Commission Delegated Regulation (EU) 2021/1698

July 13, 2021

Regulation (EU) supplemented with procedural requirements for the recognition of control officers and control bodies of the European Parliament and Council of 2018/848 that are capable of controlling groups of operators and operators who are able to exercise control over groups of certified operators on organic and organic products in third countries and regulations under their supervision and the controls and other functions to be performed by those control authorities and control bodies.

(Text with EEA relevance)

European Commission,

With regard to the Treaty on the Working of the European Union,

Regulation (EU) 2018/848 In conjunction with the European Parliament and the Council of Biological Products and Biological Products of the Council of Biological Products and Biological Products (EC) No. 834/2007 ([1]) and in particular Article 22(1) in conjunction with Article 45(3), and point (b) of Article 46(7),

While:

(1) In accordance with Article 46 of the Regulation (EU) 2018/848, the Commission may recognize control authorities and control bodies capable of controlling imported organic products and issuing biological certificates to third countries.

(2) In order to ensure equal treatment between control officers and control bodies who submit a request for recognition to the Commission, this Regulation must lay down procedural requirements to be met in further third countries or categories of products when requesting initial recognition, or when requesting for an extension of the scope of their identity. Specifically, this regulation must specify the information to be included in the technical dossier which is part of the request for accreditation.

(3) Chapter VI of Regulation (EU) 2018/848, which establishes provisions of control over certified operators and other liabilities of those operators in the union, does not apply to operators in third countries. In addition, organic production in the Union is subject to official control and other official activities such as regulations of the European Parliament (EU) 2017/625 and the Council ([2]) To certify compliance with the regulations on the labeling of organic products and organic products in accordance with. Therefore, to ensure a coherent approach, this Regulation must lay down regulations on controls on operators in third countries by recognized control authorities and control bodies in accordance with Article 46(1) of the Regulation (EU) 2018/848 which is consistent with the relevant provisions of Chapter VI of that Regulation and Regulation (EU) 2017/625. The certification of operators in third countries also requires having provisions relating to certain aspects of specific controls, for example, in the context of certification of consignments intended to be imported into the Union.

(1) OJ L 150, 14.6.2018, p. 12.

(2) Regulation (EU) 2017 / 625 The European Parliament and the Council of the Council of 15 March 2017 under the official control and other official activities of Food and Dietary Law, Animal Health and Welfare, Plant Health and Plant Protection Products, Regulations (EC) No. 999/2017 2001, (EC) No. 396/2005, (EC) No. 1069/2005 2009, (EC) No. 1107/ (EU) 1151/2012, (EU) No. 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and Council, Council Regulation (EC) No. 1/2005 and (EC) No. 1099/2009 and Council Directory 98/58/EC, 1999/74/EC, 2007/43/2009. Council Directory 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Control Regulation) (OJ L 95, 7.4.2017, page 1).

(4) With regard to groups of operators, it follows from point (b)(i) of article 45(1) of the Regulation (EU) 2018/848 that the provisions of that rule regarding groups of operators also apply to groups of operators in third countries. Therefore, it is appropriate to clarify that the provisions outlined in the Delegated and Enforcement Acts adopted in accordance with The Regulations (EU) 2018/848 apply to groups of operators in third countries.

(5) In order to enable the Commission to conduct its supervision on the controlling authorities and control bodies recognized as capable of controlling and issuing certificates in third countries, they must submit an annual report to the Commission with information about their control activities and the implementation of biological regulations. This regulation should specify the information to be included in the annual report.

(6) For the purpose of enforcing detailed production regulations on algae and aquaculture animal production as set out in regulation (EU) 2018/848 and especially in Annex II to that Regulation, it is appropriate to set up certain procedures to meet such obligations by control authorities and control bodies in third countries.

(7) Control officers and control bodies must set up procedures to ensure the exchange of information between them and the Commission and other control authorities and control bodies, accreditation bodies and member states. This should be done through a computer system provided by the Commission, which enables electronic exchange of documents and information.

(8) In addition to the regulations on non-compliance set out in Regulation (EU) 2018/848, suspected and established cases of non-compliance need to be investigated and the requirements set in that regard , including the need to develop a list of measures.

(9) According to point (b) (i) of Article 45(1) of the Rules (EU) 2018/848, the precautionary measures and measures to be taken in case of suspicious or established non-compliance mentioned in the Said Rules and the delegated and implementation actions adopted thereunder shall apply to third countries. Therefore, it is appropriate to lay down the necessary rules regarding third countries and their specific circumstances.

(10) Chapter 3 of the Regulation (EU) 2018/848, and the delegated and implementation actions adopted in accordance with it set rules on the backward recognition of the conversion period and the previous period. Conversion to organic production method requires a certain period of adaptation of all the means in use. The required conversion period begins soon after the concerned operator informs the control officer or control body about the activity. As an exception, and under certain conditions, the previous period can be recognized as retrograde as part of the conversion period. Documents to be submitted by operators in third countries to the control authority or control body for the purpose of retroactive accreditation of the previous period should be specified.

(11) Furthermore, it is necessary to put certain reporting requirements in respect of certain specific insults or authorities in accordance with general production regulations as well as regulation (EU) 2018/848.

(12) By analogy with the rules laid down in the Commission Delegated Regulation (EU) 2020/2146[3]) regarding member states , this Regulation must specify the conditions under which insults may be provided for catastrophic situations occurring in third countries and the roles and obligations of the controlling authority or control body in that regard.

(3) Commission Delegated Regulation (EU) 2020 /2146 of 24 September 2020 Supplementary Regulation (EU) 2018 / 848 European Parliament and Council regarding exceptional production regulations on organic production (OJ L428, 18.12.2020, p. 5).

(13) The detailed production regulations set out in Annex II of regulation (EU) 2018/848 mention some of the functions and obligations of competent authorities in member states. Since those regulations apply by analogy to recognized control authorities and control bodies as capable of controlling imported organic products in third countries and issuing biological certificates , it is appropriate to clarify that certain references to competent authorities or member states should be read as references to control officers and control authorities recognized in accordance with Article 46(1) of the Regulation (EU) 2018/848.

(14) In the interest of clarity and legal certainty, this Regulation Regulation (EU) should come into force from the date of application of 2018/848,

This rule is adopted:

Chapter 1

Procedural requirements for accreditation of control officers and control bodies

Article 1

Requirements outlined in point (n) of Article 46(2) of the Regulation (EU) 2018/848

1. The controlling authority or control body shall submit a request for recognition as outlined in Article 46(4) of the Regulation (EU) 2018/848 using the model provided by the Commission. Only full requests will be taken into account.

2. The technical dossier mentioned in Article 46(4) of the 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 the 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 third countries or related third countries, including indications of organic products, with their joint nomenclature (CN) code in accordance with Council Regulation (EEC) No. 2658/87(4), is distributed per category of products mentioned in Article 35(7). of Regulation (EU) 2018/848, which is in accordance with the point (b)(i) of Article 45(1) of the Regulation (EU) 2018/848 to import into the Union during the first year of activity after recognition by the Commission;

(C) Details of control authority or control body:

(I) its structure and shape;

(II) its IT management system;

(III) its branch offices, if any;

(IV) its type of activities, including delegated activities, if any;

(V) its organizational chart;

(VI) managing its quality;

(D) certification procedures, especially for acceptance or rejection, suspension or withdrawal of certificates mentioned in point (b)(i) of Article 45(1) of the Regulations (EU) 2018/848;

(4) Council Regulation (EEC) dated 23 July 1987 2658/87 on Tariff and Statistical Nomenclature and General Customs Duties (O.J. L. 256, 7.9.1987, p.

(E) The translation of production rules and control measures set out in Regulation (EU) 2018/848, and delegated and enforcement actions adopted in accordance with it in languages understandable to contracted operators in third countries for which the controlling authority or control body requests recognition;

(F) Documents certifying that the criteria set out in Article 46(2) of the Regulation (EU) 2018/848 have been met, especially a copy of the Accreditation Certificate granted by a recognized body, contains all kinds of products for which accreditation is requested;

(G) Procedures to describe in detail the action and implementation of control measures to be set up in accordance with this regulation, where relevant, control specifications for a group of operators;

(H) List of measures to be taken in case of established non-compliance as mentioned in Section 22 of these Rules;

(I) A copy of the most recent assessment report mentioned in the second sub-paragraph of Article 46(4) of the Regulation (EU) 2018/848, prepared by the accrediting body or, appropriately, by the competent authority, contains the information outlined in Part A of Annexure 1 of this Regulation, which includes the Witness Audit Report on the Witness Audit carried out two years before the submission of the request for recognition, and giving the following guarantees:

(I) The ability to ensure that products imported from third countries meet the conditions outlined in point (a), (b) (i) and (c) of Article 45(1) and article 46(2) of the Regulation (EU) 2018/848 has been satisfactorily evaluated by the controlling authority or the controlling body;

(II) that the control authority or control body has the capabilities and competencies to effectively implement the control requirements and meet the criteria set out in Article 46(2) of the Regulation (EU) 2018/848 and to meet the criteria set out in this Rule in every third country for which it requests recognition;

(J) The control authority or control body has notified its activities to the concerned authorities of the third country concerned and its undertaking to respect the legal requirements imposed therein by the authorities of the respective third country ;

(K) A website address, with content available in at least one of the official languages of the Union and is also understandable to contracted operators, where the list mentioned in point (a) of Article 17 of this Regulation can be found;

(L) An undertaking by the Control Authority or the Control Body to provide access to all its offices and facilities to independent experts designated by the Commission and to make available and disseminate all information related to its control activities in the relevant third country;

(M) A statement by the control authority or the control body that is not subject to withdrawal by this Commission, or not returned or suspended by any accreditation body, is that they request recognition in the 24 months prior to their request for a third country and/or category of products. This requirement does not apply in the case of withdrawal in accordance with point (k) of Article 46(2A) of the Regulations (EU) 2018/848;

(N) Any other information deemed relevant by the Controlling Authority or the Controlling Body, or the Accreditation Body.

