



Organic Food Development & Certification Center of China

Implementing Rules for Organic Certification Scheme

(EU compliance)

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1. Objective

In order to regulate the activities of organic production and certification of OFDC and OFDC certified operators, so as to ensure the consistence and effectiveness of OFDC certification procedure and management requirements, the rule is established according to the Regulation on Certification and Accreditation of P.R.C, Regulation (EU) 2018/848 on organic production and labelling of organic products, and other related laws, regulations.

2. Applicable Scope

The rule is applicable to OFDC certification activity of EU Compliance of product categories, including unprocessed plant products and processed agricultural products for use as food and feed, as defined in Regulation (EU) 2018/848 on organic production and labelling of organic products.

3. Applicable Standard

Regulation (EU) 2018/848 on organic production and labelling of organic products.

4. Certification Procedure

4.1 Application

4.1.1 OFDC must open at least the following information for the operators:

4.1.1.1 The Recognition of OFDC by the EU Commission and the EU Compliance certification scheme registered at the Certification and Accreditation Administration of PRC (hereafter shorted as CNCA).

4.1.1.2 Certification Procedures and requirements;

4.1.1.3 Certification standards;

4.1.1.4 Certification fee structure;

4.1.1.5 Right and obligations of OFDC and applicant;

4.1.1.6 OFDC procedure for handling compliance, appeal and dispute;

4.1.1.7 OFDC procedure for approve, deny, suspend and withdraw of certification;

4.1.1.8 Requirements for usage of EU Organic Logo (if applicable), OFDC logo and name by certified operator;

4.1.1.9 Requirements for promotion within scope of certificate by certified operator.

4.1.2 The operator must supply at least the following documents according to requirements of OFDC:

4.1.2.1 Legal licenses, such as Business License, Land Usage Verification, etc. If the operator subcontracts any of its activities to third parties, the operator shall supply contracts with all of its subcontracted third parties.

4.1.2.2 a document in the form of a signed declaration, setting out:

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

4.1.2.3 a confirmation that the operators have not been certified by another control body in relation to activities carried out in the same third country regarding the same category of products, including in cases in which operators operate at different stages of production, preparation or distribution;

4.1.2.4 a signed undertaking by which the operators commit themselves:

- (i) to give the control authority or control body access to all parts of all production units and all premises for control purposes, as well as to the accounts and relevant supporting documents;
- (ii) to provide the control authority or control body with any information necessary for the purposes of the controls;
- (iii) to submit, when requested by the control authority or control body, the results of its own quality assurance programmes;
- (iv) to inform buyers of the products in writing and without undue delay, and to exchange relevant information with the control authority or control body, in the event that a suspicion of non-compliance has been substantiated, that a suspicion of non-compliance cannot be eliminated, or that non-compliance that affects the integrity of the products in question has been established;
- (v) to accept the transfer of the control file in case of a change of control authority or control body or, in the case of withdrawal from organic production, the keeping of the control file for 5 years by the last control authority or control body;
- (vi) to inform immediately the control authority or control body in the event of withdrawal from organic production;
- (vii) in the event that the subcontractors of the operators are subject to controls

by different control authorities or control bodies, to accept the exchange of information among those control authorities or control bodies;

(viii) to perform the activities in accordance with the organic production rules;

(ix) to accept the enforcement of the corrective measures established by the control authority or control body in the event of non-compliances.

4.2 Accepting application

4.2.1 OFDC must complete reviewing to application documents within 10 days after receiving the application from the applicant, and decide whether to accept the application.

4.2.2 If agree to accept the application, OFDC must sign certification contract with the applicant; if not, OFDC must inform the applicant in written for explanation.

4.2.3 OFDC must ensure the reviewing to application documents:

4.2.3.1 The documents show understanding and meeting to certification standard and requirements;

4.2.3.2 Any disputing in understanding with the applicant has settled;

4.2.3.3 OFDC is applicable to conduct certification service to the applied operation, site and special requirements.

4.2.4 OFDC must keep the records of reviewing.

4.2.5 Due to OFDC's own capacity constraints, OFDC will only accept application for EU compliance certification from applicants who understand Chinese or English.

Therefore, when accepting applications from operators in Russian Federation, the following should be taken into account:

(i) Whether the submitted application documents (application form, questionnaire) are filled in Chinese or English, and whether the qualification documents (e.g. land use right documentation, business license, etc.) and key documents (e.g. field map, factory floor map, process flow diagram), etc., are in Chinese/English, or whether all the necessary information is noted in Chinese/English.

(ii) Whether the application form and questionnaire are filled out in a clearly expressed and easy to understand manner, and whether there is any serious lack of information.

(iii) Whether the contact person of the operator, when communicating with the OFDC application acceptance personnel in writing and orally, shows obvious language barrier.

If one of the above three situations occurs, it is considered that the operator is unable to understand Chinese/English, and OFDC will not accept the application submitted by him/her.

4.3 Inspection preparation and implementation

4.3.1 General requirements for the inspection

4.3.1.1 Controls performed by OFDC for the verification of compliance with Regulation (EU) 2018/848 by operators shall include:

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

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

- (a) the type, size, including newly added land parcels, and structure of the operators;
- (b) location and complexity of the activities or operations of operators;
- (c) the length of time during which operators have been involved in organic production, preparation and distribution;
- (d) the results of the controls by OFDC, in particular as regards compliance with Regulation (EU) 2018/848;
- (e) whether the holding includes non-organic or in-conversion production units;
- (f) the type, quantity and value of products;

- (g) the risk of commingling of products or contamination with non-authorised products or substances;
- (h) the application of derogations or exceptions to the rules by operators;
- (i) the critical points for non-compliance at every stage of production, preparation and distribution;
- (j) subcontracting activities;
- (k) whether operators have changed their certifying control authority or control body;
- (l) any information indicating the likelihood that consumers might be misled;
- (m) any information that might indicate non-compliance with Regulation (EU) 2018/848.

4.3.1.3 OFDC shall carry out a verification of compliance with Regulation (EU) 2018/848 for all operators at least once a year. The verification of compliance shall include a physical on-the-spot inspection.

4.3.1.4 OFDC shall ensure that it carries out every year at least 10 % of additional controls to those referred to in 4.3.1.3. Of all physical on-the-spot inspections carried out by OFDC, at least 10 % shall be without prior notice.

4.3.1.5 Controls carried out as a follow-up on a suspected or established non-compliance shall not count towards the additional controls referred to in 4.3.1.4.

