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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

(Text with EEA relevance)

CHAPTER I

PROCEDURAL REQUIREMENTS FOR THE RECOGNITION OF CONTROL AUTHORITIES AND CONTROL BODIES

Article 1

Requirements referred to in point (n) of Article 46(2) of Regulation (EU) 2018/848

1. A control authority or control body shall submit the request for recognition referred in Article 46(4) of Regulation (EU) 2018/848 using the model made available by the Commission. Only complete requests shall be taken into account.

2. The technical dossier referred to in Article 46(4) of Regulation (EU) 2018/848 shall contain the following information in one of the official languages of the Union:

- (a) the following information about the control authority or control body:
 - (i) name;
 - (ii) mailing address;
 - (iii) telephone number;
 - (iv) email contact point;
 - (v) for control bodies, the name of their accreditation body;
- (b) an overview of the intended activities of the control authority or control body in the third country or third countries concerned, including an indication of the organic products, together with their Combined Nomenclature (CN) codes according to Council Regulation (EEC) No 2658/87 ⁽¹⁾, distributed per category of products as set out in Article 35(7) of Regulation (EU) 2018/848, that are intended to be imported into the Union in accordance with point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 during the first year of activity following the recognition by the Commission;
- (c) a description of the control authority or control body as regards:
 - (i) its structure and size;

⁽¹⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

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- (ii) its IT management system;
- (iii) its branch offices, if any;
- (iv) its type of activities, including delegated activities, if any;
- (v) its organisational chart;
- (vi) its quality management;
- (d) the certification procedures, in particular for granting or rejecting, suspension or withdrawal of the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848;
- (e) the translation of the production rules and control measures set out in Regulation (EU) 2018/848, and the delegated and implementing acts adopted pursuant to it in languages that are understandable for the contracted operators in the third countries for which the control authority or control body requests recognition;
- (f) the documents proving that the criteria set out in Article 46(2) of Regulation (EU) 2018/848 are fulfilled, in particular a copy of the accreditation certificate granted by the accreditation body covering all categories of products for which recognition is requested;
- (g) the procedures describing in detail the functioning and the implementation of the control measures to be set up in accordance with this Regulation, including, where relevant, control specificities for the group of operators;
- (h) a catalogue of measures to be taken in cases of established non-compliance as laid down in Article 22 of this Regulation;
- (i) ►**M1** a copy of the most recent assessment report referred to in Article 46(4), second subparagraph, of Regulation (EU) 2018/848, drawn up by the accreditation body or, as appropriate, by the competent authority, containing the information referred to in Part A of Annex I to this Regulation, including a witness audit report on a witness audit carried out within 2 years preceding the submission of the request for recognition. By way of derogation, for requests for recognition submitted before 31 December 2024, the witness audit report may be on a witness audit carried out within 3 years preceding the submission of the request for recognition. The assessment report shall give the following guarantees: ◀
 - (i) that the control authority or control body has been satisfactorily assessed on its ability to ensure that products imported from third countries meet the conditions set out in points (a), (b)(i) and (c) of Article 45(1) and in Article 46(2) of Regulation (EU) 2018/848;
 - (ii) that the control authority or control body has the capacity and the competencies to implement effectively the control requirements and fulfil the criteria set out in Article 46(2) of Regulation (EU) 2018/848 and in this Regulation in each third country for which it requests recognition;
- (j) proof that the control authority or control body has notified its activities to the relevant authorities of the third country concerned and its undertaking to respect the legal requirements imposed on it by the authorities of the third country concerned;

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- (k) a website address, with a content available in at least one of the official languages of the Union and also understandable for the contracted operators, where the list referred to in point (a) of Article 17 of this Regulation can be found;
 - (l) an undertaking by the control authority or control body to give access to all its offices and facilities to independent experts designated by the Commission and keep available and communicate all information related to its control activities in the third country concerned;
 - (m) a statement by the control authority or control body that it has not been subject to withdrawal by the Commission, or withdrawn or suspended by any accreditation body, in the 24 months preceding their request for recognition for the third country and/or category of products they request a recognition for. This requirement does not apply in case of withdrawal pursuant to point (k) of Article 46(2a) of Regulation (EU) 2018/848;
 - (n) any other information deemed relevant by the control authority or control body, or by the accreditation body.
3. The control authority or control body shall provide any further information requested by the Commission for the purpose of its recognition.
4. If the Commission finds that the information provided pursuant to paragraph 2 or 3 is incomplete, outdated or unsatisfactory, it shall reject the request for recognition.

*Article 2***Extension of the scope of the recognition**

A control authority or control body recognised in accordance with Article 46 of Regulation (EU) 2018/848 may submit a request for extension of the scope of its recognition to an additional third country or to an additional category of products using the model made available by the Commission.

The request for extension of the scope of recognition shall consist of an update of the relevant parts of the technical dossier referred to in Article 1(2) with the appropriate information on the additional third country or the additional category of products subject to the scope extension.

CHAPTER II

SUPERVISION OF THE CONTROL AUTHORITIES AND CONTROL BODIES BY THE COMMISSION*Article 3***General requirements for the supervision of control authorities and control bodies**

1. The supervisory activities of the Commission in respect of control authorities and control bodies recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 shall focus on the evaluation of the operational performance of the control authorities and control bodies, taking into account the results of the work of the accreditation bodies referred in point (d) of Article 46(2) of that Regulation.

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2. The intensity and frequency of the supervisory activities carried out by the Commission shall be adapted according to the risk of non-compliances in accordance with Article 46(6) of Regulation (EU) 2018/848.

3. Control authorities and control bodies recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 shall maintain the ability to meet the conditions and criteria set out in points (a), (b)(i) and (c) of Article 45(1) and Article 46(2) of that Regulation as set out in the technical dossier at the moment of their recognition. They shall also maintain the capacity and 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.

For that purpose, they shall demonstrate:

- (a) that they have effectively implemented their activities according to the conditions and criteria referred to in the first subparagraph; and
- (b) compliance with their operating procedures and the effectiveness of their control measures.

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3a. Within 2 years from the initial recognition or from the extension of the scope of recognition to a new category of products in accordance with Article 2, the control authority or control body shall provide a new witness audit report on a new witness audit carried out in accordance with Sections 1 and 2 of Part B of Annex I for the categories of products for which it has been recognised or for which the scope of recognition was extended.