3. The controlling officer or the controlling body will have to provide additional information requested by the Commission for the purpose of its accreditation.

4. If the information provided pursuant to chapter 2 or 3 is found to be incomplete, outdated or unsatisfactory, the Commission shall reject the request for recognition.

Article 2

Expanding the scope of identification

According to Article 46 of the Regulation (EU) 2018/848, a recognized control authority or control body may submit a request for extension of the scope of its accreditation to additional categories of additional third countries or products using the model provided by the Commission.

The request for extension of the scope of accreditation will include an update of the relevant parts of the technical dossier mentioned in paragraph 1(2) which will include appropriate information about an additional third country or additional category of products subject to scope expansion.

Chapter 2

Supervision of control officers and control bodies by the Commission

Article 3

General requirements for supervision of control officers and control bodies

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

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

3. In accordance with Article 46(1) of the Regulation (EU) 2018/848, recognized control officers and control bodies shall retain the ability to meet the conditions and criteria set out in point (a), (b) (i) and (c) and article 46(2) of article 45(1) mentioned in the technical dossier at the moment of their recognition. They will also maintain the capabilities and competencies to implement article 46(2) and (6) of the Regulation (EU) 2018/848 and the control requirements, conditions and measures set forth in this Rule.

For that purpose, they will demonstrate:

(A) that they have effectively implemented their activities in accordance with the terms and standards outlined in the first sub-paragraph ; and

(B) Compliance with their operating procedures and the effectiveness of their control measures.

4. For the purposes of the annual report, the controlling bodies shall ensure that witness audits are carried out in accordance with Sections 1 and 2 of Part B of This Regulation and Annexure 1 of the following Rules:

(A) The period between two witness audits shall not exceed 4 years;

(B) The number of witness audits carried out for the initial request for accreditation shall not be considered for calculation of the total number of witness audits to be carried out during the 4 years mentioned in point (a);

(C) An additional witness will be audited:

  (I) Every 2 years in those third countries where the high-risk product mentioned in paragraph 8 is produced or processed;

  (II) Each is recognized for 10 third countries. This additional witness audit will be carried out within 4 years;

(D) Further witness audits will be carried out at the request of the commission or accreditation body, especially based on the risk analysis of the following factors:

  (I) number of inspectors;

  (II) number of operators;

  (III) types of activities carried out by operators;

  (IV) the number of witness audits carried out by the accreditation agency;

  (V) irregularities related to control agencies;

(VI) the number of certified groups of operators and their size;

(VII) important findings for control bodies or specific inspectors or inspectors;

(VIII) the nature of the products and the risk of fraud;

(IX) Commission feedback based on the control body's previous annual report;

(X) Suspicion of fraud by operators.

(XI) The quantity of products imported into the Union from third countries and the activity of the controlling authority or control body in recognized third countries.

5. The control body and the control body will have to submit their risk analysis procedure documents at the request of the commission.

6. For the purpose of supervision of control officers and control bodies recognized by the Commission, the latter may be assisted as a co-reporter for the examination of technical dossiers submitted by control officers and control bodies for initial accreditation by two member states or for the expansion of their scope accreditation, management and review of the list of accredited control officers and control bodies and evaluation of operational performance, Including annual reports, of control officers and control bodies.

7. The Commission may proportionately divide the requests among the member states on the basis of the number of votes of each member state in the Committee on Organic Production.

Article 4

Annual Report

Every year, by February 28, the controlling body or control body has to submit an annual report to the Commission.

The annual report shall determine the activities of the control officer or control body of the previous year in accordance with Annexure 2.

It will be introduced in one of the official languages of the Association and in English if the chosen official language is not English.

Article 5

On-site examination and audit

1. The Commission will conduct regular risk-based on-site examinations and/or audits of control agencies to evaluate the quality and effectiveness of controls conducted by each control authority or control body . Those examinations and audits can be coordinated with the relevant accreditation body. During these on-site examinations and audits, the commission may also have independent experts.

2. The Commission may request further information, including the presentation of one or more ad-hoc on-site examination reports set up by independent experts designated by it.

3. On-site examinations and audits may include the following:

(A) Visits to the offices or premises of control officers and control bodies, their outsourced services and operators or groups of operators under their control, in union and third countries;

(B) Document review of relevant documents describing the structure, functioning and quality management of control officers or control bodies;

(C) a document review of employee files, including evidence of their efficiency, training records, conflict of interest statements and records of evaluation and supervision of employees;

(D) Investigation of groups or groups of files of operators to verify the treatment of non-compliance and complaints, minimum control frequency, use of risk-based approach in the conduct of inspections, implementation of follow-up visits and visits without prior notice, sampling policy and exchange of information with other control bodies and control authorities;

(E) A review audit, which is an inspection of operators or groups of operators to certify compliance with standard control and risk assessment procedures of the control authority or control body and to prove its effectiveness, taking into account the development of the position of operators from the final inspection of the control authority or control body;

(F) A witness audit, which is an evaluation of the performance of physical on-site inspections carried out by the inspector of the control authority or the control body.

Article 6

Traceability check

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

For the purpose of finding out the content or production stages of organic products, the Commission may seek information from competent authorities or control officers or control bodies involved in the control of those products that fall under their supervision.

The Commission may conduct traceability checks on the basis of its annual risk assessment, complaints received by the Commission or member states or complaints received at random.

The Commission will check the traceability within the stipulated time period, which will be communicated to the concerned competent authorities, control officers and the concerned control agencies in a timely manner.

Article 7

Ad-hoc request by the Commission

The Commission can make an ad hoc request for information to the control authority or control body on the basis of adequate analysis to prove the need at any time.

Article 8

List of high-risk products

The controlling officers and control bodies dealing with third countries shall enforce Article 9(8), Second Sub-section and Articles 12(5) and 16(6) of this Regulation in respect of high-risk products generated from third countries as mentioned in the Implementation Act adopted pursuant to Article 46(8) of the Regulations (EU) 2018/848. Significant or repetitive non-compliances affecting the integrity of organic or in-conversion products or products.

Chapter 3

Controls by control officers and control bodies with respect to operators and groups of operators

Article 9

General Provisions

1. Verification of compliance with Regulation (EU) 2018/848 will include controls performed by control authorities and control bodies by groups of operators and operators in third countries:

(A) At each stage of production, preparation and distribution, verification of the application of preventive and precautionary measures outlined in Article 9(6) and Article 28 of the Regulation (EU) 2018/848;

(B) Where holdings include measures or procedures or arrangements to ensure a clear and effective separation between non-organic or in-conversion production units, certification of records and organic, in-conversion and non-organic production units as well as between related products produced by those units, and of substances and products used for organic, in-conversion and non-organic production units. Such certification would include checks on parcels for which the previous period was retrospectively identified as part of the conversion period, and checks on non-organic production units;

(C) Where organic, in-conversion and non-organic products are collected simultaneously by operators, prepared or stored in the same preparatory unit, area or premises, or transported to other operators or units, verification of records and ensuring that measures, procedures or arrangements are separated by location or time, appropriate cleaning measures and measures have been implemented to prevent the replacement of products. , 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 preparation operations, separated by place or time from each other, and that the traceability of each lot from individual land parcels to the collection center is ensured.

2. Controls by control authorities and control bodies for certification of compliance with Regulation (EU) 2018/848 will be routinely performed throughout the entire process by all operators and groups of operators in third countries, depending on risk and with appropriate frequencies, at all stages of production, preparation and distribution. Of the possibility of non-compliance as defined in point (57) of article 3 of the Regulation (EU) 2018/848, which shall be determined taking into account the following elements:

(A) type, size, including newly added land parcels, and the composition of groups of operators and operators, as well as the number of new members joining a 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 groups of operators and operators are involved in organic production, preparation and distribution;

(D) The results of the controls performed according to this article, especially with regard to compliance with the Regulation (EU) 2018/848;

(E) In the case of a group of operators, the result of an internal inspection carried out in accordance with the documentation procedures of the system for internal control of the group of operators;

(F) whether holdings include non-organic or in-conversion production units;

(G) the type, quantity and price of products;

(H) exposure to products or contamination with non-authorized products or substances;

(I) the application of insults or exceptions to rules by operators and groups of operators;

(J) critical points for non-compliance at each stage of production, preparation and delivery;

(K) subcontracting activities;

(L) whether operators or groups of operators have changed their certification control authority or control body;

(M) any information indicating the possibility that consumers may be confused;

(N) Any information that may indicate non-compliance with regulation (EU) 2018/848.