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

For the high-risk production (major, critical or repetitive non-compliances affecting the integrity of organic or in-conversion products or production), OFDC shall carry out, at least, two physical on-the-spot inspections per year of operators. One of these physical on-the-spot inspections shall be without prior notice.

4.3.1.7 Where operators run several production units or premises, including purchase and collection centres, all production units or premises, including purchase and collection centres, used for non-organic products shall also be subject to the control requirements set out in 4.3.1.4.

4.3.1.8 The delivery or renewal of the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 shall be based on the results of the verification of compliance referred to in section 4.3.

4.3.2 Assignment of inspection

4.3.2.1 OFDC must issue inspection assignment which must include content of, but not limited to:

- a. The operator's contact information, address, etc.
- b. Applicable standards and related laws/regulations for the inspection;

- c. Inspection scope, including the product scope, site scope, and process scope.
- d. Inspection key points, including the input use, packaging and labeling, traceability system, efficiency of the management system, and if applicable the corrective actions to the non-compliances issued by OFDC last year.

4.3.2.2 OFDC must assign applicable inspector according to the inspection types and qualification of inspector. The assignment of the inspector must be approved by the applicant, but the applicant is not allowed to appoint inspector. An inspector is not allowed to inspect a same operator continuously for 3 years or more.

4.3.3 Document review

OFDC must review the management system documents of the applicant/operator before the on-site inspection, so as to ensure the suitability, adequacy and compliance to standard, and keep the reviewing record.

4.3.4 Inspection Plan

4.3.4.1 OFDC must make inspection plan and confirm it with the applicant before on-site inspection. The inspection plan must include: inspection basis, inspection content, person to be interviewed in inspection, sites to be visited in inspection, and time arrangement of the inspection, etc.

4.3.4.2 The inspection time must be arranged in proper stage during the production/processing, at least once in the production/processing period.

4.3.5 Implementation of the Inspection

OFDC must conduct inspection according to related laws/regulations, standards and quality system documents of the applicant/inspected operator, to evaluate the production system, the consistency of the operation with the documents, the conformity of the operation with the standards. OFDC shall verify that the operators comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation. The verification shall include at least one physical on-the-spot inspection. Additional requirements described in Annex 1: Inspection Implementation and Annex 2: EU Guidelines on Additional Controls on Organic Products originated from China shall also be implemented.

The inspection contents must include at least the following:

- a) Inspect the production/processing system, including the farm (fields), processing plant, equipments, storage facilities, etc., and include non-organic production/processing site, if needed. The initial certification inspection shall cover at least one-third of the farm plots. The plots to be inspected shall be selected based on crop variety and the risk posed by surrounding conventional plots. At least one plot of a high-risk crop variety shall be inspected, along with all plots adjacent with conventional cultivation. Recertification inspections shall cover at least one-third of the plots, avoiding duplication with the previous

inspection whenever possible. However, plots where non-compliance occurred in the previous year shall be included in the inspection scope. All plots on the farm shall be inspected within at least a three-year period. High-risk crop varieties shall be those listed in Annex 2.

- b) Verify the information provided by the operator, including to interview the production management staff, internal inspector, and producers;
- c) Identify and evaluate the environmental situation of the production base/processing plant, and evaluate whether there is risk of contamination to the organic production/processing;
- d) Identify and investigate area of high risk, such as the risk of potential contamination from adjoining farm, flood;
- e) Where an operator runs several production units in the same area, some of them are for non organic products, the inspection must include non-organic production site, include visual observation to the non-organic production site;
- f) Review the production/processing records, including the evaluation to audit trail system (including production/sales balance, input/output balance, so as to ensure the audit can be traced from raw materials to processing) and mass balance, as refer to section 4.3.10;
- g) If there is any change in standard or OFDC certification requirement, the inspector must verify whether the operator is compliant with the changed standard or requirement;
- h) Evaluate the continuous improvement to the production system; Evaluate if applicable;
- i) Make conclusion to the inspection at the exit interview before end of the inspection; any problem found in the inspection must be communicated with and confirmed by the applicant/inspected operator, who is approved to give any explanation to the problem.

4.3.6 Confirmation of conversion period

4.3.6.1 If the applicant can provide real verification materials and land usage history documents in written, the conversion can be calculated from the date that the producer start organic production, after been confirmed by OFDC. The period of time before application recognised as part of the conversion period may be the full three years or a shorter period, depending on the evidence provided and results of the CB inspection.

4.3.6.2 Evidence of no use of prohibited products for the required period is sufficient grounds for recognising retroactively the conversion period. Prohibited products include use of GMO technologies and/or seed treated with prohibited products;

4.3.6.3 Satisfactory documentary proof that no prohibited products have been

applied include:

- a) Declarations must be accompanied by a signed/stamped map or named land parcels or GPS coordinates, which clearly identifies each land parcels covered by the request for retroactive recognition of conversion, total surface of those parcels, and defined and verifiable boundaries; and
- b) Declaration that no prohibited products with specific reference to the (EU) 2018/848 have been applied in the period of time for which retroactive recognition is requested from a relevant authority – i.e. one that has knowledge of the land in question. OFDC shall have some knowledge of the authority in question whether accepting a government or non – governmental authority. The declaration must give some detail of the prohibition e.g. reference to no prohibited inputs does not provide sufficient confidence. A declaration of no chemical or artificial fertilisers or pesticides or a reference to organic agriculture or a specific organic scheme is required. Declarations alone might not be satisfactory if it is clear that the land has been previously intensively farmed; or
- c) Declaration from the operator or land owner that no prohibited products with specific reference to the (EU) 2018/848 have been applied in the period of time for which retroactive recognition is requested; in such cases, farming activity records of all the parcels concerned shall be provided.

4.3.6.4 Verification of proof

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

4.3.6.5 Based on the information provided by the operator in accordance with 4.3.6.3 and after having completed the steps set out in 4.3.6.4, OFDC shall draw up a final written report. The final written report shall include a justification why the previous

period can be recognised retroactively as part of the conversion period. This final written report shall also indicate the starting period considered as organic for each land parcel concerned as well as the total surface of the land parcels benefiting from this retroactive recognition of a period.

4.3.6.6 OFDC shall immediately notify the Commission, the Member States and IOAS of any retroactive recognition granted as an exception. For each retroactive recognition granted, OFDC shall provide the final written report referred to in 4.3.6.3.

4.3.6.7 OFDC shall ensure that the operator to whom the granted retroactive recognition applies keeps documentary evidence relating to that recognition, as well as documentary evidence on the use of the land parcels covered by that recognition, for 3 years.