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4. For the purpose of the annual report, the control bodies shall ensure that witness audits are carried out in accordance with Sections 1 and 2 of Part B of Annex I to this Regulation and the following rules:

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- (a) the period between two witness audits shall not exceed 4 years, starting from the date of the first witness audit carried out after the initial recognition or the initial extension of scope to a new category of products;

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- (b) the number of witness audits carried out for the initial request for recognition shall not be considered for the calculation of the total number of witness audits to be carried out during the 4 years referred to in point (a);
- (c) one additional witness audit shall be carried out:
 - (i) every 2 years in those third countries where the high-risk product as referred to in Article 8 is produced or processed;
 - (ii) for every 10 third countries recognised. This additional witness audit shall be carried out within 4 years;
- (d) more witness audits shall be performed at the request of the Commission or of the accreditation body based on a risk analysis of, in particular, the following factors:
 - (i) the number of inspectors;
 - (ii) the number of operators;
 - (iii) the type of activities carried out by the operators;
 - (iv) the number of witness audits carried out by the accreditation body;

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- (v) the irregularities concerning the control bodies;
- (vi) the number of certified groups of operators and the size of them;
- (vii) the critical findings for the control bodies or the specific inspector or inspectors;
- (viii) the nature of the products and the risk of fraud;
- (ix) Commission feedback based on the previous annual report of the control body;
- (x) suspicions of fraud by operators.
- (xi) the volume of products imported from a third country into the Union and the activity of the control authority or control body in recognised third countries.

5. Control authorities and control bodies shall submit documentation on their risk- analysis procedure at the Commission's request.

6. For the purpose of supervision of the control authorities and control bodies recognised by the Commission, the latter may be assisted by two Member States to act as co-reporters for the examination of technical dossiers submitted by control authorities and control bodies for initial recognition or the extension of their scope of recognition, the management and review of the list of recognised control authorities and control bodies and the evaluation of the operational performance, including annual reports, of the control authorities and control bodies.

7. The Commission may divide the requests between the Member States proportionally with the number of votes of each Member State in the Committee on organic production.

Article 4

Annual report

By 28 February every year, the control authority or control body shall submit an annual report to the Commission.

That annual report shall set out the activities of the control authority or control body in the previous year in accordance with Annex II

It shall be submitted in one of the official languages of the Union and in English if the official language chosen is not English.

Article 5

On-the-spot examinations and audits

1. The Commission shall regularly organise risk-based on-the-spot examinations and/or audits of the control authorities and control bodies to evaluate the quality and effectiveness of the controls carried out by each control authority or control body. Those examinations and audits may be coordinated with the relevant accreditation body. The Commission may be accompanied by independent experts during these on-the-spot examinations and audits.

2. The Commission may request any further information, including the presentation of one or more ad-hoc on-the-spot examination reports established by independent experts that it designates.

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3. On-the-spot examinations and audits may include:
- (a) a visit to the offices or premises of the control authorities and control bodies, their outsourced services and operators or groups of operators under their control, in the Union and in third countries;
 - (b) a document review of the relevant documents describing the structure, functioning and quality management of the control authorities or control bodies;
 - (c) a document review of staff files, including evidence of their competencies, training records, conflict of interest statements and records of evaluation and supervision of staff;
 - (d) a check of operators' or groups of operators' files in order to verify the treatment of non-compliances and complaints, the minimum control frequency, the use of a risk-based approach in the conduct of inspections, the implementation of follow-up visits and visits without prior notice, the sampling policy and the exchange of information with other control bodies and control authorities;
 - (e) a review audit, which is the inspection of operators or groups of operators to verify compliance with the standard control and risk assessment procedures of the control authority or control body and to verify its effectiveness, taking into account the evolution of the operators' situation from the last inspection of the control authority or control body;
 - (f) a witness audit, which is the evaluation of the performance of the physical on-the-spot inspection carried out by an inspector of the control authority or control body.

*Article 6***Traceability checks**

The Commission may perform traceability checks on products or consignments covered by the scope of the recognition of a control authority or control body recognised in accordance with Article 46(1) of Regulation (EU) 2018/848.

For the purpose of tracing the ingredients or production phases of an organic product, the Commission may ask information from the competent authorities or from control authorities or control bodies involved in the control of those products falling under their supervision.

The Commission may perform traceability checks based on the annual risk assessment performed by it, complaints received by the Commission or Member States, or randomly.

The Commission shall perform traceability checks in a timeframe defined by it, which shall be communicated in time to the relevant competent authorities, control authorities and control bodies involved.

*Article 7***Ad hoc request by the Commission**

The Commission may, at any time, based on a substantial analysis proving the necessity, make ad-hoc requests for information to a control authority or control body.

▼M2*Article 8***List of high-risk third countries and high-risk products**

High-risk products and the third countries in which they originate shall be listed together with the shares of consignments of those products to be subject to identity and physical checks and sampling by control authorities and control bodies in third countries, and by the competent authorities of the Member States, as appropriate, in an implementing act adopted in accordance with Article 46(8) of Regulation (EU) 2018/848 on the basis of a selection made after major, critical or repetitive non-compliances affecting the integrity of organic or in-conversion products or production.

The shares referred to in the first subparagraph can be lower than 100 % and may, for the same product, be different for controls by control authorities and control bodies in third countries and the competent authorities of the Member States respectively.

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CHAPTER III

CONTROLS IN RESPECT OF OPERATORS AND GROUPS OF OPERATORS BY THE CONTROL AUTHORITIES AND CONTROL BODIES*Article 9***General provisions**

1. Controls performed by control authorities and control bodies for the verification of compliance with Regulation (EU) 2018/848 by operators and groups of operators in third countries shall include:

- (a) the verification of the application of preventive and precautionary measures, as referred to in Article 9(6) and in Article 28 of Regulation (EU) 2018/848, at every stage of production, preparation and distribution;
- (b) where the holding includes non-organic or in-conversion production units, the verification of the records and of the measures or procedures or arrangements in place to ensure the clear and effective separation between organic, in-conversion and non-organic production units as well as between the respective products produced by those units, and of the substances and products used for organic, in-conversion and non-organic production units. Such verification shall include checks on parcels for which a previous period was recognised retroactively as part of the conversion period, and checks on the non-organic production units;
- (c) where organic, in-conversion and non-organic products are collected simultaneously by operators, are prepared or stored in the same preparation unit, area or premises, or are transported to other operators or units, the verification of the records and of the measures, procedures or arrangements in place to ensure that operations are carried out separated by place or time, that suitable cleaning measures and measures to prevent substitution of products are implemented, that organic products and in-conversion products are identified at all times, that organic, in-conversion and non-organic products are stored, before and after the preparation operations, separated by place or time from each other, and that traceability of each lot from the individual land parcels to the collection centre has been ensured.