3. Article 2 of the Commission Delegated Regulation (EU) 2021/771([5]) and Articles 4, 5 and 6 of the Commission Implementation Regulations (EU) 2021/279(6) shall impose mutational mutations *in controls in relation to a group of operators in third countries*.

4. The controlling authority or control body will certify compliance with the Regulation (EU) 2018/848 at least once a year for all operators and groups of operators. Verification of compliance will include physical on-site inspection.

5. The control authority or the control body must ensure that it has at least 10% additional controls each year as outlined in paragraph 4. Of all physical on-site inspections carried out by the control authority or control body, at least 10% will be without prior notice.

6. Controls performed as follow-up in suspected or established non-compliance will not be counted toward the additional controls mentioned in paragraph 5.

7. Each year, the controlling authority or control body will re-inspect at least 5% of the members of the group of operators, but not at least 10 members. If there are 10 or fewer members in the board of directors, all the members will be re-inspected.

8. Physical on-site inspections and samples will be carried out by the control authority or the control body at critical control points at the most appropriate time to verify compliance.

For high-risk products mentioned in paragraph 8, the controlling authority or control body will conduct at least two physical on-site inspections per year of operators or groups of operators. One of these physical on-site inspections will take place without prior notice.

9. When operators or groups of operators operate multiple production units or premises, including procurement and collection centers , all production units or premises, including procurement and collection centers used for non-organic products, will also be subject to the control requirements set out in paragraph 4.

10. The distribution or renewal of the certificate mentioned in point (b)(i) of article 45(1) of the Regulation (EU) 2018/848 shall be based on the result of the verification of compliance mentioned in this paragraph.

Article 10

Checks for authentication of operators or groups of operators

1. Before accepting to certify operators or a group of operators, the controlling authority or the controlling body will ensure that the operators or group of operators have provided the following:

(A) A document, as a signed declaration, setting:

(I) details of biological and/or in-conversion production units and, where relevant, of non-organic production units and activities to be performed in accordance with regulation (EU) 2018/848;

(5) Commission Delegated Regulation (EU) 2021/771 of 21 January 2021 Supplementary Regulation (EU) 2018 / 848 Specific criteria and conditions for examining document accounts in the framework of official control over organic production of the European Parliament and Council and official control of groups of operators (OJ L 165, 11.5.2021, p. 25).

(6) Commission Implementation Regulations (EU) 2021/279 of 22 February 2021 detailed regulations for the implementation of the European Parliament's Regulation (EU) 2018/848 and council on controls and other measures ensuring traceability and compliance in organic products (OJ L62, 23.2.2021, p. 6).

(II) relevant measures to be taken at the level of biological and/or in-conversion units and/or premises and/or activities to ensure compliance with regulation (EU) 2018/848;

(III) Precautionary measures taken to reduce the risk of pollution by non-authorized products or substances and to reduce cleaning measures taken at the stages of production, preparation and distribution;

(B) confirmation that operators or groups of operators are not certified by another controlling body with respect to activities carried out in the same third country regarding the same category of products , in which operators or groups of operators operate at different stages of production, preparation or distribution;

(C) it is confirmed by the members of the group of operators that they have not been certified on an individual basis for the same activity as for the product covered by the certification of the group of operators that belongs to them;

(D) A signed undertaking by which operators or groups of operators commit themselves to:

(I) to provide the control authority or control body access to all parts of all production units and all premises for control purposes , as well as accounts and relevant support documents;

(II) to provide the controlling authority or control body with any information necessary for the purpose of control;

(III) To present, when requested by the control authority or the control body, the results of its own quality assurance programs;

(IV) To inform buyers of products in writing and without unnecessary delay, and to exchange relevant information with the controlling authority or control body, if doubts of non-compliance have been proved, that doubts of non-compliance cannot be removed, or non-compliance that affects the integrity of the products in question is established;

(V) accepting 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, keeping the control file for 5 years by the final control authority or control body;

(VI) immediately notifying the control authority or control body in case of withdrawal from organic production;

(VII) In the event that subcontractors of operators or groups of operators are under control by various control officers or control bodies, to accept the exchange of information between those control officers or control bodies;

(VIII) to perform activities in accordance with biological production regulations;

(IX) To accept the enforcement of corrective measures established by the control authority or control body in the event of non-compliance.

2. Before certifying the operator or group of operators, the controlling authority or control body will confirm:

(A) that operators or groups of operators comply with Chapters 2, 3 and 4 of the Regulation (EU) 2018/848 and Article 36 of that Regulation. Authentication will involve at least one physical on-the-spot inspection;

(B) that, where operators or groups of operators subcontract any of its activities to third parties, both operators or groups of operators and third parties for whom those activities are sub-contracted, certified by recognized control officers or control bodies that they comply with Chapters 2, 3 and 4 of the Regulation l (EU) 2018/848 and Article 36 of that Rule, unless operators or groups of operators inform the concerned controlling authority or control body that they remain responsible in relation to organic production and that they have not transferred that responsibility to the subcontractor. In such cases, the controlling authority or control body complies with Chapters 2, 3 and 4 of the Subcontracted Activities Regulation (EU) 2018/848 and Article 36 of that Regulation that it does in relation to the control activities of operators or groups of operators who have sub-contracted their activities.

3. In addition to any other element considered relevant by the control authority or the control body, before certifying the operators or group of operators that were previously certified by another controlling authority or control body, the new control authority or control body will evaluate the following information transmitted by the previous control authority or control body:

(A) The status and validity of certification, including cases of scope reduction, suspension and withdrawal, outlined in the International Organization for Standardization (ISO) Standard ISO/IEC 17065;

(B) Reports of inspections carried out in the previous 3 years;

(C) the list of non-compliances and measures to address them, and the fact that all non-compliances were addressed;

(D) granted or requests for contempt processed by a previous control authority or control body;

(E) Information relating to any ongoing dispute relevant to the authentication of operators or groups of operators.

If the previous control officer or control body does not transmit the information required under Article 21(5) of this Regulation to the new control authority or control body or if there is any doubt regarding the information sent, the new control authority or control body will not issue the certificate referred to in point (b)(i) of Article 45(1) of the Rules. (EU) 2018 / 848 operators or groups of operators unless this new controlling authority or control body removes their doubts by other means of control.

4. The control authority or the control body shall not certify the operators or group of operators that their previous controlling authority or control body has withdrawn in the last 2 years, unless withdrawn by the previous controlling authority or the Recognition Commission of the control body for the category of specific third countries and products in accordance with Article 46(2A) of Regulation (EU) 2018/848.

Article 11

Methods and Techniques for Control

1. Control methods and techniques implemented by the control authority or control body will include the following:

(A) Check whether maps or sketches with cardinal directions and terrain of production units and premises to be physically inspected as provided by operators or groups of operators are up to date;

(B) An inspection of, appropriately:

  (I) production units, equipment, means of transport, premises and other places under the control of a group of operators or a group of operators ;

  (II) animals, plants and commodities, semi-finished goods, raw materials, ingredients, processing equipment and other products that are used for the preparation and production of commodities or for feeding or treating animals, and authorized substances for use in organic production;

  (III) traceability, labeling, presentation, advertising and contextual packaging materials;

(C) Documents, traceability records and examination of other records and practices and procedures that are relevant for evaluating compliance with regulation (EU) 2018/848. These include documents entering or leaving with food, grains and any substance or material;

(D) interviews with operators and their employees;

(E) Sampling and laboratory analysis;

(F) Examination of the control system that operators and groups of operators have placed, including an assessment of its effectiveness ;

(G) examination of non-compliances found during previous inspections and measures taken by operators or by a group of operators to address them;

(H) Any other action required to identify cases of non-compliance.

2. The annual physical on-site inspection mentioned in paragraph 9(4) will include a traceability check and a collective balance check of operators or groups of operators, which is carried out through scrutiny of documented accounts and any other relevant element deemed necessary by the controlling authority or the control body.

3. For the purposes of traceability checks and mass balance checks, the selection of products, group of products and the period under certification will be based on risk assessment by the control authority or control body.

4. In addition to any other relevant element deemed necessary by the control authority or the control body, traceability checks contain the following elements appropriate by appropriate documents, including stocks and financial records:

(A) name and address of the supplier and, where different, owner or seller, or exporter of products;

(B) the name and address of the consignee and, where different, of the buyer or importer of the product;

(C) Certificate of supplier in accordance with the Enforcement Act adopted in accordance with Article 45(4) of the Regulation (EU) 2018/848;

(D) Information outlined in the first paragraph of point 2.1 of Annexure III of Regulation (EU) 2018/848;

(E) Suitable braided identification;

(F) In the case of processors, the information needed to allow internal traceability and to guarantee the biological status of the components .