4.3.7 Parallel production

The entire holding shall be managed in compliance with the requirements of this Regulation that apply to organic production. A holding may be split into clearly and effectively separated production units for organic, in-conversion and non-organic production, provided that for the non-organic production units different varieties that can be easily differentiated are involved.

By way of derogation from point (b) of paragraph 7, in the case of perennial crops which require a cultivation period of at least three years, different varieties that cannot be easily differentiated, or the same varieties, may be involved, provided that the production in question is within the context of a conversion plan, and provided that the conversion of the last part of the area related to the production in question to organic production begins as soon as possible and is completed within a maximum of five years. In such cases, the producer shall:

- a) notify OFDC of the start of harvest of each of the products concerned at least 48 hours at least 48 hours in advance;
- b) upon completion of the harvest, inform OFDC of the exact quantities from the units concerned, and of the measures taken to separate the products.
- (c) the conversion plan and the measures to be taken to ensure the effective and clear separation shall be confirmed each year by OFDC, after the start of the conversion plan.

4.3.8 Sample collection and test

4.3.8.1 Samples of plant product may be taken to be analyzed for plant protection products during the annual inspection for detecting the use of non-authorised products and substances for organic production, for checking production techniques not in compliance with the organic production rules or for detecting possible contamination by non-authorised products and substances for organic production.

4.3.8.2 OFDC shall carry out sampling on at least 5 % of the number of individual

operators under its control.

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

4.3.8.4 When there is reason to suspect that prohibited substances or technologies were used, or the production unit/product has been contaminated, the inspector shall collect samples for test (residues or GMOs), unless the inspector considers that sufficient evidence is available without sampling. Samples may also be taken and analysed by OFDC in any other case (unannounced or additional inspection, or complaint investigation, etc.).

4.3.8.5 The items for residue test shall be decided by inspector based on risk evaluation. Besides the routine test items, the following plant protection products (but not limited to) that are not authorized under EU organic farming legislation shall also be tested: glyphosate, benzalkoniumchlorid (BAC), didecyldimethylammoniumchlorid (DDAC), endosulfan, cyromazin, acetamiprid, biphenyl, cyalotrin or cyhalothrin, fenvalerato, esfenvalerato, cypermethrin, imidacloprid, hexachloro benzene, isofenphos-methyl, aldicarb. Samples shall be tested for each residues that were suspected to be used.

4.3.8.6 For the high-risk products referred to in (EU)2021/1698 Article 8, OFDC shall take, in addition to the sampling rate set in 4.3.8.2 and 4.3.8.3, at least one field sample of the crop each year. That sample shall be taken from crops in the field, at the most appropriate moment to detect potential use of non-authorized substances according to the assessment of OFDC. For operators not growing crops, a relevant sample of incoming raw material or intermediate product or processed product shall be taken.

4.3.8.7 OFDC shall ensure that the laboratories used comply with the following:

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

Commission Implementing Regulation (EU) 2019/533 (7).

4.3.9 Subcontracted activities

4.3.9.1 All the points of organic production/processing/packaging procedure must be covered during inspection. If the operator subcontracts part of its activities to third parties, the inspection shall verify that:

Where the operator subcontract any of its activities to third parties, both the operator and the third parties to whom those activities have been subcontracted, have been certified by recognized control authorities or control bodies confirming that they comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation, unless the operator informs OFDC that it remains responsible as regards organic production and that it has not transferred that responsibility to the subcontractor. In such cases, OFDC shall verify that the subcontracted activities comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation in the context of the certification activities it carries out in respect of the operator that has subcontracted its activities.

4.3.9.2 Once the certified operator plans to subcontract any of its activities to third parties, it shall inform OFDC about its plan for approval. Only after been approved by OFDC, the operator can subcontract its activities to third parties.

4.3.10 Verification of traceability and mass balance

4.3.10.1 In the annual physical on-the-spot inspection, OFDC shall include a traceability check and a mass balance check of the operator carried out by means of checks of documentary accounts.

4.3.10.2 For the purpose of the traceability check and mass balance check, the selection of products, groups of products and period under verification shall be made on a risk basis.

4.3.10.3 The traceability check shall cover at least the following elements justified by appropriate documents including stock and financial records:

- (a) the name and address of the supplier and, where different, of the owner or the seller, or the exporter of the products;
- (b) the name and address of the consignee and, where different, of the buyer or importer of the products;
- (c) the certificate of the supplier in accordance with Article 35(6) of Regulation (EU) 2018/848;
- (d) the information referred to in the first paragraph of point 2.1 of Annex III to Regulation (EU) 2018/848;
- (e) the appropriate lot identification;
- (f) in the case of processors, the necessary information to allow internal traceability and guarantee the organic status of ingredients.

- 4.3.10.4 Where relevant, the mass balance check shall cover at least the following elements justified by appropriate documents including stock and financial records:
- (a) the nature and the quantities of products delivered to the unit and, where relevant, of materials bought and the use of such materials, and, where relevant, the composition of products;
 - (b) the nature and the quantities of products held in storage at the premises;
 - (c) the nature and the quantities of the products that have left the unit of operator to the consignee's premises or storage facilities;
 - (d) in case of operators who buy and sell the product(s) without physically handling the product(s), the nature and the quantities of products that have been bought and sold, and the suppliers, and where different, the sellers or the exporters and the buyers, and where different, the consignees;
 - (e) the yield of the products obtained, collected or harvested over the previous year;
 - (f) the actual yield of the products obtained, collected or harvested over the current year;
 - (g) the number and/or weight in case of livestock managed over the current and previous year;
 - (h) any losses, increase or decrease in quantity of products at any stage of production, preparation and distribution;
 - (i) organic or in-conversion products that are sold on the market as non-organic.

4.3.11 Transfer Certification from other certification bodies

Before certifying operators or groups of operators that were previously certified by another control authority or control body, inspection shall assess the following information to be transmitted by the previous control authority or control body:

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

4.3.12 Inspection report

4.3.12.1 The inspection checklist/report must be in fixed format provided by OFDC.

4.3.12.2 The inspection checklist/report must provide enough information so as to ensure impartial, objective and complete judgment to any operation.

4.3.12.3 The inspection checklist/report must include inspection date, inspection areas or facilities, reviewed documents, cover contents of standard, information that provided by the operator, and explanation to any non-compliance, including verification that whether corrective actions have been fulfilled for previously imposed conditions, risk evaluation and judgment to conformity of the operation.