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2. Controls by control authorities and control bodies for the verification of compliance with Regulation (EU) 2018/848 shall be performed on all operators and groups of operators in third countries regularly, on a risk basis and with appropriate frequency, throughout the entire process at all stages of production, preparation and distribution on the basis of the likelihood of non-compliance as defined in point (57) of Article 3 of Regulation (EU) 2018/848, which shall be determined taking into account the following elements:

- (a) the type, size, including newly added land parcels, and structure of the operators and groups of operators, as well as the number of new members joining the group of operators;
- (b) location and complexity of the activities or operations of operators and groups of operators;
- (c) the length of time during which operators and groups of operators have been involved in organic production, preparation and distribution;
- (d) the results of the controls performed in accordance with this Article, in particular as regards compliance with Regulation (EU) 2018/848;
- (e) in the case of a group of operators, the results of the internal inspections carried out in accordance with the documented procedures of the system for internal controls of the group of operators;
- (f) whether the holding includes non-organic or in-conversion production units;
- (g) the type, quantity and value of products;
- (h) the risk of commingling of products or contamination with non-authorised products or substances;
- (i) the application of derogations or exceptions to the rules by operators and groups of operators;
- (j) the critical points for non-compliance at every stage of production, preparation and distribution;
- (k) subcontracting activities;
- (l) whether operators or groups of operators have changed their certifying control authority or control body;
- (m) any information indicating the likelihood that consumers might be misled;
- (n) any information that might indicate non-compliance with Regulation (EU) 2018/848.

3. Article 2 of Commission Delegated Regulation (EU) 2021/771 ⁽²⁾ and Articles 4, 5 and 6 of Commission Implementing Regulation (EU) 2021/279 ⁽³⁾ shall apply *mutatis mutandis* to controls in respect of groups of operators in third countries.

⁽²⁾ 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 (OJ L 165, 11.5.2021, p. 25).

⁽³⁾ 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 (OJ L 62, 23.2.2021, p. 6).

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4. The control authority or control body shall carry out a verification of compliance with Regulation (EU) 2018/848 for all operators and groups of operators at least once a year. The verification of compliance shall include a physical on-the-spot inspection.

5. The control authority or control body shall ensure that it carries out every year at least 10 % of additional controls to those referred to in paragraph 4. Of all physical on-the-spot inspections carried out by the control authority or control body, at least 10 % shall be without prior notice.

6. Controls carried out as a follow-up on a suspected or established non-compliance shall not count towards the additional controls referred to in paragraph 5.

7. Every year, the control authority or control body shall re-inspect at least 5 % of the members of a group of operators, but not less than 10 members. Where the group of operators has 10 members or less, all members shall be re-inspected.

8. The physical on-the-spot inspection and the sampling shall be carried out by the control authority or control body at the most appropriate times in order to verify compliance on critical control points.

For the high-risk products referred to in Article 8, the control authority or control body shall carry out, at least, two physical on-the-spot inspections per year of operators or groups of operators. One of these physical on-the-spot inspections shall be without prior notice.

9. Where operators or groups of operators run several production units or premises, including purchase and collection centres, all production units or premises, including purchase and collection centres, used for non-organic products shall also be subject to the control requirements set out in paragraph 4.

10. The delivery or renewal of the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 shall be based on the results of the verification of compliance referred to in this Article.

Article 10

Checks for the certification of operators or groups of operators

1. Before accepting to certify operators or groups of operators, a control authority or control body shall ensure that the operators or groups of operators have provided the following:

- (a) a document in the form of a signed declaration, setting out:
 - (i) a description of the organic and/or in-conversion production unit and, where relevant, of the non-organic production units and of the activities to be performed in accordance with Regulation (EU) 2018/848;
 - (ii) the relevant measures to be taken at the level of the organic and/or in-conversion unit and/or premises and/or activities to ensure compliance with Regulation (EU) 2018/848;
 - (iii) the precautionary measures to be taken in order to reduce the risk of contamination by non-authorised products or substances and the cleaning measures to be taken throughout the stages of production, preparation and distribution;

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- (b) a confirmation that the operators or groups of operators have not been certified by another control body in relation to activities carried out in the same third country regarding the same category of products, including in cases in which operators or groups of operators operate at different stages of production, preparation or distribution;
- (c) a confirmation by the members of a group of operators that they have not been certified on an individual basis for the same activity for a given product covered by the certification of the group of operators to which they belong;
- (d) a signed undertaking by which the operators or groups of operators commit themselves:
 - (i) to give the control authority or control body access to all parts of all production units and all premises for control purposes, as well as to the accounts and relevant supporting documents;
 - (ii) to provide the control authority or control body with any information necessary for the purposes of the controls;
 - (iii) to submit, when requested by the control authority or control body, the results of its own quality assurance programmes;
 - (iv) to inform buyers of the products in writing and without undue delay, and to exchange relevant information with the control authority or control body, in the event that a suspicion of non-compliance has been substantiated, that a suspicion of non-compliance cannot be eliminated, or that non-compliance that affects the integrity of the products in question has been established;
 - (v) to accept the transfer of the control file in case of a change of control authority or control body or, in the case of withdrawal from organic production, the keeping of the control file for 5 years by the last control authority or control body;
 - (vi) to inform immediately the control authority or control body in the event of withdrawal from organic production;
 - (vii) in the event that the subcontractors of the operators or of groups of operators are subject to controls by different control authorities or control bodies, to accept the exchange of information among those control authorities or control bodies;
 - (viii) to perform the activities in accordance with the organic production rules;
 - (ix) to accept the enforcement of the corrective measures established by the control authority or control body in the event of non-compliances.

2. Before certifying operators or groups of operators, the control authority or control body shall verify:

- (a) that the operators or groups of operators comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation. The verification shall include at least one physical on-the-spot inspection;

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(b) that, where the operators or groups of operators subcontract any of its activities to third parties, both the operators or groups of operators and the third parties to whom those activities have been subcontracted, have been certified by recognised control authorities or control bodies confirming that they comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation, unless the operators or groups of operators inform the relevant control authority or control body that they remain responsible as regards organic production and that they have not transferred that responsibility to the subcontractor. In such cases, the control authority or control body shall verify that the subcontracted activities comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation in the context of the control activities it carries out in respect of the operators or groups of operators that have subcontracted their activities.