5. Mass balance checks contain the following elements justified by appropriate documents, including stocks and financial records, where relevant are:

(A) the nature and quantity of products distributed in the unit and, where relevant, of the materials purchased and the use of such materials , and, where relevant, the structure of the products;

(B) the nature and quantity of products stored in storage in the premises, including during physical on-site inspections;

(C) the nature and quantity of products that have left the unit of operators or the group of operators to the premises or storage facilities of Consigni;

(D) In the case of operators or groups of operators who purchase or sell the product(s) without storing or physically handling the product(s), the nature and quantity of products that are purchased and sold;

(E) yield of products obtained, collected or harvested compared to the previous year;

(F) estimated or actual production of products received, collected or harvested in the current year;

(G) the number and/or weight of livestock managed in the current and previous years;

(H) any loss, increase or decrease in the quantity of production at any stage of production, preparation and distribution;

(I) Total production of holdings in terms of organic and non-organic products.

Article 12

Methods used for sampling, sampling laboratories for sampling, sample analysis, and selection

1. The control officer or control body will take and analyze samples to detect the use of non-authorized products and substances for organic production, to check production techniques that do not comply with organic production regulations, or to detect potential contamination by non-authorized products and substances for organic production.

2. The controlling authority or control body will sample at least 5% of the number of individual operators under its control. For a group of operators, the control authority or control body conducts samples on at least 2% of the members of each group.

3. The selection of operators and groups of operators where samples should be taken will be based on a risk assessment in which the possibility of non-compliance with biological production regulations, taking into account all stages of production, preparation and distribution .

4. In addition to the minimum sampling rate set out in paragraph 2, the control authority or control body will take samples in each case and analyze the samples where the use of non-authorized products and substances or technologies for organic production is questionable, unless the control authority or control body considers that sufficient evidence is available without sampling .

5. For high-risk products mentioned in paragraph 8, the control authority or control body will sample at least one area of the crop each year, in addition to the sampling rates set in paragraphs 2 and 3 of this article. That sample will be taken from crops in the field at the most appropriate time to find out the possible use of non-authorized substances according to the assessment of the control officer or the control body. For non-crop growing operators, relevant sampling of incoming raw materials or intermediate produce or processed produce will be taken.

6. The control authority and the 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 in 'general requirements for the capacity of testing and calibration laboratories';

(B) Their accreditation bodies are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Accreditation Arrangement;

(C) They have sufficient capacity for analysis and testing and they can ensure that samples are always tested with relevant methods included in their range of validation;

(D) In the context of residue pesticide testing, they are accredited for gas and liquid spectrometry to be able to cover the list of pesticide residues monitored under the coordinated multi-annual control program of the Union set out in the Commission Implementation Regulation (EU) 2019/533 (7).

7. The control authority or control body may delegate sample tasks to other control officers or control bodies accredited by the commission or commission recognized in accordance with the ISO standard ISO/IEC 17025 on 'General Requirements for the Capacity of Testing and Calibration Laboratories'.

Article 13

Documented control procedures

1. Control officers and control bodies will perform controls in accordance with documentation procedures in groups of operators and operators.

Those documented procedures will include:

(A) a statement about the objectives to be achieved;

(B) the functions, responsibilities and duties of employees;

(C) including sampling strategies, procedures and methodologies, control methods and techniques, laboratory analysis, testing and interpretation and evaluation of results and resulting decisions;

(D) cooperation and communication with other control officers, other control bodies and commissions;

(E) A procedure for evaluating the risks associated with operators or groups of operators and for physical on-site inspection and sampling ;

(7) Commission Implementation Regulation (EU) Regarding a coordinated multi-annual control program of the Association for Implementation Regulation (EU) March 28, 2019/533 2020, 2021 and 2022 to ensure compliance with maximum residue levels of pesticides and to assess consumer exposure to pesticide residues in and in food of plant and animal origin (OJ L88, 29.3.2019, page 28).

(F) validation of the suitability of methods of sampling and laboratory analysis, testing and diagnosis;

(G) any other activity or information required for the effective function of control in relation to the training of inspectors and the evaluation of their competencies ;

(H) For groups of operators, the effectiveness of the system for internal controls.

2. Control officers and control agencies:

(A) Take corrective measures in all cases where the procedures provided in paragraph 1 identify weaknesses; and

(B) Suitably update the documentation procedures provided in paragraph 1.

Article 14

Written records of controls

1. Control authorities and control bodies will prepare written records of each control to certify compliance with Regulation (EU) 2018/848. These records can be on paper or electronically. The control authorities and control bodies should keep these records for 5 years from the date of the decision on certification by the controlling authority or the control body .

Those records will specifically include:

(A) description of the purpose of control;

(B) Control methods and techniques were applied;

(C) the results of control, especially the results of verifying the elements listed in Articles 11 and 12 of this Regulation; and

(D) Actions that are required to be taken as a result of controls carried out by the controlling authority or the controlling body by the concerned operator or a group of related operators, with an indication of a time frame to act.

2. Written records shall be countersigned by the operator or a member inspected by a group of operators as confirmation of the receipt of the said written record. A copy of the said record should be placed on paper or in electronic form by an inspected member of the operator or group of operators.

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 the Regulation (EU) 2018/848, the control authority or control body shall ensure that the operators or groups of operators producing algae or aquaculture animals inform the controlling authority or control body of the respective activity.

2. The control authority or the control body must ensure that algae or aquaculture occur in places with no exposure to pollution in accordance with point 1.1 of Part 3 of Appendix 2 of the Biological Production Regulation of Animals (EU) 2018/848. In particular, the controlling officer or control body shall ensure that adequate separation measures are adopted in accordance with point 1.2 of that Part III.

3. For the purposes of point 3.1.3.1(c) of Part 3 of Annexure 2 of The Regulation (EU) 2018/848, the control authority or control body will ensure that the plant fraction of the feed is organic and that the feed fraction derived from aquatic animals originates from organic aquaculture or originates from fisheries that have been permanently validated for the ecolabeling of fish and fish products from marine capture fisheries of the 2009 FAO.

4. For the purposes of point 3.1.4.2(e) of Part 3 of Annexure 2 of The Regulation (EU) 2018/848, the controlling authority or the control body shall ensure that they have information about all treatments, and they will check that these treatments are carried out in accordance with the requirements of that Regulation.

5. For the purpose of authorizing the use of wild seeds within the meaning of point 3.2.1 of Part 3 of Appendix 2 of The Regulations (EU) 2018/848, the controlling authority or control body shall ensure that points (a), (b) and (c) of that point are respected.

Article 16

Certification of consignments intended to be imported into the union

1. The concerned control authority or control body shall certify the coubsignments to be imported into the Union in relation to the Regulation (EU) 2018/848 and compliance with this Regulation. This certification will include systematic documentary checks and risk assessment, as appropriate according to physical checks, before the consignment exports or leaves a third country of origin.

2. For the purposes of this article, the concerned controlling authority or controlling body shall be:

(A) the producer's controlling authority or controlling body or processor of the related product; or

(B) Where the group of operators or operators performing the final operation for the purpose of preparation is different from the producer or processor of the product, the controlling authority of the operator or the control body or the group of operators who perform the final operation for the purpose of preparation as defined in point (44) of paragraph 3 of the Regulations (EU) 2018/848.

The concerned controlling authority or control body shall be recognized in accordance with Article 46(1) of the Regulations (EU) 2018/848 for the relevant products and for a third country in which the products have origin, or, where applicable, in which the final operation is carried out for the purpose of preparation.

3. The purpose of the documentary checks mentioned in paragraph 1 is to verify:

(A) traceability of products and ingredients;

(B) that the quantity of products included in the consignment is consistent with the mass balance check of the respective operators or groups of operators according to the assessment made by the control authority or the control body;

(C) relevant transportation documents and commercial documents of the products (including invoices);

(D) In the case of processed products, all organic materials of such products are certified in a third country by operators or groups of operators that are recognized in accordance with Article 46(1) or by a controlling authority or control body recognized in accordance with Article 46(1) or by a third country recognized in accordance with Article 57 of the Regulation (EU) 2018/848, Or has been produced and certified in the union in accordance with the rules.

Those documentary checks will all be based on relevant documents, including certificates mentioned in point (b)(i) of article 45(1) of the Regulation (EU) 2018/848, the latest record of inspection, the production plan for the related product and records maintained by operators or groups of operators, available transport documents, commercial and financial documents and any other documents considered relevant by the controlling authority or the controlling body.

4. In relation to the risk assessment prior to physical examination mentioned in chapter 1, the concerned controlling officer or control body shall take into account the following criteria:-

(A) the relevant criteria listed in paragraph 9(2);

(B) whether there are many operators involved in the distribution chain of products that do not store organic products or physically handle them;

(C) high-risk products mentioned in paragraph 8;

(D) Any criteria deemed relevant by the Controlling Authority or the Controlling Body.

5. For consignments made from bulk organic products, the concerned controlling authority or control body will prepare a travel plan in a trade control and expert system (TRACE), which includes all premises used during travel from a third country of origin or will be exported to the Union.

6. For consignment of high-risk products mentioned in paragraph 8, the concerned control authority or control body will conduct a systematic physical check and take at least one representative sample of each consignment. In addition, the controlling authority or the control body will have complete documents including traceability of operators or groups of operators and invoices including production, transportation and commercial documents. At the request of the Commission or the Competent Authority of the Member State, the Controlling Authority or the Control Body must send this traceability document as well as the results of the sample analysis to the controlling authority or control body of the importer and the competent authority of the member state where the consignment is certified.

