) for each operator or group of operators:

(i) the inspections carried out, indicating the date of each inspection;

(ii) the sampling and analyses carried out;

(iii) non-compliances found;

(iv) the measures applied;

(v) for each operator or group of operators that changed its control authority or control body, the corrective measures and/or sanctions applied if non-compliances were noted in the report of the previous control authority or control body;

(c) for each consignment showing a non-compliance:

(i) reference to the certificate of inspection for imported consignments;

(ii) overview of sampling analysis results that indicate the presence of residues of non-authorised substances;

(iii) investigations and follow-up measures taken by the control authority or control body in case of commingling or residues of non-authorised substances found in the consignment, including the decision concerning the consignment as well as confirmation that operators have taken corrective measures.

7. For authorisations for the use of non-organic plant reproductive material in accordance with point 1.8.5.2. of Part I of Annex II to Regulation (EU) 2018/848, the following information shall be provided:

   (a) scientific and common name (common and Latin name);

   (b) variety;

   (c) number of derogations and total weight of seeds or number of plants derogated;

   (d) number of operators and groups of operators which have been granted an authorisation.

8. For derogations granted in accordance with points 1.3.4.3 and 1.3.4.4 of Part II of Annex II to Regulation (EU) 2018/848 for each non-organic livestock species (bovine, equine, ovine, caprine, porcine and cervine animals, rabbits, poultry), the following information shall be provided:

   (a) scientific and common name (common and Latin name i.e. species and genus);

   (b) breeds and strains;

   (c) production purposes: meat, milk, eggs, dual purpose or breeding;

   (d) number of derogations and total number of animals derogated;

   (e) number of operators and groups of operators, which have been granted a derogation.

9. For authorisations granted for the use of non-organic aquaculture juveniles in accordance with point 3.1.2.1 of Part III of Annex II to Regulation (EU) 2018/848, the following information shall be provided :

   (a) species and genus (common and Latin name);

   (b) breeds and strains when applicable;

   (c) total number of derogations and number of juveniles for each species;

   (d) number of operators and groups of operators, which have been granted an authorisation.

10. The annual report shall contain any other information deemed relevant to satisfy a specific requirement of Regulation (EU) 2018/848 by the control authority, the control body or the accreditation body.

ANNEX III
OFIS template as referred to in Article 21(2)

Template for a standard reply to a standard international notification on suspected or established non-compliance

A. Investigation
1) Which control authority(-ies) and/or control body(-ies) are/were in charge of the investigation?:
2) Describe cooperation between the different operators and competent authority(-ies) or, where appropriate, control authority(-ies) and/or control body(-ies) involved, in the different countries involved (if any)?:
3) Which investigation methods/procedures have been used?:
For instance, have the operators concerned been submitted to a specific control?:
Have samples been taken and analysed?:
4) What is the outcome of the investigation?:
What are the results of the inspections/analyses (if any)?:
Has the origin of the non-compliance/suspicion of non-compliance/other problem raised been cleared up?:
What is your assessment of the seriousness of the non-compliance/suspicion of non-compliance/other problem raised?:
5) Has the origin of the contamination/non-compliance/suspicion of non-compliance/other problem raised and the responsibility of the actors been clearly identified and established?:
Comment on the origin of the contamination/non-compliance/other problem raised and the responsibility of the actors:
6) Have the operators identified been involved in other non-compliance/suspicion of non-compliance/other problem raised cases in the last 3 years?
Comment on the operators identified in other non-compliance/suspicion of non-compliance/other problems in the last 3 years:
B. Measures and penalties:
*1) What preventive and corrective measures have been taken (e.g. as regards the distribution/circulation of the product on the Union market and third-country markets)?:
*2) What actions in case of non-compliance/suspicion of non-compliance/other problem raised were taken on the operators and/or the products concerned? [2]:

[2] Measure pursuant to Article 29(1) and (2) of Regulation (EU) 2018/848 and Article 22(1), (2) and (3) and Article 23(1) and (4) of this Regulation.