3. Besides any other element that may be considered relevant by the control authority or control body, before certifying operators or groups of operators that were previously certified by another control authority or control body, the new control authority or control body shall assess the following information to be transmitted by the previous control authority or control body:

- (a) the status and validity of certification, including cases of scope reduction, suspension and withdrawal as referred to in International Organisation for Standardisation (ISO) standard ISO/IEC 17065;
- (b) reports of inspection carried out in the preceding 3 years;
- (c) the list of non-compliances and the measures put in place to address them, and the fact that all non-compliances were addressed;
- (d) derogations granted or requests for derogation being processed by the previous control authority or control body;
- (e) information relating to any ongoing dispute relevant for the certification of the operators or groups of operators.

If the previous control authority or control body does not transmit the information as required in Article 21(5) of this Regulation to the new control authority or control body or in case of doubts concerning the information transmitted, the new control authority or control body shall not issue the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 to operators or groups of operators until this new control authority or control body has eliminated their doubts by other means of control.

4. The control authority or control body shall not certify operators or groups of operators that have been withdrawn by their previous control authority or control body in the last 2 years, unless the recognition of the previous control authority or control body has been withdrawn by the Commission in accordance with Article 46(2a) of Regulation (EU) 2018/848 for the specific third country and category of products.

▼B*Article 11***Methods and techniques for controls**

1. Control methods and techniques applied by a control authority or control body shall include the following:

- (a) a check whether the maps or sketches with cardinal directions and geo-location of the production units and premises to be physically inspected, as provided by the operators or groups of operators, is up-to-date;
- (b) an inspection of, as appropriate:
 - (i) the production units, equipment, means of transport, premises and other places under the control of the operator or group of operators;
 - (ii) animals, plants and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals, and substances authorised for use in organic production;
 - (iii) traceability, labelling, presentation, advertising and relevant packaging materials;
- (c) an examination of documents, traceability records and other records and practices and procedures that are relevant for the assessment of compliance with Regulation (EU) 2018/848. This includes documents accompanying food, feed and any substance or material entering or leaving an establishment;
- (d) interviews with operators and their staff;
- (e) sampling and laboratory analysis;
- (f) the examination of the control system that operators and groups of operators have put in place, including an evaluation of its effectiveness;
- (g) the examination of non-compliances found during previous inspections and the measures taken by the operators or by the groups of operators to address them;
- (h) any other action required to identify cases of non-compliance.

2. The annual physical on-the-spot inspection referred to in Article 9(4) shall include a traceability check and a mass balance check of the operators or groups of operators, carried out by means of checks of documentary accounts and of any other relevant element deemed necessary by the control authority or control body.

3. For the purpose of the traceability check and the mass balance check, the selection of products, groups of products and period under verification shall be based on a risk assessment by the control authority or control body.

4. Besides any other relevant element deemed necessary by the control authority or control body, the traceability check shall cover the following elements justified by appropriate documents including stock and financial records:

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- (a) the name and address of the supplier and, where different, of the owner or the seller, or the exporter of the products;
- (b) the name and address of the consignee and, where different, of the buyer or importer of the products;
- (c) the certificate of the supplier in accordance with an implementing act adopted pursuant Article 45(4) of Regulation (EU) 2018/848;
- (d) the information referred to in the first paragraph of point 2.1 of Annex III to Regulation (EU) 2018/848;
- (e) the appropriate lot identification;
- (f) in the case of processors, the necessary information to allow internal traceability and guarantee the organic status of ingredients.

5. The mass balance check shall cover the following elements justified by appropriate documents including stock and financial records, where relevant:

- (a) the nature and the quantities of products delivered to the unit and, where relevant, of materials bought and the use of such materials, and, where relevant, the composition of products;
- (b) the nature and the quantities of products held in storage at the premises including at the time of the physical on-the-spot inspection;
- (c) the nature and quantities of the products that have left the unit of the operators or groups of operators to the consignee's premises or storage facilities;
- (d) in case of operators or groups of operators who buy or sell the product(s) without storing or physically handling the product(s), the nature and the quantities of products that have been bought and sold;
- (e) the yield of the products obtained, collected or harvested over the previous year;
- (f) the estimated or actual yield of the products obtained, collected or harvested over the current year;
- (g) the number and/or weight of livestock managed over the current and previous year;
- (h) any losses, increase or decrease in quantity of products at any stage of production, preparation and distribution;
- (i) the total output of the holding in terms of organic and non-organic products.

Article 12

Sampling, methods used for sampling and selection of laboratories for sample analysis

1. The control authority or control body shall take and analyse samples for detecting the use of non-authorised products and substances for organic production, for checking production techniques not in compliance with the organic production rules or for detecting possible contamination by non-authorised products and substances for organic production.

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2. The control authority or control body shall carry out sampling on at least 5 % of the number of individual operators under its control. For a group of operators, the control authority or control body carry out sampling on at least 2 % of the members of each group.

3. The selection of the operators and groups of operators where samples have to be taken shall be based on risk assessment including the likelihood of non-compliance with the organic production rules, taking into account all stages of production, preparation and distribution.

4. In addition to the minimum sampling rate set in paragraph 2, the control authority or control body shall take and analyse samples in each case where the use of non-authorised products and substances or techniques for organic production is suspected, unless the control authority or control body considers that sufficient evidence is available without sampling.

5. For the high-risk products referred to in Article 8, the control authority or control body shall take, in addition to the sampling rate set in paragraphs 2 and 3 of this Article, at least one field sample of the crop each year. That sample shall be taken from crops in the field, at the most appropriate moment to detect potential use of non-authorised substances according to the assessment of the control authority or control body. For operators not growing crops, a relevant sample of incoming raw material or intermediate product or processed product shall be taken.

6. The control authority and control body shall ensure that the laboratories used comply with the following:

- (a) they are accredited laboratories that meet the applicable requirements of ISO standard ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
- (b) their accreditation bodies are signatory of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;
- (c) they have sufficient capacity for analysis and testing and they can ensure that samples are always tested with relevant methods included in the scope of their accreditation;
- (d) as regards residue pesticide testing, they are accredited for gas and liquid spectrometry in order to be able to cover the list of pesticide residues monitored under the coordinated multi-annual control programme of the Union set out in Commission Implementing Regulation (EU) 2019/533 ⁽⁴⁾.

7. The control authority or control body may delegate sampling tasks to other control authorities or control bodies recognised by the Commission or bodies accredited in accordance with ISO standard ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'.

⁽⁴⁾ Commission Implementing Regulation (EU) 2019/533 of 28 March 2019 concerning a coordinated multiannual control programme of the Union for 2020, 2021 and 2022 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin (OJ L 88, 29.3.2019, p. 28).

*Article 13***Documented control procedures**

1. Control authorities and control bodies shall perform controls on operators and groups of operators in accordance with documented procedures.