7. In the event of suspicion of non-compliance, the commission or the competent authority of the member state may request the concerned controlling authority or control body to make available without delay a list of all operators and all groups of operators in the organic production chain of which consignment is part, and that of their controlling authorities or control bodies.

Chapter 4

Other actions to be performed by control officers and control agencies

Article 17

List of operators to be publicly available and other relevant information

The controlling authority or the control body must provide the following information on its website in at least one official language of the Union:

(A) List of certified operators and certified groups of operators, including:

  (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 related to the certificate, in particular, the category of products covered by the certificate number, certification, status of certification and validity, including cases of range reduction, suspension and withdrawal mentioned in the 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 mentioned in point (a) will be updated immediately after any change in the status of authentication. In case of withdrawal, the information mentioned in point (a) (3) should be put on the list for 5 years after return;

Article 18

Database of operators and groups of operators

The controlling authority or the control body should maintain an updated electronic database of operators and groups of operators. That database will contain the following information:

(A) Names and addresses of operators or groups of operators. In the case of a group of operators, the size of the group, the name and address of each member of the group;

(B) information about the scope of certification, certificate number, status and validity of the certificate;

(C) the position of operators or groups of operators, whether in transformation (including the duration of conversion) or organic;

(D) Risk levels of operators or groups of operators according to Article 9;

(E) In the case of sub-contracting activities under the control of certified operators or groups of operators, the name and address of the sub-contracted third party or third party;

(F) geographical coordinates and surface area of all production units and premises;

(G) The results of inspection reports and sample analysis, as well as the results of any other controls, including controls performed on consignments;

(H) non-compliance and applicable measures;

(I) notices through the system mentioned in paragraph 20(1);

(J) Supporting documents provided and relevant in accordance with the requirements of this Regulation; and

(K) Any other information deemed relevant by the controlling body or the controlling authority.

This information should be kept by the controlling officer or the control agency for five years. The control officer or the controlling body will have to provide this information if requested by the commission.

Article 19

Information Requirements

1. After its recognition, the controlling authority or control body will notify the Commission in due course, and within 30 calendar days, about the occurrence of changes in the contents of its technical dossier.

2. The control officer or control body shall, at the request of the competent authorities of the Commission or member states, make available and disseminate all information related to its control activities in the third country.

3. Supporting documents relating to the request for recognition under Article 46 of The Regulation (EU) 2018/848 and those required under this Regulation shall be kept at the disposal of the Commission and Member States by the controlling authorities or control bodies for 5 years in which the control was exercised or had the certificates and documentary evidence mentioned in point (b)(i) of Article 45(1) of the Regulation (EU) 2018/848. has been delivered.

Article 20

Systems and procedures for exchange of information

1. The control officer or control body will use the Organic Farming Information System (OFIS) to exchange information with the Commission, other control officers and other control bodies, and competent authorities of member states and the respective third countries.

2. The control authority or control body will take appropriate measures to ensure timely exchange of information with the Commission and other control officers and control bodies and establish documentation procedures.

3. Documents or procedures provided in Article 46 of the Regulations (EU) 2018/848 or the delegated and executed tasks adopted pursuant to that Paragraph require the signature of an authorized person or the approval of an individual at one or more stages of that process, a computer system set up for the communication of those documents makes it possible to identify each person and guarantee that its integrity is the content of the document, Including regarding the stages of the process, changes cannot be made in accordance with federal law, and especially with the Commission decision 2004/563/EC, Uratom ([8]).

(8) The Commission's decision 2004/563/EC, 7 July 2004 of Uratom amending the rules of its process (OJ L 251, 27.7.2004, p. 9).

Article 21

Exchange of information between commissions, control officers, control bodies and competent authorities

1. The control authority or control body shall immediately share information with the Commission, other control authorities and control bodies, and competent authorities of member states and the relevant third country in any suspicion of non-compliance affecting the integrity of biological or conversion products.

2. (a) After the Commission receives information from the Member State pursuant to Article 9 of the Implementation Regulations (EU) 2021/279 in respect of suspected or established non-compliance affecting the integrity of imported organic or conversion products, the Commission shall conduct an inquiry in accordance with Article 22 of this Regulation. The controlling authority or control body shall notify the Commission and the Member State who sent the preliminary notice (informing the Member State), using the framework outlined in Annexure 3 of these Rules. The controlling officer or control body shall respond within 30 calendar days from the date of receipt of that notice and shall inform about the actions and measures taken, including the outcome of the investigation, and shall provide any other information available by the informed member state and/or if necessary.

3. The notified control authority or control body shall provide additional necessary information if requested by the informed member state.

4. Where operators or groups of operators and/or their subcontractors are under the control of various control officers or control bodies, those control officers or control bodies will exchange relevant information on operations covered by their control activities.

5. If the operator or group of operators and/or their subcontractors change their controlling authority or control body, the new control authority or control body will request a control file from the previous controlling authority or control body to the respective operator or group of operators. The previous control authority or control body shall, within 30 days, provide to the new controlling authority or control body the control file of the concerned operator or group of operators and written records mentioned in paragraph 14, status of certification, list of non-compliance and related measures taken by the previous control authority or control body.

The new control authority or control body will ensure that the non-compliances mentioned in the previous control authority or control body report are addressed by operators or groups of operators.

6. Where operators or groups of operators are subject to traceability checks and mass balance checks, control officers and control bodies will exchange relevant information allowing these checks to be finalized.

Article 22

More rules on actions to be taken if not followed

1. In addition to the measures outlined in Article 29(1), (2) and (3) of the Regulation (EU) 2018/848 and article 2 of the Implementation Regulation (EU) 2021/279, where a controlling authority or control body suspects or receives verifiable information including information from other control authorities or control bodies, that a product, which may not be in compliance with the Regulation (EU) 2018/848, Intended to place that product in the market within the Union is intended to be imported from a third country, but which places conditions indicating organic production, or where such controlling authority or control body is notified by the operator of suspicion of non-compliance in accordance with Article 27 of that Regulation:

(A) It shall carry out immediate investigations for the purpose of certifying compliance with Regulation (EU) 2018/848 or with delegated or executed functions adopted pursuant to that Rule; such investigation shall be completed within a reasonable period, as soon as possible, and shall take into account the durability of the product and the complexity of the issue;

(B) (a) Import from a third country shall be prohibited for the purpose of keeping the relevant goods as organic or transformative goods in the market within the Union until the results of the research mentioned in (a) are obtained. Before making such a temporary decision, the controlling authority or the controlling body will give the operator or a group of operators a chance to comment.

2. If the results of the research outlined in point (a) of paragraph 1 do not show any non-compliance affecting the integrity of organic or in-conversion products, those products will be allowed to be used and labeled as organic or in-conversion products.

3. The control authority or control body will develop a list of measures to be taken in case of established non-compliance. That list of measures shall be based on the elements specified in Annexure 4 of this Regulation and shall include at least:

(A) List of non-compliance with reference to specific regulations of the Regulation (EU) 2018/848 or delegated or implemented actions adopted in accordance with that Regulation. That list will include at least non-compliances listed in Part B of Annexure 4 of this Regulation;

(B) The classification of non-compliance is divided into three categories: small, major and critical, set out in Part A of Annexure 4 of this Regulation, taking into account at least the following criteria:

(I) The application of precautionary measures outlined in paragraph 28(1) of the Regulation (EU) 2018/848, the practical measures outlined in point (a) (2) of paragraph 10(1) of this Rule and the reliability of one's own control exercised by the operator or group of operators in accordance with point (f) of paragraph 11(1) of this Regulation;

(II) the effect on the integrity of organic or in-conversion of products;

(III) the ability of the traceability system to detect the affected product(s) in the supply chain and the prohibition of import from a third country for the purpose of placing the product(s) in the market within the union in terms of organic production;

(IV) response of operators or groups of operators to previous requests from the controlling authority or control body;

(C) Measures to be applied for each non-compliance.

4. The control authority or the control body shall document the results of the research outlined in point (a) of Article 29(1) of the 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 at any stage of production, preparation and distribution, for example as a result of the use of non-authorized products, substances or technologies, or in conjunction with non-organic products, the controlling authority or the controlling body shall ensure, in addition to the measures to be taken in accordance with paragraphs 2 and 3 of this article, There is no reference to organic production as outlined in Chapter 4 of the Regulation (EU) 2018/848, in the labeling and advertising of the entire lot or for the purpose of placing that product in the market within the product run association of the product intended to be imported from a third country .

2. Where non-compliance has been established, the controlling authority or the controlling body:

(A) Do any action necessary to determine the origin and extent of non-compliance and to establish the responsibilities of operators or groups of operators ; and

(B) Take appropriate measures to ensure that the operator or group of operators treats non-compliance and prevents further incidents of such non-compliance .

When deciding which measures to take, the controlling authority or control body must take into account the nature of that non-compliance and the past record of the operator or group of operators regarding compliance.