4.3.12.4 The inspector must make evaluation to the general situation of the applicant/operation, but shall not make written conclusion to the operation/products of whether it can be certified.

4.3.12.5 The inspection report must be confirmed by the applicant by written.

4.4 Certification decision

4.4.1 When the operation is inspected and the inspection report is submitted to OFDC, OFDC must conduct review according to all the information and make certification decision, and inform the applicant of the result in time. The review and decision making process follow “OFDC-PR12-02 OFDC Certification Decision-making Procedure”. The process of granting, extending, reducing or changing certification follows “OFDC-PR4.6-01 OFDC Procedure for Granting Extending, Reducing and Changing of Certification”.

The process of suspending, revoking, denying, or withdrawing voluntarily certification follows “OFDC-PR4.6-02 OFDC Procedure for Suspension, Revocation, Denial and Withdrawal of Certification”.

4.4.2 Granting certification

OFDC shall grant certification if the applicant/operation compliant with following conditions:

4.4.2.1 The operation and management system is in line with related standards and regulations; or

4.4.2.2 The operation and management system is not totally compliant with related standards and regulations, but the applicant has taken corrective actions, or has been verified its capability of take correction in limited time, and has been approved by OFDC;

4.4.2.3 The applicant admits to fulfill the certification contract, and has paid certification fees according to the contract.

4.4.2.4 If applicable, even though the previous control authority or control body does not transmit the information as required by OFDC in 30 days or in case of doubts concerning the information transmitted, OFDC has eliminated their doubts by other means of control.

4.4.3 Extension of certification

In the valid period of the certificate, the certificate holder can be approved for extension, if it compliant with following conditions:

4.4.3.1 The scope applied for extension is within the scope of legal documents and qualification requirements;

4.4.3.2 The management system must cover the scope applied for extension, which is in line with related standard, sampling requirements and other related requirements;

4.4.3.3 The plan of extension includes production amount, products, and production areas to be enhanced in line with related standard.

4.4.4 Reduction of certification

In the valid period of the certificate, the certificate holder can be approved for reduction in the following conditions:

4.4.4.1 Part of the product scope, production scope, or main producing procedure is not able to compliant with standard or other related requirements continuously;

4.4.4.2 Part of the product scope, production scope, or main producing procedure is not willing to keep the certification qualification;

4.4.4.3 Part of the product scope, production scope cannot meet the requirements of Regulation (EU)2018/848, and as a consequence OFDC takes a control measure defined in OFDC Catalogue of Control Measures for Non-compliances.

4.4.5 Changing of certification

In the valid period of the certificate, the certificate holder must apply for changing of its certification in the following conditions:

4.4.5.1 The certificate holder has changed;

4.4.5.2 The operator has changed;

4.4.5.3 change of extension/reduction (refer to 4.4.3 and 4.4.4)

4.4.5.4 When the producer finishes conversion period.

4.4.6 Denying/Rejecting certification

In one of the following situations, an initial application of an operator is denied certification:

4.4.6.1 The operator was found critical noncompliances defined in OFDC Catalogue of Control Measures for Non-compliances;

4.4.6.2 The operator does not take corrections of noncompliances or does not provide a plan for corrective actions to satisfy certification requirements in the due time required by OFDC;

4.4.6.3 if applicable, the previous control authority or control body does not transmit the information as required by OFDC in 30 days or in case of doubts concerning the information transmitted;

4.4.6.4 The Operator has been withdrawn by its previous control authority or control body in the last 2 years, unless the recognition of the previous control authority or control body has been withdrawn by the Commission in accordance with Article 46(2a) of Regulation (EU) 2018/848 for the specific third country and category of

products.

4.4.7 Suspending certification

In the valid period of the certificate, the certification must be suspended, while the certificate holder must stop using the organic certificate and logo, where OFDC identified one of the critical or major noncompliances defined in OFDC Catalogue of Control Measures for Non-compliances that may lead to suspension.

4.4.8 Reinstating certification

In case of the certificate holder has taken correction and/or corrective actions, and the reason for certification suspension has been eliminated, the certification can be reinstated.

4.4.9 Withdrawal of certification

In the valid period of the certificate, the certification must be withdrawn, while the certificate holder must stop using the organic certificate and logo, in one of the following situations:

4.4.9.1 The operator was found critical or persistent major noncompliances defined in OFDC Catalogue of Control Measures for Non-compliances;

4.4.9.2 The operator has failed to take corrective and/or remedial action within the time limit set by the OFDC for the suspension.

4.4.9.3 The operator violates the contract with OFDC.

4.4.10 Withdrawal of certification voluntarily

OFDC will cancel certification under the following cases:

4.4.10.1 The certificate holder/operator is not willing to or not able to comply with new standard or regulations, if the certification standard or regulation has been changed;

4.4.10.2 The operator or the sub-contracted operator stopped to produce the certified products;

4.4.10.3 The operator submit written request for withdrawal of its certificate. At any point within the certification cycle preceding the decision made by OFDC, the applicant may request that the processing of its application be stopped. The applicant shall, however, be liable for the costs of services provided up to the time of withdrawal of its application. In such case, OFDC shall not issue a decision regarding the products that were the subject of the certification request.

4.5 OFDC shall issue certificate to the applicant and authorise it to use the EU certification logo and the OFDC logo when the applicant or operator is granted certification.

4.6 OFDC must sign contract with the certificate holder for usage of certification logo and CB logo, so as to specify the conditions and requirements for using the logos.

5. Certificate, logo and labeling

5.1 OFDC shall provide operators and exporters in third countries that have been subject to its controls referred to in point (b)(i) of Article 45(1) of that Regulation with a certificate confirming that such operators and exporters comply with Regulation (EU) 2018/848.

The certificate shall:

(a) be issued as follows:

- (i) in accordance with the model set out in Annex I to Regulation (EU) 2021/1378;
- (ii) in electronic form by using the electronic Trade Control and Expert System (TRACES) referred to in Article 2, point (36), of Commission Implementing Regulation (EU) 2019/1715;
- (iii) it shall bear a qualified electronic seal as defined in Article 3, point (27), of Regulation (EU) 910/2014 of the European Parliament and of the Council;

(b) allow the identification of:

- (i) the operator or exporter covered by the certificate;
- (ii) the category of products covered by the certificate, classified in the same way as provided for in Article 35(7) of Regulation (EU) 2018/848; and
- (iii) its period of validity;

(c) certify that the activity of the operator or exporter complies with Regulation (EU) 2018/848; and

(d) be updated whenever changes occur concerning the data included in it.