Those documented procedures shall cover:

- (a) a statement on the objectives to be achieved;
- (b) tasks, responsibilities and duties of staff;
- (c) sampling strategy, procedures and methodology, control methods and techniques, including laboratory analysis, testing and interpretation and evaluation of results and consequent decisions;
- (d) cooperation and communication with other control authorities, other control bodies and the Commission;
- (e) a procedure for assessing the risk linked to operators or groups of operators and for carrying out physical on-the-spot inspections and sampling;
- (f) verification of the appropriateness of methods of sampling and of laboratory analysis, testing and diagnosis;
- (g) any other activity or information required for the effective functioning of the controls, including in relation to training of inspectors and evaluation of their competencies;
- (h) for groups of operators, the effectiveness of the system for internal controls.

2. Control authorities and control bodies shall:

- (a) take corrective measures in all cases where the procedures provided for in paragraph 1 identify shortcomings; and
- (b) update the documented procedures provided for in paragraph 1 as appropriate.

*Article 14***Written records of controls**

1. Control authorities and control bodies shall draw up written records of each control they perform to verify compliance with Regulation (EU) 2018/848. Those records may be on paper or in electronic form. The control authorities and control bodies shall keep these records for 5 years from the day of the decision on certification by the control authority or control body.

Those records shall contain in particular:

- (a) a description of the purpose of the controls;
- (b) the control methods and techniques applied;
- (c) the outcome of the controls, in particular the results of verifying the elements listed in Articles 11 and 12 of this Regulation; and
- (d) actions that the operator or group of operators concerned is required to take as a result of the controls carried out by the control authority or control body, with an indication of the deadline to take action.

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2. The written records shall be countersigned by the operator or the inspected member of the group of operators as confirmation of their receipt of that written record. A copy of that record shall be kept by the operator or the inspected member of the group of operators either on paper or in electronic form.

*Article 15***Specific control requirements for algae and aquaculture animal production**

1. For the purpose of determining the start of the conversion period provided in Article 10(2) of Regulation (EU) 2018/848, the control authority or control body shall ensure that operators or groups of operators producing algae or aquaculture animals notify the control authority or control body of the relevant activity.

2. The control authority or control body shall ensure that organic production of algae or aquaculture animals takes place in a location with no risk of contamination in accordance with point 1.1 of Part III of Annex II to Regulation (EU) 2018/848. In particular, the control authority or control body shall ensure that adequate separation measures have been taken in accordance with point 1.2 of that Part III.

3. For the purposes of point 3.1.3.1(c) of Part III of Annex II to Regulation (EU) 2018/848, the control authority or control body shall ensure that the plant fraction of feed is organic and the feed fraction derived from aquatic animals originates from organic aquaculture or from fisheries that have been certified as sustainable in line with the 2009 FAO's Guidelines for the ecolabelling of fish and fisheries products from marine capture fisheries.

4. For the purposes of point 3.1.4.2(e) of Part III of Annex II to Regulation (EU) 2018/848, the control authority or control body shall ensure that they have information on all treatments, and they shall check that these treatments are carried out in accordance with the requirements of that Regulation.

5. For the purpose of authorising the use of wild seed within the meaning of point 3.2.1 of Part III of Annex II to Regulation (EU) 2018/848, the control authority or control body shall ensure that points (a), (b) and (c) of that point are respected.

*Article 16***Verification of consignments intended for import into the Union**

1. The relevant control authority or control body shall verify consignments intended for import into the Union with regard to the compliance with Regulation (EU) 2018/848 and this Regulation. This verification shall include systematic documentary checks and, as appropriate according to a risk assessment, physical checks, before the consignment leaves the third country of export or of origin.

2. For the purposes of this Article, the relevant control authority or control body shall be:

- (a) the control authority or control body of the producer or the processor of the product concerned; or

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- (b) where the operator or group of operators carrying out the last operation for the purpose of preparation is different from the producer or processor of the product, the control authority or control body of the operator or group of operators carrying out the last operation for the purpose of preparation as defined in point (44) of Article 3 of Regulation (EU) 2018/848.

The relevant control authority or control body shall be recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 for the products concerned and for the third country in which the products have their origin, or, where applicable, in which the last operation for the purpose of preparation has been carried out.

3. The documentary checks referred to in paragraph 1 shall aim at verifying:

- (a) the traceability of the products and ingredients;
- (b) that the volume of the products included in the consignment is in line with the mass balance checks of the respective operators or groups of operators according to the assessment carried out by the control authority or control body;
- (c) the relevant transport documents and commercial documents (including invoices) of the products;
- (d) in case of processed products, that all organic ingredients of such products have been produced by operators or groups of operators certified in a third country by a control authority or control body recognised in accordance with Article 46(1) or referred to in Article 57 of Regulation (EU) 2018/848 or by a third country recognised in accordance with Articles 47 and 48 of Regulation (EU) 2018/848, or have been produced and certified in the Union in accordance with that Regulation.

Those documentary checks shall be based on all relevant documents, including the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848, the latest record of the inspections, the production plan for the product concerned and records kept by the operators or groups of operators, available transport documents, commercial and financial documents and any other documents deemed relevant by the control authority or control body.

4. In relation to the risk assessment preceding physical checks as referred to in paragraph 1, the relevant control authority or control body shall take into account the following criteria:

- (a) the relevant criteria listed in Article 9(2);
- (b) whether there are several operators involved in the distribution chain of the products who do not store or physically handle organic products;
- (c) high-risk products referred to in Article 8;
- (d) any criteria deemed relevant by the control authority or control body.

5. For consignments made out of bulk organic products, the relevant control authority or control body shall draw up a travel plan in the Trade Control and Expert System (TRACES), including all the premises to be used during the travel from the third country of origin or export to the Union.

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6. ► **M2** For consignments of high-risk products referred to in Article 8, the relevant control authority or control body shall carry out physical checks and take at least one representative sample in accordance with the applicable percentage laid down in the implementing act referred to in Article 8. ◀ Moreover, the control authority or control body shall have complete documentation of the traceability of the operators or groups of operators and the product, including transport and commercial documents, including invoices. At the request of the Commission or the competent authority of a Member State, the control authority or control body shall send this traceability documentation as well as the results of the sampling analysis to the control authority or control body of the importer and to the competent authority of the Member State where the consignment is verified.

7. In case of suspicion of non-compliance, the Commission or the competent authority of a Member State may request the relevant control authority or control body to make available without delay the list of all operators and all groups of operators in the organic production chain of which the consignment is part, and of their control authorities or control bodies.