3. In acting in accordance with Article 2 of this Article, the Controlling Authority or the Controlling Body shall take any measures as it deems fit to ensure compliance with the Regulation (EU) 2018/848 and the delegated and executed actions adopted in accordance with that Regulation, including:

(A) To apply the list of measures mentioned in Section 22(3) of these Rules;

(B) Ensure that the operator or group of operators increases the frequency of their own controls;

(C) Ensures that certain activities of the operator or group of operators are subject to increased or systematic control by the controlling authority or the controlling body.

4. In the event of serious, or repetitive or persistent non-compliance, the controlling authority or the control body shall ensure that the operator or group of operators, in addition to the measures set out in paragraphs 2 and 3, are prohibited from being placed in the market within the union for products of a certain period that refer to organic production, and its certificate mentioned in point (b) (i) of Article 45(1) of the Regulations (EU) 2018/848 may be suspended or withdrawn, appropriately.

5. The controlling authority or the controlling body shall provide to the operator or group of operators in writing of its decision with respect to the action or measures to be taken pursuant to this article, including the reasons for that decision .

Article 24

Checks for the purpose of backward recognition of the previous period

1. Before granting retrospective recognition of the previous period as part of the conversion period for the purposes of the point
(b) Of Article 10(3) of The Regulation (EU) 2018/848, the Controlling Authority or the Control Body shall ensure that the operator submits the following documents stating that the land parcels were natural or agricultural areas which, for a period of at least 3 years, have not been treated or contaminated with products or substances that are not authorized for use in organic production in accordance with Regulations (EU) 2018/848:

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

(B) Any other relevant documents are considered necessary to evaluate a request for retroactive accreditation by the control authority or control body.

2. In addition, the controlling authority or the controlling body will take the following steps:

(A) It will carry out detailed risk analysis based on documentary evidence to assess whether any land parcel covered by a request for retrograde recognition has been treated with products or substances not authorized for use in organic production for a period of at least 3 years , especially taking into account the total surface size . Agricultural practices carried out during that period in each land parcel which is related to the request and subject to the request . The control authority or the control body will keep documents on the risk analysis;

(B) It will take samples from each land parcel to soil and/or plant in line with the results of the risk analysis outlined in point (a), those land parcels identified as presenting a risk of contamination;

(C) It will prepare an inspection report in one of the union's official languages, including photographs of parcels after the operator's physical inspection , including land parcels covered by a request for retroactive accreditation aimed at confirming the consistency of the collected information, but before the operator takes any farming measures.

3. Based on the information provided by the operator in accordance with paragraph 1 and after completing the steps laid down in paragraph 2, the controlling authority or the controlling body shall prepare a final written report. The final written report will include a justification for identifying the previous period backward as part of the conversion period . This final written report indicates the initial period considered organic for each of the respective land parcels as well as the total surface of the land parcel that benefits from this retrospective recognition of the period.

4. The control authority or control body will immediately notify the recognized body of any retrograde recognition in the case of the Commission, member states and control bodies. For each retroactive accreditation granted, the controlling authority or control body will provide the final written report as outlined in paragraph 3.

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

Article 25

Permission for use of non-organic plant breeding materials

1. Before granting permission for the use of non-organic plant breeding materials mentioned in point 1.8.5.2 of Part 1 of Appendix 2 of The Regulation (EU) 2018/848, the control authority or the control body shall evaluate the following information and draw justification for each insult provided:

(A) scientific and common names (common and Latin names);

(B) diversity;

(C) total weight of seeds or number of related plants;

(D) availability of organic or in-transforming plant breeding materials;

(E) A statement from the document or operator proves that the requirements set out in point 1.8.5.2 of Part 1 of AnnexURE II of the Regulation (EU) 2018/848 have been met.

2. For each authority for the use of non-organic plant breeding materials mentioned in point 1.8.5.2 of Part 1 of Appendix 2 of the Regulation (EU) 2018/848, the controlling authority or the controlling body shall include relevant information in the annual report mentioned in paragraph 4 of this Regulation.

Article 26

Insults regarding the use of non-organic animals and aquaculture juveniles

1. In accordance with points 1.3.4.3 and 1.3.4.4 of Part 2 of Appendix 2 of the Regulation (EU) 2018/848 regarding the use of non-biological livestock species (bovine, equine, ovine, caprine, porcine and cervine animals, rabbits, and poultry), the control authority or control body will evaluate the following information and prepare justification for each insult:

(A) scientific and common names (common and Latin names, i.e. species and genus);

(B) breeds and strains;

(C) Production objectives: meat, milk, eggs, dual purpose or reproduction;

(D) total number of animals;

(E) availability of relevant organic livestock species;

(F) A statement from the document or operator proves that the requirements set out in point 1.3.4.3.3 and 1.3.4.4 of Part II of Annexure II of the Regulation (EU) 2018/848 have been met.

2. For each non-organic livestock species (bovine, equine, ovine, caprine, porcine and cervine animals, rabbits, and poultry), the control authority or control body will include relevant information on the insult provided in accordance with points 1.3.4.3 and 1.3.4 of Part 2 of Annex 2 in the annual report mentioned in paragraph 4 of this Regulation.

3. In accordance with point 3.1.2.1 of Part 3 of Appendix 2 of the Regulation (EU) 2018/848, before granting an insult with respect to the use of non-organic aquaculture juveniles, the control authority or the control body shall evaluate the following information and draw a justification for each insult:

(A) species and genus (common and Latin names);

(B) breeds and strains when applied;

(C) life stages (e.g. eggs, fries, juveniles) available for sale organically;

(D) The quantity available as estimated by the operator;

(E) Total number of teenagers;

(F) availability of relevant biological aquaculture species;

(G) Document or statement from the operator certifying that the requirements laid down in point 3.1.2.1 of Part 3 of Annex 2 of Regulation (EU) 2018/848 have been met.

4. For every insult provided in relation to the use of non-organic aquaculture juveniles in accordance with point 3.1.2.1 of Part 3 of Appendix 2 of Appendix 2 of the Regulation (EU) 2018/848, the Controlling Authority or the Controlling Body shall include relevant information in the Annual Report mentioned in Paragraph 4 of this Regulation.

Article 27

Reporting to the Temporary Authority for the Use of Non-Organic Agricultural Ingredients for Processed Organic Food

The Control Authority or Control Body shall immediately notify the Commission, Member States, Accreditation Bodies and other control bodies and control bodies of any temporary authority recognized in accordance with Article 46(1) of the Regulations (EU) 2018/848 that any temporary authorization provided for the use of non-organic agricultural ingredients for processed organic food in accordance with Article 25(4) of the Regulations. The notice shall include the justification submitted in the dedicated form provided by the Commission, that such authorization is provided in accordance with Article 25(1) of the Regulation (EU) 2018/848.

Chapter 5

Deerogations from Regulation (EU) 2018/848 in Catastrophic Situations

Article 28

Identification of catastrophic situations[edit]

For the purposes of exceptional production regulations outlined in Articles 22(1) and 45(3) of The Regulations (EU) 2018/848, 'adverse climate events', 'animal diseases', 'environmental events', ' natural disasters' or 'catastrophic events', as well as a situation qualified as a catastrophic situation arising from any comparable situation, the control authority or the control body may recognize the situation as a catastrophic situation based on the 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 the control body will be based on data provided by official organizations that justify the catastrophic situation.

Article 29

Conditions for devaluation

1. After the recognition mentioned in Section 28, the controlling officer or the controlling body may, after identifying the affected operators in the relevant area or at the request of the individual operator or a member of the group of concerned operators, grant that the relevant depreciations mentioned in Paragraph 3 of the Delegated Regulation (EU) 2020/2146 and the conditions connected therewith apply, provided that those insults and conditions apply:

(A) for a limited period and not more than necessary, and in no case longer than 12 months, to continue or resume organic production made before the date of application of those insults;

(B) particularly affected types of production or, where relevant, with respect to land parcels; and

(C) Individual operators or members of a group of related operators.

2. The application of depreciations mentioned in paragraph 1 shall be without prejudice to the validity of the certificates mentioned in point (b)(i) of article 45(1) of the Regulations (EU) 2018/848 where the deerogations apply, provided that the operator or operators meet the conditions under which the offending was provided.

3. The Control Officer and the Control Body shall, through the system referred to in Article 20(1), immediately inform the Commission, member states and, in the case of the control body, their recognized body about the contempt granted under this Regulation. In particular, the controlling officer or control body shall include the name of the operator or operators concerned, the time period for devaluation, the type of production or, where relevant, the land parcels, the justification for the devaluation and the statement of the relevant authority of the third country mentioned in Article 28. Where such a statement is not available, the controlling authority or the control body will justify the non-inclusion of such statement and provide the relevant data on which the assumption is based.

4. The controlling authority or the control body must ensure that any operator to whom the insult granted applies holds documentary evidence relating to the insult provided as well as documentary evidence about the use of those insults during the period during which those insults apply. The controlling authority or the controlling body will certify the compliance of the operator or operators with the terms of the offending granted.

Chapter 6

General and Final Provisions

Article 30

References to competent authorities and member states in Annex II of regulation (EU) 2018/848

1. References to competent authorities at the following points of Annexure 2 of regulation (EU) 2018/848 should be read as references to control officers and control bodies recognized in accordance with Article 46(1) of that Regulation:

(A) The first paragraph of point 1.7.2 and point 1.7.3 of part 1;

(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 2;

(C) 3.1.2.1 and 3.1.3.1 points of Part III.