5.2 The certificate holder shall use OFDC logo and EU logo (if applicable) in line with related OFDC and EU requirements.

6. Post certification management

6.1 OFDC must conduct effective measures to ensure the continuously compliance of the certified operator, including obtain information of important change of the operator, conduct additional inspection or unannounced inspection if necessary.

OFDC shall visit all operators at least once a year; minimum of 10% of OFDC operators must receive additional visits and minimum 10% of all visits must be unannounced, and these two can be overlapped. For example, If OFDC has 100 operators, 10% of those operators must receive an additional visit = 10 inspections. Of those 10 inspections, 10% must be unannounced = 1 unannounced inspections. These may be part of the annual or additional inspections, but must total 1.

If OFDC certified operators under EU Compliance is less than 10, there also requires a minimum of one for unannounced Inspection.

6.2 OFDC must conduct audit to the logo usage of the products, so as to ensure consistency of products with the certificate (including amount of logo used).

6.3 OFDC must control handling of certificate of inspection (Col), so as to ensure the products and logo is in the scope of the certificate.

6.4 Verification of consignments intend for export into EU

6.4.1 OFDC shall verify consignments intended for import into the European Union with regard to the compliance with Regulation (EU) 2018/848 and (EU) 2021/1698. The verification shall include systematic documentary checks and, as appropriate according to a risk assessment, physical checks, before the consignment leaves the third country of export or of origin.

6.4.2 OFDC shall only verify the product of the producer or the processor of the product concerned under its control, or the operator carrying out the last operation for the purpose of preparation as defined in point 44 of Article 3 of Regulation (EU) 2018/848 where the operator carrying out the last operation for the purpose of preparation is different from the producer or processor of the product.

The country of origin of the product or, where applicable, of the last operation carried out for the purpose of preparation, shall be within the scope of OFDC recognition in accordance with Article 46(1) of Regulation (EU) 2018/848 for the products concerned and for the third country.

6.4.3 The documentary checks referred to in 3.5.1 shall aim at verifying:

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

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

documents, commercial and financial documents and any other documents deemed relevant by OFDC.

6.4.4 In relation to the risk assessment preceding physical checks, OFDC shall take into account the following criteria:

- (a) the relevant criteria listed in Article 9(2) of (EU) 2021/1698;
- (b) whether there are several operators involved in the distribution chain of the products who do not store or physically handle organic products;
- (c) high-risk products: major, critical or repetitive non-compliances affecting the integrity of organic or in-conversion products or production;
- (d) any criteria deemed relevant by the certification body.

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

6.4.6 For consignments of high-risk products (major, critical or repetitive non-compliances affecting the integrity of organic or in-conversion products or production), OFDC shall carry out systematic physical checks and take at least one representative sample of each consignment. Moreover, OFDC shall have complete documentation of the traceability of the operators and the product, including transport and commercial documents, including invoices. At the request of the Commission or the competent authority of a Member State, OFDC shall send this traceability documentation as well as the results of the sampling analysis to OFDC of the importer and to the competent authority of the Member State where the consignment is verified.

6.4.7 At the request of the Commission or the competent authority of a Member State in case of suspicion of non-compliance, OFDC shall make available without delay the list of all operators and all groups of operators in the organic production chain of which the consignment is part, and of their control authorities or control bodies.

6.5 Issuance of the certificate of inspection

6.5.1 OFDC shall issue a certificate of inspection in accordance with template of Col for every consignment before the consignment leaves the third country of export or of origin when it has verified the consignment in accordance with 6.4.

6.5.2 OFDC shall issue the certificate of inspection for consignments containing high risk products (major, critical or repetitive non-compliances affecting the integrity of organic or in-conversion products or production) only once it is in possession of the complete documentation of the traceability and it has received and assessed the

results of the analyses of the samples taken on the consignment in accordance with 6.4.6.

6.5.3 OFDC shall issue in the Trade Control and Expert System (TRACES) the certificate of inspection in accordance with OFDC template of certificate of inspection and shall complete boxes 1 to 18 of that certificate.

6.5.4 When issuing the certificate of inspection, OFDC shall upload into TRACES all the supporting documents, including the following:

- (a) the results of analyses or tests carried out on the samples taken, where applicable;
- (b) the commercial and transport documents such as the bill of lading, invoices and packaging list and, the travel plan as drawn up in accordance with 6.4.5.

6.5.5 The certificate of inspection shall be issued in TRACES and shall bear a qualified electronic seal.

If unavailable at the moment of the issuance, the information relating to the number of packages referred to in box 13 of the certificate of inspection and the information referred to in boxes 16 and 17 thereof, as well as the documents referred to in 6.3.4, shall be included or updated in the certificate of inspection within 10 days from its issuance and, in any case, before its verification and endorsement by the competent authority in accordance with Article 6 of (EU) 2021/2306.

6.5.6 The certificate of inspection shall be drawn up:

- (a) in the official language or in one of the official languages of the Member State of the border control post of entry into the Union, in the case of products subject to official controls at border control posts;
- (b) in the official language or in one of the official languages of the Member State where the consignment is to be released for free circulation, in the case of products exempted from official controls at border control posts in accordance with Delegated Regulation (EU) 2021/2305.

6.6 Contingency arrangements for TRACES in case of unavailability and in case of force majeure

6.6.1 OFDC shall maintain available a fillable template of that certificate in accordance with the OFDC template certificate of inspection and of all documents required by Regulation (EU) 2018/848 that may be uploaded in TRACES.

6.6.2 Where TRACES or one of its functionalities is continuously unavailable for more than 24 hours, its users may use a fillable printed or electronic template, as referred to in 6.6.1, to record and exchange information.

OFDC shall give a reference to each issued certificate and keep a register of the

issued certificates in chronological order to ensure the correspondence with the alphanumeric reference given by TRACES once it becomes functional.

In case paper certificates of inspection are used, uncertified alterations or erasures shall invalidate it.

6.6.3 Once TRACES or its functionalities become available again, its users shall use the information recorded in accordance with 6.6.2 to produce electronically the certificate of inspection and upload the documents referred in 6.6.1.

6.6.4 Certificates and documents produced in accordance with 6.6.2 shall bear the text “produced during contingency”.

6.6.5 In case of an event of force majeure, 6.6.1 to 6.6.4 shall apply. In addition, OFDC shall inform the EU Commission without delay about such an event and OFDC shall insert all the necessary details in TRACES within ten calendar days following the end of this event.