CHAPTER IV

OTHER ACTIONS TO BE CARRIED OUT BY THE CONTROL AUTHORITIES AND CONTROL BODIES*Article 17***List of operators and other relevant information to be publicly available**

The control authority or control body shall make the following information available on its website, in at least one official language of the Union:

- (a) a list of certified operators and certified groups of operators, containing:
 - (i) for operators, their name and address;
 - (ii) for groups of operators, the name and address of the group and the number of its members;
 - (iii) information relating to the certificates, in particular, the certificate number, category of products covered by the certification, status and validity of certification, including cases of scope reduction, suspension and withdrawal as referred to in ISO standard ISO/IEC 17065;
- (b) in the case of control bodies, updated information on their accreditation, including a link to the latest accreditation certificate issued by its accreditation body.

The list referred to in point (a) shall be immediately updated after any change of the status of the certification. In case of withdrawal, the information referred to in point (a)(iii) shall be kept in the list for 5 years after the withdrawal;

▼B*Article 18***Database of operators and groups of operators**

The control authority or control body shall keep an updated electronic database of operators and groups of operators. That database shall include the following information:

- (a) name and address of the operators or groups of operators. In case of a group of operators, the size of the group, name and address of each member of the group;
- (b) information concerning the scope of the certification, certificate number, status and validity of the certificate;
- (c) status of the operators or groups of operators, whether in conversion (including period of conversion) or organic;
- (d) risk level of the operators or groups of operators in accordance with Article 9;
- (e) in case of subcontracting activities that are under the control of the certified operators or groups of operators, name and address of the subcontracted third party or third parties;
- (f) the geographical coordinates and surface area of all the production units and premises;
- (g) inspection reports and the results of sampling analysis, as well as the results of any other controls performed, including the controls carried out on consignments;
- (h) non-compliances and measures applied;
- (i) notifications via the system referred to in Article 20(1);
- (j) derogations granted and relevant supporting documents in accordance with the requirements of this Regulation; and
- (k) any other information deemed relevant by the control body or the control authority.

The information shall be kept by the control authority or control body for 5 years. The control authority or control body shall make that information available to the Commission upon request.

*Article 19***Information requirements****▼M1**

1. After its recognition, the control authority or control body shall notify the Commission in due time, and not later than within 30 calendar days, of the occurrence of changes to the content of its technical dossier, including the new witness audit reports referred to in Article 3(3a).

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2. The control authority or control body shall keep available and communicate at the request of the Commission or the competent authorities of the Member States all information related to its control activities in the third country.

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3. The supporting documents relating to the request for recognition under Article 46 of Regulation (EU) 2018/848 and those required under this Regulation shall be kept by the control authorities or control bodies at the disposal of the Commission and the Member States for 5 years following the year in which the controls took place or the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 and documentary evidence were delivered.

*Article 20***Systems and procedures for the exchange of information**

1. The control authority or control body shall use the Organic Farming Information System (OFIS) for the exchange of information with the Commission, with other control authorities and other control bodies, and with the competent authorities of the Member States and of the third countries concerned.

2. The control authority or control body shall take the appropriate measures and establish documented procedures to ensure timely exchanges of information with the Commission and with other control authorities and control bodies.

3. Where a document or procedure provided for in Article 46 of Regulation (EU) 2018/848 or in the delegated and implementing acts adopted pursuant to that Article requires the signature of an authorised person or the approval by a person at one or more of the stages of that procedure, the computer systems set up for the communication of those documents shall make it possible to identify each person and guarantee that the integrity of the content of the documents, including as regards the stages of the procedure, cannot be altered, in accordance with Union law, and in particular with Commission Decision 2004/563/EC, Euratom ⁽⁵⁾.

*Article 21***Exchange of information between the Commission, control authorities, control bodies and competent authorities**

1. The control authority or control body shall immediately share information with the Commission, with other control authorities and control bodies, and with the competent authorities of the Member States and of the third countries concerned on any suspicion of non-compliance that affects the integrity of organic or in-conversion products.

2. Where a control authority or control body is notified by the Commission, after the Commission has received a notification from a Member State in accordance with Article 9 of Implementing Regulation (EU) 2021/279 as regards suspected or established non-compliance affecting the integrity of imported organic or in-conversion products, it shall carry out an investigation in accordance with Article 22 of this Regulation. The control authority or control body shall inform the Commission and the Member State that sent the initial notification (notifying Member State), using the template set out in Annex III to this Regulation. The control authority or control body shall reply within 30 calendar days from the date of receiving that notification and shall inform about the actions and measures taken, including the results of the investigation and provide any other information when available and/or required by the notifying Member State.

⁽⁵⁾ Commission Decision 2004/563/EC, Euratom of 7 July 2004 amending its Rules of Procedure (OJ L 251, 27.7.2004, p. 9).

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3. The notified control authority or control body shall provide further necessary information if requested by the notifying Member State.

4. Where operators or groups of operators and/or their subcontractors are subject to controls by different control authorities or control bodies, those control authorities or control bodies shall exchange the relevant information on the operations covered by their control activities.

5. Where operators or groups of operators and/or their subcontractors change their control authority or control body, the new control authority or control body shall request the control file of the operator or group of operators concerned from the previous control authority or control body. The previous control authority or control body shall, within 30 days, provide to the new control authority or control body the control file of the operator or group of operators concerned and the written records referred to in Article 14, the status of the certification, the list of non-compliances and the corresponding measures taken by the previous control authority or control body.

The new control authority or control body shall ensure that non-compliances noted in the report of the previous control authority or control body have been addressed by the operators or groups of operators.

6. Where operators or groups of operators are subject to a traceability check and a mass balance check, control authorities and control bodies shall exchange the relevant information allowing finalisation of these checks.

Article 22

Additional rules on actions to be taken in case of non-compliance

1. In addition to the measures referred to in Article 29(1), (2) and (3) of Regulation (EU) 2018/848 and Article 2 of Implementing Regulation (EU) 2021/279, where a control authority or control body suspects or receives substantiated information, including information from other control authorities or control bodies, that a product, which may not be in compliance with Regulation (EU) 2018/848, is intended to be imported from a third country for the purpose of placing that product on the market within the Union, but which bears terms referring to the organic production, or where such a control authority or control body has been informed by an operator of a suspicion of non-compliance in accordance with Article 27 of that Regulation:

- (a) it shall immediately carry out an investigation with a view to verifying compliance with Regulation (EU) 2018/848 or with the delegated or implementing acts adopted pursuant to that Regulation; such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case;
- (b) it shall prohibit the import from that third country for the purpose of placing the product concerned on the market within the Union as organic or in-conversion product pending the results of the investigation referred to in point (a). Before taking such a provisional decision, the control authority or control body, shall give the operator or group of operators an opportunity to comment.