The information mentioned in point 1.9.4.1 of Part II will be sent to the Commission only.

2. References to member states in point 1.9.4.4(c) of Part 2 of Annexure 2 of the Regulation (EU) 2018/848 may be read as controlling authorities and control bodies recognized in accordance with Article 46(1) of that Regulation(EU).

Article 31

Enter force and application

This rule will apply on the 20th day of publication in the *official journal of the European Union*.

This will come into effect from 1st January 2022.

This regulation will be completely binding and will apply directly to all member states.

Brussels, done 13 July 2021.

President for the
Commission
Ursula VON DER LEYEN

Annex I

Contents of the Evaluation Report mentioned in Section 1(2)(i)

Part A

The assessment report referred to in point (i) of Section 1(2) shall consist of documents and record review reports, on-site assessment reports and witness audit reports and may include any other information as the accrediting body or competent authority deems necessary.

1. Documents and Records Review Report

The document and record review report will include the following elements:

1.1. Evaluate the following:

(A) structure and size;

(B) IT Management System;

(C) branch offices;

(D) types of activities, including sub-contract activities other than inspection and sampling;

(E) organizational charts;

(F) quality management;

1.2. evaluation of procedures for the exchange of information between headquarters and branch offices, and sub-contracted laboratories, as well as commissions, member states, other control authorities and other control bodies;

1.3. evaluation of employees' knowledge and qualifications in relation to union legislation on organic production regulations and controls;

1.4. Documents issued by the chosen language governance and control authority or control body can be understood for contracted operators or groups of operators, especially for employees involved in the certification process or controls, especially in internal processes;

1.5. evaluation of continuous training programs, and effective monitoring by the control authority or control body of competencies obtained during training;

1.6. Evaluation of the experience and qualifications of employees in the category(s) of products set out in Article 35(7) of the Regulation (EU) 2018/848 subject to control and in every third country covered by accreditation, including the employment status of the respective inspectors and their contractual relationship with the controlling body;

1.7. evaluation of internal processes related to control activities in relation to operators and groups of operators, if any, and the specific skills and training required for inspectors of control authorities or control bodies controlling the system for internal control of groups of operators;

1.8. Details and evaluations of the performance of the control system for each third country, where relevant, control specifications for groups of operators are included;

1.9. Any other information deemed necessary by the Accreditation Body.

2. Site Evaluation Report

An on-site assessment report by an accreditation agency or, if appropriate, by an empowered authority, shall include the following elements:

2.1. The evaluation report of the office(s) where certification decisions are taken, which includes the following information:

(A) The results of the examination of the files of all categories of products set out in Article 35(7) of the Regulation (EU) 2018/848 for which accreditation is requested, and confirms that the controlling body has correctly enforced the requirements on the controls in relation to the operators and groups of operators as set out in Chapter 3 of this Regulation and in particular in Articles 9 and 10 of this Regulation;

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

(C) Evaluation of risk analysis procedures for the purpose of inspection, including inspection without prior notice ;

(D) Evaluation of sampling strategy, process and methodology;

(E) evaluation of communication with the Commission and other control officers and other control bodies;

(F) Findings from interviews with control and certification staff about their performance and competence in certification and control tasks ;

(G) The control authority or control body has the means to implement a control system consistent with this rule in every third country for which it requests accreditation, especially enough inspectors to carry out any physical check at any stage of production, preparation and distribution, appropriately, on the basis of their risk assessment, additional inspections or samples and documents that can be understood by contracted operators, When these documents are intended for operators or groups of operators;

(H) Confirmation of the ability and efficiency of the control authority or control body to perform its functions for each third country for which it requests recognition, in particular, the expected number of operators or members of a group of operators, the quantity of products exported, the nature and origin of products, including the evaluation of operators and inspectorfiles.

2.2. A witness audit report, as a result of a witness audit carried out in accordance with Part B, includes the following elements :

(A) operator's name, audited inspector and evaluator of the accreditation body;

(B) general information about witness audits such as location, time, audit plans or parties, and a set of experiences of operators regarding operators' or organic production regulations;

(C) Scope of inspection;

(D) Inspector preparation and knowledge, such as work planning, work instruction, documents and materials provided to the Inspector, inspector's knowledge of the relevant category of products, evaluation of the robustness of the operator's biological system plan or system of internal control of a group of operators, investigation of conflicts of interest, knowledge in regulation (EU) 2018/848, knowledge of the internal processes of its control body in relation to the functioning or implementation of the control system and certification process;

(E) Inspector performance, such as relevance of the period of inspection, evaluation of interviews, verification of previous non-compliance, collection of relevant information, authorization and analytical skills, communication and questioning techniques, effective language skills, knowledge of local agricultural conditions and agricultural practices , processing practices and social skills in that country;

(F) The quality of physical inspection of the facility/holding/unit such as the method and quality of the inspection checklist used, the information provided by the operator in the biological system plan, the robustness of the mass balance and traceability check, the methodology used for sampling and inspection of important areas;

(G) Findings, the status of non-compliances has been explored and corrective measures have been implemented;

(H) Assessment of non-compliance identified by the assessor of the accreditation body but not detected by the inspector;

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

(J) an overall assessment of the effectiveness of the inspection;

(K) a list of detected non-compliances, a timeline for description and corrective measures to be addressed by the Control Authority or control body;

(L) In the case of a group of operators, a specific section that provides a description and evaluation of the effectiveness of the system for internal controls ; and

(M) Overall assessment of the ability and reliability of the control authority or control body to perform certification activities, taking into account the results of the assessment carried out according to the section 2.1. Any other information deemed necessary by the accreditation agency or competent authority, for example, including the report and findings of further witness audits.

Part B

1. The witness audit mentioned in point 2.2 of Part A shall be as follows:-

   (A) made by the accreditation body or, appropriately, competent authority;

   (B) Based on a risk analysis and the entire activity under witness will be documented;

   (C) It is done physically and can be done remotely only if the commission decides.

2. Additional witness of Section 1 shall be audited:-

   (A) For each category of products set out in Article 35(7) of the Regulation (EU) 2018/848 for which accreditation is requested. All non-compliance detected by the accrediting body or the competent authority will be fully addressed by the controlling authority or the controlling body, respectively, and confirmed by the accreditation body or the competent authority;

   (B) For each category of products in a different third country, if requested by the controlling authority or control body or is already recognized for more than a third of the country; and

   (C) As a matter of priority in a group of operators, if the controlling authority or the control body certifies the group of operators.

3. For a controlling authority or control body recognized 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 the Regulation (EU) 2018/848 , the information mentioned in point 2.2 of Part A of this Annex will be from witness audit:

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

   (B) In a third country for which the controlling authority or controlling body is recognized under Article 33(3) of Regulation (EC) No. 834/2007.

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

(1) Council Regulation (EC) No. 834/2007 of 28th June 2007 Organic Products and Labeling and Regulation of Organic Products (EEC) No. 2092/91 (O.J. L. 189, 20.7.2007, page 1).

Annexure II

General and specific requirements for annual reports mentioned in paragraph 4

1. The annual report will update all the elements contained in the technical document mentioned in Section 1(2).

2. The annual report will include information from the control authority or control body to be updated for the purposes of the annual report and will include the name and code number of the controlling authority or control body, mailing address, telephone number, email contact point and website address, including a direct link with easy access from the home webpage, to the updated list of operators or groups of operators.

3. For the purposes of the annual report, the technical dodger will be completed with the following:

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

   (B) an undertaking that the controlling authority or the controlling body has displayed the necessary updates of the translation of the production rules in accordance with Article 1(2)(e) of this Regulation or any other relevant documents required for the purposes of Regulation (EU) 2018/848 or Article 46(2) of this Regulation;

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

   (D) A link to the website of the controlling authority or the control body, with the necessary information in accordance with article 17;

   (E) The annual assessment report of the office(s) where certification decisions are made is stated in point 2.1 of Part A of Annex 1:

      (I) Products imported from third countries comply with Regulations (EU) 2018/848 in order to ensure that the control authority or control body is satisfactorily evaluated by a recognized body or competent authority in the previous year;

      (II) Affirming that the control authority or control body still has the capabilities and competencies to implement the control requirements, conditions and measures set out in Article 46(2) and (6) and (6) of Rule (EU) 2018/848 and, in this Rule, in every third country for which it is recognized;

      (III) With regard to the results and its evaluation, including any updated information of the Annual Assessment Report :

         — examining files of operators or groups of operators;

         — the list of non-compliant, as well as the number of certified operators or the number of non-compliants with respect to a group of operators;

         — Non-compliance and handling of complaints, if any, with an explanation of the corrective measures implemented by operators or groups of operators for the permanent closure of its non-compliance;

         — list of measures and its implementation;

         — risk analysis process;

         — annual risk planning;

         — Sampling strategy, process and methodology;

         — changes in any process;

— exchange of information with other control officers, control bodies and commissions;

— the capacity of employees involved in the inspection and certification process;

— training programs;

— knowledge and capabilities of new employees;

— an overall assessment of the effectiveness and reliability of the observed activity and the performance of the control authority or control body;

— other elements that the accreditation body or competent authority consider relevant for the purposes of regulation (EU) 2018/848;

(IV) Confirming in relation to the expansion of the scope of accreditation to more third countries or categories of products in the previous year, the capabilities and competencies of the controlling authority or control body to control in accordance with this regulation in each new third country or to control for each new category of related products, if there are active operators or groups of operators.