6.6.6 Rules in 6.6.4 and 6.6.5 shall apply mutatis mutandis to certificates and documents produced in accordance with 6.6.2.

6.7 Measures to be taken in the event of the presence of non-authorised products or substances

6.7.1 Where OFDC receives substantiated information about the presence of products or substances that are not authorised pursuant to the first subparagraph of Article 9(3) of Regulation (EU) 2018/848 for use in organic production, or has been informed by an operator in accordance with point (d) of Article 28(2) of Regulation (EU) 2018/848, or detects such products or substances in an organic or an in-conversion product:

(a) it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 with a view to determining the source and the cause in order to verify compliance with the first subparagraph of Article 9(3) and with Article 28(1) of Regulation (EU) 2018/848; such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case;

(b) it shall provisionally prohibit both the placing on the market of the products concerned as organic or in-conversion products and their use in organic production pending the results of the investigation referred to in point (a).

6.7.2 The product concerned shall not be marketed as an organic or in-conversion product or used in organic production where OFDC has established that the operator concerned:

(a) has used products or substances not authorised pursuant to the first subparagraph of Article 9(3) of Regulation (EU) 2018/848 for use in organic

production;

(b) has not taken the precautionary measures referred to in Article 28(1) of Regulation (EU) 2018/848; or

(c) has not taken measures in response to relevant previous requests OFDC.

6.7.3 The operator concerned shall be given an opportunity to comment on the results of the investigation referred to in 6.7.1. OFDC shall keep records of the investigation it has carried out.

Where required, the operator concerned shall take such corrective measures as necessary to avoid future contamination.

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

6.8.1 In addition to the measures referred to in 6.7 and Article 2 of Implementing Regulation (EU) 2021/279, where OFDC suspects or receives substantiated information, including information from other control authorities or control bodies, that a product, which may not be in compliance with Regulation (EU) 2018/848, is intended to be imported from a third country for the purpose of placing that product on the market within the Union, but which bears terms referring to the organic production, or where OFDC has been informed by an operator of a suspicion of non-compliance in accordance with Article 27 of that Regulation:

(a) it shall immediately carry out an investigation with a view to verifying compliance with Regulation (EU) 2018/848 or with the delegated or implementing acts adopted pursuant to that Regulation; such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case;

(b) it shall prohibit the import from that third country for the purpose of placing the product concerned on the market within the Union as organic or in-conversion product pending the results of the investigation referred to in point (a). Before taking such a provisional decision, OFDC shall give the operator an opportunity to comment.

6.8.2 In the event that the results of the investigation referred to in point (a) of 6.8.1 do not show any non-compliance affecting the integrity of organic or in-conversion products, those products shall be allowed to be used and labelled as organic or in-conversion products.

6.8.3 OFDC has developed a catalogue of measures to be taken in case of established non-compliance. That catalogue of measures are recorded in “List of non-compliances and control measures”, which is based on the elements specified in Annex IV to Regulation (EU) 2021/1698 and cover at least:

(a) a list of non-compliances with reference to the specific rules of Regulation (EU)

2018/848 or of the delegated or implementing acts adopted pursuant to that Regulation. That list shall include, at least the non-compliances listed in Part B of Annex IV to Regulation (EU) 2021/1698;

(b) the classification of the non-compliances into three categories: minor, major and critical as set out in Part A of Annex IV to Regulation (EU) 2021/1698, taking into account at least the following criteria:

(i) the application of precautionary measures referred to in Article 28(1) of Regulation (EU) 2018/848, the practical measures referred in point (a)(ii) of Article 10(1) of Regulation (EU) 2021/1698 and the reliability of own controls carried out by the operator in line with point (f) of Article 11(1) of Regulation (EU) 2021/1698;

(ii) the impact on the integrity of the organic or in-conversion of products;

(iii) the ability of the traceability system to locate the affected product(s) in the supply chain and prohibition of importing from a third country for the purpose of placing the product(s) on the market within the Union with reference to organic production;

(iv) the response of the operator to previous requests from the control authority or control body;

(c) the measures to be applied for each non-compliance.

6.8.4 OFDC shall document the results of the investigations referred to in point (a) of Article 29(1) of Regulation (EU) 2018/848.

6.9 Additional rules on measures in the event of non-compliance

6.9.1 In the event of non-compliance affecting the integrity of organic or in-conversion products throughout any of the stages of production, preparation and distribution, for example as a result of the use of non-authorised products, substances or techniques, or commingling with non-organic products, OFDC shall ensure, in addition to the measures to be taken in accordance with 6.9.2 and 6.9.3, that no reference is made to organic production as set out in Chapter IV of Regulation (EU) 2018/848, in the labelling and advertising of the entire lot or production run of the product intended to be imported from a third country for the purpose of placing that product on the market within the Union.

6.9.2 Where the non-compliance is established, OFDC shall:

(a) take any action necessary to determine the origin and extent of the non-compliance and to establish the responsibilities of the operator; and

(b) take appropriate measures to ensure that the operator remedies the non-compliance and prevents further occurrences of such non-compliance.

When deciding which measures to take, OFDC shall take account of the nature of

that non-compliance and the past record of the operator with regard to compliance.

6.9.3 When acting in accordance with 6.9.2, OFDC shall take any measure it deems appropriate to ensure compliance with Regulation (EU) 2018/848 and the delegated and implementing acts adopted pursuant that Regulation, including:

- (a) applying the catalogue of measures referred to in section 6.8.3 of this rule;
- (b) ensuring that the operator increases the frequency of own controls;
- (c) ensuring that certain activities of the operator are subject to increased or systematic controls by OFDC.

6.9.4 In the event of serious, or repetitive or continued non-compliance, OFDC shall ensure that the operator, in addition to the measures laid down in 6.9.2 and 6.9.3, is prohibited from placing on the market within the Union for a given period products which refer to organic production, and that its certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 be suspended or withdrawn, as appropriate.

6.9.5 OFDC shall provide the operator with a written notification of its decision concerning the action or measure to be taken in accordance with this section, together with the reasons for that decision.

7. Re-certification

The certificate holder must apply for re-certification within 3 months of the expiration date of the certificate. For any reason that the certification can't be conducted in time, the application must be submitted within valid date of the certificate, with the reason of delaying which must be approved by OFDC.