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2. In the event that the results of the investigation referred to in point (a) of paragraph 1 do not show any non-compliance affecting the integrity of organic or in-conversion products, those products shall be allowed to be used and labelled as organic or in-conversion products.

3. The control authority or control body shall develop a catalogue of measures to be taken in case of established non-compliance. That catalogue of measures shall be based on the elements specified in Annex IV to this Regulation and shall cover at least:

- (a) a list of non-compliances with reference to the specific rules of Regulation (EU) 2018/848 or of the delegated or implementing acts adopted pursuant to that Regulation. That list shall include, at least the non-compliances listed in Part B of Annex IV to this Regulation;
- (b) the classification of the non-compliances into three categories: minor, major and critical as set out in Part A of Annex IV to this Regulation, taking into account at least the following criteria:
 - (i) the application of precautionary measures referred to in Article 28(1) of Regulation (EU) 2018/848, the practical measures referred in point (a)(ii) of Article 10(1) of this Regulation and the reliability of own controls carried out by the operator or group of operators in line with point (f) of Article 11(1) of this Regulation;
 - (ii) the impact on the integrity of the organic or in-conversion of products;
 - (iii) the ability of the traceability system to locate the affected product(s) in the supply chain and prohibition of importing from a third country for the purpose of placing the product(s) on the market within the Union with reference to organic production;
 - (iv) the response of the operator or group of operators to previous requests from the control authority or control body;
- (c) the measures to be applied for each non-compliance.

4. The control authority or control body shall document the results of the investigations referred to in point (a) of Article 29(1) of Regulation (EU) 2018/848.

Article 23

Additional rules on measures in the event of non-compliance

1. In the event of non-compliance affecting the integrity of organic or in-conversion products throughout any of the stages of production, preparation and distribution, for example as a result of the use of non-authorised products, substances or techniques, or commingling with non-organic products, the control authority or control body shall ensure, in addition to the measures to be taken in accordance with paragraphs 2 and 3 of this Article, that no reference is made to organic production as set out in Chapter IV of Regulation (EU) 2018/848, in the labelling and advertising of the entire lot or production run of the product intended to be imported from a third country for the purpose of placing that product on the market within the Union.

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2. Where the non-compliance is established, the control authority or control body shall:

- (a) take any action necessary to determine the origin and extent of the non-compliance and to establish the responsibilities of the operator or group of operators; and
- (b) take appropriate measures to ensure that the operator or group of operators remedies the non-compliance and prevents further occurrences of such non-compliance.

When deciding which measures to take, the control authority or control body shall take account of the nature of that non-compliance and the past record of the operator or of the group of operators with regard to compliance.

3. When acting in accordance with paragraph 2 of this Article, the control authority or control body shall take any measure it deems appropriate to ensure compliance with Regulation (EU) 2018/848 and the delegated and implementing acts adopted pursuant that Regulation, including:

- (a) applying the catalogue of measures referred to in Article 22(3) of this Regulation;
- (b) ensuring that the operator or group of operators increases the frequency of own controls;
- (c) ensuring that certain activities of the operator or of the group of operators are subject to increased or systematic controls by the control authority or control body.

4. In the event of serious, or repetitive or continued non-compliance, the control authority or control body shall ensure that the operator or group of operators, in addition to the measures laid down in paragraphs 2 and 3, is prohibited from placing on the market within the Union for a given period products which refer to organic production, and that its certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 be suspended or withdrawn, as appropriate.

5. The control authority or control body shall provide the operator or group of operators with a written notification of its decision concerning the action or measure to be taken in accordance with this Article, together with the reasons for that decision.

Article 24

Checks to be carried out for the purpose of the retroactive recognition of a previous period

1. Before granting retroactive recognition of a previous period as part of the conversion period for the purposes of point (b) of Article 10(3) of Regulation (EU) 2018/848, the control authority or control body shall ensure that the operator submits the following documents proving that the land parcels were natural or agricultural areas that, for a period of at least 3 years, have not been treated or have not been contaminated with products or substances that are not authorised for use in organic production in accordance with Regulation (EU) 2018/848:

- (a) maps identifying clearly each land parcel covered by the request for retroactive recognition and information on the total surface of those land parcels and, if relevant, on the nature and the volume of the ongoing production and their geolocation coordinates;

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- (b) any other relevant documents deemed necessary by the control authority or control body to assess the request for retroactive recognition.

2. In addition, the control authority or control body shall take the following steps:

- (a) it shall carry out a detailed risk analysis based on documentary evidence to assess whether any land parcel covered by the request for retroactive recognition has been treated with products or substances that are not authorised for use in organic production for a period of at least 3 years, taking into account in particular the size of the total surface to which the request relates and the agronomic practices carried out during that period on each land parcel subject to the request. The control authority or control body shall keep documents on the risk analysis;
- (b) it shall take samples on soil and/or plant from each land parcel in line with the results of the risk analysis referred to in point (a), including those land parcels identified as presenting the risk of being contaminated;
- (c) it shall draw up an inspection report in one of the official languages of the Union, including photographs of the parcels, following a physical inspection of the operator, including the land parcels covered by the request for retroactive recognition for the purpose of verifying the consistency of the information collected, but before any cultivation measures have been taken by the operator.

3. Based on the information provided by the operator in accordance with paragraph 1 and after having completed the steps set out in paragraph 2, the control authority or control body shall draw up a final written report. The final written report shall include a justification why the previous period can be recognised retroactively as part of the conversion period. This final written report shall also indicate the starting period considered as organic for each land parcel concerned as well as the total surface of the land parcels benefiting from this retroactive recognition of a period.

4. The control authority or control body shall immediately notify the Commission, the Member States and in case of a control body its accreditation body of any retroactive recognition granted. For each retroactive recognition granted, the control authority or control body shall provide the final written report referred to in paragraph 3.

5. The control authority or control body shall ensure that the operator to whom the granted retroactive recognition applies keeps documentary evidence relating to that recognition, as well as documentary evidence on the use of the land parcels covered by that recognition, for 3 years.

Article 25

Authorisations for the use of non-organic plant reproductive material

1. Before granting authorisations for the use of non-organic plant reproductive material as set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848, the control authority or control body shall assess the following information and draw up a justification for each derogation granted:

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- (a) scientific and common name (common and Latin name);
- (b) variety;
- (c) total weight of seeds or number of plants concerned;
- (d) the availability of organic or in-conversion plant reproductive material;
- (e) documentation or a statement from the operator proving that the requirements set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848 have been fulfilled.