4. The annual report will include the following information regarding the events not followed and the measures taken:

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

(B) the number of samples collected under inspection with and without prior notice and where applicable, actions;

(C) Number of samples collected during the course of the investigation pursuant to point (a) of section 22(1) notified through OFIS referred to in section 21(2) (OFIS case);

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

(E) The number of non-compliants divided into small, major and significant according to the classification of non-compliants of organic or in-conversion products placed in Annexure IV;

(F) Measures outlined in Annex IV taken in relation to operators or groups of operators in case of non-compliance.

5. When the control authority or control body has certified another controlling authority or a group of operators from the controlling authority or the control body, the annual report of the received control authority or control body will indicate for each transferred operator or group of operators:

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

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

(C) date of transfer of control file;

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

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

(F) An indication of whether operators or groups of operators were involved in any OFIS case.

6. Regarding the high-risk products mentioned in paragraph 8, the following information will be provided:

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

(B) For each operator or group of operators:

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

(II) sampled and analyzed;

(III) Non-compliance was found;

(IV) applicable measures;

(V) For each operator or group of operators who changed its controlling authority or control body, corrective measures and/or restrictions were implemented if non-compliances were noted in a previous control authority or control body report;

(C) For each consignment showing non-compliance:

(I) reference to certificate of inspection for imported consignments;

(II) overview of sample analysis results that indicate the presence of residues of non-authorized substances;

(III) Investigations and follow-up measures taken by the control authority or control body in cases of cumming or residues of non-authorized substances found in the consignment, including decisions about consignment as well as confirmation that operators have taken corrective measures.

7. For the Authority for the Use of Non-Organic Plant Breeding Materials in accordance with point 1.8.5.2 of Part 1 of Appendix 2 of The Regulations (EU) 2018/848, the following information will be provided:

(A) scientific and common names (common and Latin names);

(B) diversity;

(C) the total weight of the seed and the total weight of the seed or the number of plants;

(D) The number of operators and groups of operators to whom authorization is granted.

8. The following information will be provided for the insults provided in accordance with points 1.3.4.3 and 1.3.4 of Part 2 of Appendix 2 of the Regulation (EU) 2018/848 for each non-biological livestock species (bovine, equine, ovine, caprine, porcine and cervine animals, rabbits, poultry):

(A) scientific and common names (common and Latin names i.e. species and genus);

(B) breeds and strains;

(C) Production objectives: meat, milk, eggs, dual purpose or reproduction;

(D) the number of insults and the total number of animals;

(E) the number of operators and groups of operators, to whom depreciation is provided.

9. For the authorities granted for the use of non-organic aquaculture juveniles in accordance with point 3.1.2.1 of Part 3 of Appendix 2 of The Regulations (EU) 2018/848, the following information will be provided:

(A) species and genus (common and Latin names);

(B) breeds and strains when applied;

(C) the total number of insults and the number of juveniles for each species;

(D) number of operators and groups of operators, to whom authorization is granted.

10. The annual report will contain any other information deemed relevant by the controlling authority, the controlling body or the accreditation body to meet the specific requirements of regulation (EU) 2018/848.

Annexure III

OFIS template mentioned in paragraph 21(2)

Template for standard answers to standard international information on questionable or established non-compliance

A. **Research[edit]**

1) Which control authority (-I) and/or control body (-IES) are/were in charge of the investigation?:

2) Describe the cooperation between different operators and competent authorities(-s) or, where appropriate, the controlling authority (-i) and/or the controlling body (-i), engaged in different countries (if any)?:

3) What research methods/procedures have been used?:

For example, are the respective operators introduced under a specific control?:

Have samples been taken and analyzed?:

4) What are the results of the research?:

What is the result of inspection/analysis (if any)?:

Has the origin of the suspicion of non-compliance/non-compliance/other problem become clear?:

What is your assessment of the severity of non-compliance/non-compliance/other problems?:

5) Is the origin/non-compliance/other problem of pollution suspected and the responsibility of actors clearly identified and established?:

Comment on the origins of contamination/non-compliance/other problems raised and the responsibilities of actors:

6) Are the identified operators involved in other non-compliant/non-compliant/other issues raised in the last 3 years?

Comments on operators identified in the last 3 years suspected of other non-compliance/non-compliance/other problems:

B. **Remedies and Penalties:**

*1) What preventive and corrective measures have been taken (e.g. in terms of distribution/circulation of products in union markets and third-country markets)?:

*2) What action was taken against operators and/or related products in case of suspicion of non-compliance/non-compliance/other problems? ([1]):

* Mode of actions (written form, warning, etc.)?:

Was certification of the manufacturer/processor limited, suspended or withdrawn?:

Date of entry (if any) (DD/MM/YYYYY):

Duration of tasks (if any) (in months):

Control authority and/or control body who adopted and enforced the actions (if any):

3) Is there a plan for further inspections on the respective operators?:

4) What other measures are being planned by the control authority or the control body to prevent the occurrence of similar incidents?:

([1]) Measures in accordance with Articles 29(1) and (2) and Articles 22(1), (2) and (3) of the Regulation (EU) 2018/848 and its Articles 23(1) and (4) Regulation.

C. **Other Information**
D. **attachment**
Reply to comments:
contact point

* *Mandatory areas.*

Annex IV

List of remedies mentioned in Section 22(3)

Part A

Elements for the development and application of a list of measures

1. Subject to Part B, the controlling officer or the controlling body may classify incidents of non-compliance as minor, prominent or severe on the basis of the classification criteria in point (b) of section 22(3) if one or more of the following circumstances apply:

   (A) The case of non-compliance is minor when:

      (I) Precautionary measures put in place by the operator are proportional and appropriate, and the controls placed by the operator are efficient according to the assessment by the controlling authority or the control body;

      (II) Non-compliance does not affect the integrity of a biological or in-conversion product;

      (III) Traceability systems can detect the affected product(s) in the supply chain and prevent the product from being imported from a third country with the aim of placing the product in the market within the union in terms of organic production;

   (B) The case of non-compliance is prominent when:

      (I) Precautionary measures are not proportional and appropriate and the controls placed by the operator are inefficient according to the assessment by the control authority or the control body;

      (II) Non-compliance affects the integrity of a biological or in-conversion product;

      (III) The operator did not improve in time a little non-compliance;

      (IV) Traceability can detect the affected product(s) in the supply chain and prevent the product from being imported from a third country with the aim of placing the product in the market within the union in terms of organic production;

   (C) The case of non-compliance is critical when:

      (I) Precautionary measures are not proportional and appropriate and the controls placed by the operator are inefficient according to the assessment by the control authority or the control body;

      (II) Non-compliance affects the integrity of a biological or in-conversion product;

      (III) The operator fails to correct previous major non-compliances or repeatedly fails to correct other categories of non-compliance; and

      (IV) There is no information from the traceability system to detect the product(s) affected in supply and in the context of organic production products cannot be prevented from being imported from a third country for the purpose of placing that product in the market within the union.

2. measures

   Control officers or control bodies may apply one or more of the following measures proportionately to listed categories of non-compliance:

Non-compliant category	& Measure
minor	Submission by operator of action plan within a time frame setting on improvement of non-compliance(s)

major	In accordance with Article 42(1) of the Regulation (EU) 2018/848 relating to labeling of the entire lot or production run and any reference to organic produce in advertising (affected crop(s) or animal(s)) According to Article 42(2) of the Regulation (EU) 2018/848, import from a third country is prohibited for the purpose of placing the product in the market within the Union as an organic product for a specified period. The range limit of the certificate required for the new conversion period Improvements and controls of the implementation of precautionary measures that the operator has put in place to ensure compliance
critical	There is no reference to organic produce in labeling and advertising of whole lot or related product (crop) (s) or animal(s) affected) Regulations (EU) in accordance with Article 42(1) of 2018/848 According to Article 42(2) of the Regulation (EU) 2018/848, import from a third country is prohibited for the purpose of placing the product in the market within the Union as an organic product for a specified period. Withdrawal of suspension certificate of certificate limit of range of certificate required for new conversion period

Part B

List of cases of non-compliance and essentially related classification to be included in the catalog of measures

non-compliance	Category
Significant divergence between input and output calculation (mass balance)	major
Absence of records and financial records showing compliance with Regulation (EU) 2018/848	critical
Deliberate omission of information leading to incomplete records	critical
Falsification of documents related to certification of organic products	critical
Deliberate re-labeling of organically degraded products	critical
In-conversion or intentional organic mixing with non-organic products	critical
Deliberate use of non-authorized substances or products within the scope of Regulations (EU) 2018/848	critical

Deliberate use of GMOs	critical
The operator refuses to allow the controlling authority or control body to have access to the premises under control, or to keep its book with financial records, or to allow the control authority or control body to take samples.	critical