8. Appeals and Compliance

If the applicant has dispute to OFDC certification decision, it can appeal to OFDC within 10 days. OFDC must handle the appeal within 30 days after the reception, and then inform the result of treatment to applicant. If the applicant still has dispute to the treatment, it can appeal to accreditation body or related authorities.

9. Exchange of information

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

9.2 OFDC shall immediately share information with the EU Commission, with other

control authorities and control bodies, and with the competent authorities of the Member States and of the third countries concerned on any suspicion of non-compliance that affects the integrity of organic or in-conversion products.

9.3 Where OFDC is notified by the Commission, after the Commission has received a notification from a Member State in accordance with Article 9 of Implementing Regulation (EU) 2021/279 as regards suspected or established non-compliance affecting the integrity of imported organic or in-conversion products, it shall carry out an investigation in accordance with 6.8. OFDC shall inform the EU Commission and the Member State that sent the initial notification (notifying Member State), using the template set out in Annex III to EU1698/2021. OFDC shall reply within 30 calendar days from the date of receiving that notification and shall inform about the actions and measures taken, including the results of the investigation and provide any other information when available and/or required by the notifying Member State.

9.4 OFDC shall provide further necessary information if requested by the notifying EU Member State.

9.5 Where operators and/or their subcontractors are subject to controls by different control authorities or control bodies, OFDC shall exchange the relevant information on the operations covered by their control activities with relevant control authorities or control bodies.

9.6 Where operators and/or their subcontractors change their control authority or control body, (when transfer in) OFDC shall request the control file of the operator concerned from the previous control authority or control body. (When transfer out) OFDC shall, within 30 days, provide to the new control authority or control body the control file of the operator concerned and the written records of controls, the status of the certification, the list of non-compliances and the corresponding measures taken by OFDC.

(When transfer in) OFDC shall ensure that non-compliances noted in the report of the previous control authority or control body have been addressed by the operators.

9.7 Where operators are subject to a traceability check and a mass balance check, OFDC shall exchange the relevant information allowing finalization of these checks.

9.8 Information to be provided by OFDC on suspected or established non-compliances on consignments

9.8.1 Where OFDC is notified by the Commission, after the Commission has received a notification from a Member State in accordance with Article 9 of Implementing Regulation (EU) 2021/2307 as regards suspected or established non-compliance affecting the integrity of the organic products or in-conversion products in a

consignment, it shall carry out an investigation. OFDC shall reply to the Commission and the Member State that sent the initial notification (notifying Member State) within 30 calendar days from the date of receiving that notification and shall inform about the actions and measures taken, including the results of the investigation and provide any other available information and/or required by the notifying Member State, using the template set out in Section X of Annex II to Commission Implementing Regulation (EU) 2021/279.

9.8.2 OFDC shall provide any further information requested by a Member State as regards additional actions or measures taken.

OFDC shall make available, without delay, the list of all operators or groups of operators in the organic production chain of which the consignment is part, and of their control authorities or control bodies to the Commission or a Member State when requested by them.

9.9 After its recognition, OFDC shall notify the Commission in due time, and not later than within 30 calendar days, of the occurrence of changes to the content of its technical dossier, including the new witness audit reports referred to in Article 3(3a) of (EU) 2021/1698.

Annex 1: Inspection Implementation (EU)

1 Inspection arrangement

OFDC has three types of inspection, including the routine inspection, additional inspection and unannounced inspection.

1.1 Arrangement of routine inspection

In December of each year, the Inspection Dept. must make the routine inspections plan for next year of all the certified operators, send the application form, questionnaire and other files to the operators for re-certification, inform each operator 4 months before the expiration date of the certificate, and remind the operator for more times within 3 months before the expiration date.

The inspection procedure is specified OFDC Product Certification Inspection Procedure.

1.2 Arrangement of Post-certification Supervision

There are two types of post-certification supervision, including announced inspection and unannounced inspection. The announced inspection is used for on-site verification according to OFDC Procedure for Suspension, Withdrawal, Rejection and Cancellation of Certification. The unannounced inspection is used for random sampled or specified unannounced inspection according to OFDC Guidance on Organic Certification Risk Management.

1.2.1 Arrangement of additional inspection

- a) In the following situations, the Certification Dept. may decide to arrange additional inspection:
 - 1) The certified operator applies for extending/reducing certification, and the Inspection Dept. consider additional inspection is needed to be arranged for verification.
 - 2) Immediately after weeding in spring there shall be unannounced visits to verify that the use of plant protection products can be excluded for risky plants. Soil samples can be taken where appropriate, which should then be analyzed in an appropriate laboratory.
 - 3) At the same time samples of the products in question of the first spring production (raw material production) shall be taken during an inspection at each processing plant buying the product in question and shall be analyzed for plant protection products.
 - 4) The same shall be repeated immediately after weeding in summer.
 - 5) If there is parallel production/processing exist in the farm or processing plant.

- b) In the following situations, the Certification and Accreditation Dept. must decide to arrange additional inspection to the certified operator:
- 1) OFDC CC considers that information from the inspection or corrective actions to non-conformities are not enough, and additional inspection is needed for verification;
 - 2) Significant changes occurred in the certified operator, and OFDC CC considers that additional inspection is needed for verification;
 - 3) When the compliance of the operation is in doubt or for other valid reasons, OFDC must conduct additional inspections according to requirements for related authorities.

The Certification and Accreditation Dept. decides the additional inspection time, and inform the Inspection Dept. to arrange additional inspection.

- c) The additional inspections can be conducted as announced or unannounced inspections. The Inspection Dept. is responsible for assign inspector for the additional inspection. The fees for additional inspection can be paid by the operator or OFDC. The inspection procedure is specified in OFDC Product Certification Inspection Procedure.

1.2.2 Arrangement of unannounced inspection

- a) The Certification Dept. shall establish annual unannounced inspection plan in Dec. of every year or Jan. of next year, and inform the Inspection Dept. to arrange the unannounced inspection in beginning of each year.
- b) The annual unannounced inspection plan shall be established according to OFDC Guidance of Unannounced Inspection based on different risk levels described in OFDC Guidance on Organic Certification Risk Management.
- c) For operator that was found any of the following situations, the Certification and Accreditation Dept. must add the operator in the unannounced inspections plan, and inform the Inspection Dept. to arrange the unannounced inspection before expiration date of the certificate:
 - 1) The products of the certified operator may not be able to constantly compliant with standards, technical criteria or related laws/regulations; or
 - 2) The operation of the certified operator may not be able to constantly compliant with main requirements in standards; or
 - 3) The certified operator is complained, and OFDC accepted the compliance and decide unannounced inspection is needed for investigate for the compliance;
 - 4) Other situation that may not in line with OFDC certification requirements, and may affect the certification status of the operator.