2. For each authorisation for the use of non-organic plant reproductive material as set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848, the control authority or control body shall include the relevant information in the annual report referred to in Article 4 of this Regulation.

*Article 26***Derogations as regards the use of non-organic animals and aquaculture juveniles**

1. Before granting derogations as regards the use of non-organic livestock species (bovine, equine, ovine, caprine, porcine and cervine animals, rabbits, and poultry) in accordance with points 1.3.4.3 and 1.3.4.4 of Part II of Annex II to Regulation (EU) 2018/848, the control authority or control body shall assess the following information and draw up a justification for each derogation:

- (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) total number of animals;
- (e) availability of the relevant organic livestock species;
- (f) documentation or a statement from the operator proving that the requirements set out in point 1.3.4.3 and 1.3.4.4 of Part II of Annex II to Regulation (EU) 2018/848 have been fulfilled.

2. For each non-organic livestock species (bovine, equine, ovine, caprine, porcine and cervine animals, rabbits, and poultry), the control authority or control body shall include the relevant information on the 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 in the annual report referred to in Article 4 of this Regulation.

3. Before granting derogations as regards 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 control authority or control body shall assess the following information and draw up a justification for each derogation:

- (a) species and genus (common and Latin name);
- (b) breeds and strains when applicable;
- (c) life stage (such as eggs, fry, juveniles) as available for sale as organic;

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- (d) quantity available as estimated by the operator;
- (e) total number of juveniles;
- (f) availability of the relevant organic aquaculture species;
- (g) documentation or a statement from the operator proving that the requirements set out in point 3.1.2.1 of Part III of Annex II to Regulation (EU) 2018/848 have been fulfilled.

4. For each derogation granted as regards 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 control authority or control body shall include the relevant information in the annual report referred to in Article 4 of this Regulation.

*Article 27***Reporting on provisional authorisation for the use of non-organic agricultural ingredients for processed organic food**

The control authority or control body shall immediately notify the Commission, the Member States, accreditation bodies and other control authorities and control bodies recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 of any provisional authorisation granted for the use of non-organic agricultural ingredients for processed organic food in accordance with Article 25(4) of that Regulation. That notification shall include the justification, presented in the dedicated form made available by the Commission, that such authorisation has been granted in accordance with Article 25(1) of Regulation (EU) 2018/848.

CHAPTER V

DEROGATIONS FROM REGULATION (EU) 2018/848 IN CATASTROPHIC CIRCUMSTANCES*Article 28***Recognition of catastrophic circumstances**

For the purposes of the exceptional production rules referred to in Articles 22(1) and 45(3) of Regulation (EU) 2018/848, in order for a situation to qualify as catastrophic circumstances deriving from an ‘adverse climatic event’, ‘animal diseases’, an ‘environmental incident’, a ‘natural disaster’ or a ‘catastrophic event’, as well as any comparable situation, the control authority or control body may recognise a situation as catastrophic circumstances based on a statement issued by the relevant authorities of the third country in which the situation occurs, where available. If such a statement is not available, any such recognition by the control authority or control body shall be based on data provided by official organisations justifying the catastrophic circumstances.



Article 29

Conditions for derogations

1. Following the recognition referred to in Article 28, a control authority or control body may, upon identification of the operators affected in the area concerned or upon request from the individual operator or the member of the group of operators concerned, grant the relevant derogations set out in Article 3 of Delegated Regulation (EU) 2020/2146 and the conditions related thereto, provided that those derogations and conditions apply:

- (a) for a limited period and no longer than necessary, and in no case longer than 12 months, to continue or recommence organic production as carried out before the date of application of those derogations;
- (b) in relation to specifically affected types of production or, where relevant, land parcels; and
- (c) to the individual operator or the member of the group of operators concerned.

2. The application of the derogations referred to in paragraph 1 shall be without prejudice to the validity of the certificates referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 during the period where the derogations apply, provided that the operator or operators concerned fulfil the conditions under which derogations were granted.

3. Control authorities and control bodies shall immediately notify the Commission, the Member States and, in case of a control body their accreditation body, of the derogations granted by them pursuant to this Regulation via the system referred to in Article 20(1). In particular, the control authority or control body shall indicate the name of the operator or operators concerned, the time period for the derogation, the type of production or, where relevant, land parcels, the justification for the derogation and include a statement from the relevant authority of the third country as referred to in Article 28. Where such a statement is not available, the control authority or control body shall justify the non-inclusion of such a statement and provide the relevant data on which the recognition is based.

4. The control authority or control body shall ensure that any operator to whom the granted derogations apply keep documentary evidence relating to the granted derogations as well as documentary evidence on the use of those derogations during the period where those derogations apply. The control authority or control body shall verify the compliance of the operator or operators with the conditions of the granted derogations.

CHAPTER VI

GENERAL AND FINAL PROVISIONS

Article 30

References to competent authorities and Member States in Annex II to Regulation (EU) 2018/848

1. References to competent authorities in the following points of Annex II to Regulation (EU) 2018/848 shall be read as referring to control authorities and control bodies recognised in accordance with Article 46(1) of that Regulation:

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- (a) point 1.7.2 and the first paragraph of point 1.7.3 of Part I;
- (b) points 1.3.4.3, 1.3.4.4.3, 1.6.7, 1.7.5, 1.7.8, 1.9.3.1, 1.9.4.1 and 1.9.4.2 of Part II;
- (c) points 3.1.2.1 and 3.1.3.1 of Part III.

The information referred to in point 1.9.4.1 of Part II shall be sent to the Commission only.

2. The reference to Member States in point 1.9.4.4(c) of Part II of Annex II to Regulation (EU) 2018/848 shall be read as referring to control authorities and control bodies recognised in accordance with Article 46(1) of that Regulation.

*Article 31***Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.



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:

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- (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;

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- (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) 2018/848, the information referred to in point 2.2 of Part A of this Annex shall result from witness audits carried out:

⁽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).

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- (a) during the last 3 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

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- (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.



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 dossier 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;

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- 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:

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- (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.

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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? ⁽¹⁾:

(*)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?:

⁽¹⁾ 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.

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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:

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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	<p>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</p> <p>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</p> <p>New conversion period required</p> <p>Limitation of the certificate's scope</p> <p>Improvement of the implementation of the precautionary measures and the controls that the operator has put in place to ensure compliance</p>
Critical	<p>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</p> <p>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</p> <p>New conversion period required</p> <p>Limitation of the certificate's scope</p> <p>Suspension of the certificate</p> <p>Withdrawal of the certificate</p>

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

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Non-compliance	Category
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