*Mode of actions (written form, warning, etc.)?:
Was the certification of the producer/processor limited, suspended or withdrawn?:
Date of entry into force of the actions (if any) (DD/MM/YYYY):
Duration of the actions (if any) (in months):
Control authority and/or control body which adopted and applied the actions (if any):
3) Are additional inspections planned at the operators concerned?:
4) What other measures are the control authority or control body planning to prevent the occurrence of similar cases?:
C. Other information:
D. Annexes:
Reply comments:
Contact point

(*) Mandatory fields.

ANNEX IV
Catalogue of measures referred to in Article 22(3)

PART A

ELEMENTS FOR THE DEVELOPMENT AND APPLICATION OF THE CATALOGUE OF MEASURES

1. Subject to Part B, the control authority or control body may classify cases of non-compliance as minor, major or critical, on the basis of the classification criteria in point (b) of Article 22(3) when one or more of the following situations apply:

   (a) the case of non-compliance is minor when:

      (i) the precautionary measures put in place by the operator are proportionate and appropriate, and the controls that the operator has put in place are efficient according to the assessment by the control authority or control body;

      (ii) the non-compliance does not affect the integrity of the organic or in-conversion product;

      (iii) the traceability system can locate the affected product(s) in the supply chain and the product can be prevented from being imported from a third country for the purpose of placing that product on the market within the Union with reference to organic production;

   (b) the case of non-compliance is major when:

      (i) the precautionary measures are not proportionate and appropriate and the controls that the operator has put in place are inefficient according to the assessment by the control authority or control body;

      (ii) the non-compliance affects the integrity of the organic or in-conversion product;

      (iii) the operator did not correct in a timely manner a minor non-compliance;

      (iv) the traceability can locate the affected product(s) in the supply chain and the product can be prevented from being imported from a third country for the purpose of placing that product on the market within the Union with reference to organic production;

   (c) the case of non-compliance is critical when:

      (i) the precautionary measures are not proportionate and appropriate and the controls that the operator has put in place are inefficient according to the assessment by the control authority or control body;

      (ii) the non-compliance affects the integrity of the organic or in-conversion product;

      (iii) the operator fails to correct previous major non-compliances or repeatedly fails to correct other categories of non-compliances; and

      (iv) there is no information from the traceability system to locate the affected product(s) in the supply and the products cannot be prevented from being

imported from a third country for the purpose of placing that product on the market within the Union with reference to organic production.

2. Measures

Control authorities or control bodies may apply one or more of the following measures in a proportionate manner to the listed categories of cases of non-compliance:

Category of non-compliance	Measure
Minor	Submission by the operator of an action plan within a time limit setting on the correction of the non-compliance(s)
Major	No reference to organic production in the labelling and advertising of the entire lot or production run concerned (crop(s) or animal(s) affected) according to Article 42(1) of Regulation (EU) 2018/848 Prohibition of import from a third country for the purpose of placing that product on the market within the Union as organic production for a given period according to Article 42(2) of Regulation (EU) 2018/848 New conversion period required Limitation of the certificate's scope Improvement of the implementation of the precautionary measures and the controls that the operator has put in place to ensure compliance
Critical	No reference to organic production in the labelling and advertising of the entire lot or production concerned (crop(s) or animal(s) affected) according to Article 42(1) of Regulation (EU) 2018/848 Prohibition of import from a third country for the purpose of placing that product on the market within the Union as organic production for a given period according to Article 42(2) of Regulation (EU) 2018/848

	New conversion period required Limitation of the certificate's scope Suspension of the certificate Withdrawal of the certificate

PART B

LIST OF CASES OF NON-COMPLIANCE AND THE CORRESPONDING CLASSIFICATION MANDATORY TO BE INCLUDED IN THE CATALOGUE OF MEASURES

Non-compliance	Category
Significant deviation between input and output calculation (mass balance)	Major
Absence of records and financial records showing the compliance with Regulation (EU) 2018/848	Critical
Intentional omission of information leading to incomplete records	Critical
Falsification of documents connected with the certification of organic products	Critical
Intentional re-labelling of downgraded products as organic	Critical
Intentional mixing organic with in-conversion or non-organic products	Critical
Intentional use of non-authorised substances or products within the scope of the Regulation (EU) 2018/848	Critical
Intentional use of GMOs	Critical
The operator refuses the control authority or the control body access to premises subject to controls, or to its book keepings, including financial records, or refuses to allow the control authority or control body to take samples	Critical