1.2.3 Requirements on sampling and testing in unannounced inspection

Samples may be taken during unannounced inspection for residue test. Samples can be product, plant tissue (such as leave), and/or soil. The items for residue test shall be decided by inspector based on risk evaluation. Besides the routine test items, the following plant protection products (but not limited to) that are not authorized under EU organic farming legislation shall also be tested: glyphosate, benzalkoniumchlorid (BAC), didecyldimethylammoniumchlorid (DDAC), endosulfan, cyromazin, acetamiprid, biphenyl, cyalotrin or cyhalothrin, fenvalerato, esfenvalerato, cypermethrin, imidacloprid, hexachlorobenzene, isofenphos-methyl, aldicarb.

1.2.4 OFDC assigns staff for communication with EU and accreditation/evaluation body for any major findings in the unannounced inspections.

2 Inspector allocations

2.1 The allocated inspector's specialty shall match the related inspected units. Lack of related experience of some inspection due to technique complexity, technical experts can be allocated to the inspection with inspectors.

2.2 Before inspection, the applicant/operator has right to know the identity of inspector, but has no right to select inspector or make some recommendations on inspector allocation. If finding some potential conflict interest, the operator has the right to refuse the inspector. This must be reported to Inspection Department I in written documentation.

2.3 It is the responsibility of the inspector to reject any inspection allocated when:

- a) The allocated items go beyond its inspection capacity;
- b) The inspector has a conflict of interests with the applicant/operator to be inspected;
- c) The inspector is unable to carry out the inspection within the scheduled period.

2.4 The inspector is not allowed to be assigned to inspect the same operation more than 3 consecutive years.

2.5 In order to ensure a complete and accurate inspection, the Inspection Dept. I should provide inspectors with complete files to do sufficient preparation. The documents to be provided shall include the inspection report and certification decision letter of previous year, questionnaire and other certification documents submitted by the applicant, and other files required by certification.

3 Inspection Plan

3.1 Arrangement of Inspection Time

- a) The inspection time shall be arranged in the proper period during production/processing period, thus implying that the inspection shall be carried out when grounds, premises, and activities subjected to compliance requirements may be observed. The detail date of inspection must be discussed by the inspection team and applicant. In cases of agricultural operations, the

timing of on-site inspection shall take place during the production season. This period begins as soon as all operations subject to inspection (seeding, tapping, etc.) begin and ends with the packaging or placing in containers for storage of products to be certified. In cases involving processing operations, on-site inspections may be carried out any time during the year. For operator that conducts both production and processing, and are not able to be conducted in one inspection, the production and processing must be inspected respectively.

- b) The frequency of inspections must be decided according to product and/or risk. For example, if the farm produces several seasons of crops within one year, the inspections may arranged in each crop production season, so that additional inspection may needed to be arranged after initial routine inspection conducted.
- c) Special requirements for high risk
 - 1) In order to avoid contamination or commingling to organic products, OFDC must verify whether the operator has definite files to identify certified and un-certified products in all points of producing, processing, storing and trading. If the certified and un-certified products are not able to be identified clearly, the operator must take necessary measures to prevent contaminations or commingling during and after harvest.
 - 2) In cases of intensive production, highly depending on outside inputs, and short production cycle, OFDC must increase inspection frequency to reduce risk of certification.
 - 3) In case of double or multiple certifications in one production scope, OFDC must require a clear record of sales, labeling, and TC (if applicable) of different certification programs, which must be reviewed to avoid any risk of selling un-certified products as certified products.
 - 4) The inspection could be arranged at following critical seasons, according to production conditions and risk evaluation of the inspected operator.
 - Sowing seasons; or
 - Fertilization using seasons; or
 - Pest/disease/weeds control seasons; or
 - Crop harvest seasons; or
 - Parallel production/processing seasons.

3.2 Inspection Scope

- a) The inspection scope covers all the points including production, processing and packaging of the operator. If some of the activities are subcontracted to other supplier, the subcontracted supplier must also be inspected, according to OFDC Guidance for Sub-contracted Operation for Certified Operator.
- b) The inspection scope shall be decided on the basis of risk analysis, cover the

production fields of the farm, growing crops, processing unit, building, or site (including vehicles) where production or preparation of agricultural and food products are carried out, and production/processing process, etc.

- c) For those products that needed to be repackaged or divided outside of the production/processing site, the place for repackaging or dividing must be inspected as well to ensure organic integrity.
- d) For CGG production, the inspection scope must be designed according to requirements in OFDC CGG Certification Guidance.

3.3 Change of Inspection Time and Inspection cancellation

- a) When the inspection has to be cancelled due to the absence of applicant/operator, or insufficient preparation for inspection, the applicant should contact the Inspection Dept. as soon as possible to adjust the inspection time.
- b) If an applicant/operator has postponed annual inspection several times for no reason, the Inspection Dept. should inform OFDC Certification Committee, who may adopt the procedure of suspending and withdrawing certification.
- c) The following reasons may be considered for the change of inspection timing, and the inspectors and/or applicants must submit written explanations, including reasons and advices to Inspection Dept.:
 - 1) The inspector has carried out necessary procedure, made inspection preparation or gone for inspection, while the applicant or certificate-holder cancels the inspection because of subjective/objective reasons; or
 - 2) The inspector consider the inspection time must be adjusted so as to arrange an more appropriate time; or
 - 3) The operation has been inspected at the same time of the year for more than 3 consecutive years; or
 - 4) Natural disasters and foreseeable conditions.

Inspection Dept. determines whether change inspection time considering the written explanations, and informs the inspector, applicants and/or operators for the change of inspection time after approved by the director of Inspection Dept.

- d) The Inspection Dept. shall keep every inspection allocation and cancellation in the file.

Annex 2: EU Guidelines on Additional Controls on Organic Products originated from China

DG AGRI has, together with the Organic Production Committee, assessed the information in the Organic Farming Information System (OFIS). This has led to the conclusion that in 2025 increased control and reporting measures are necessary for certain imported products.

The present letter is therefore addressed to all control authorities and control bodies recognised in accordance with Article 46 of Regulation (EU) 2018/848 (1) and listed in Annex II of Commission Implementing Regulation (EU) 2021/1378 (2).

1. SCOPE OF THE ADDITIONAL CONTROL MEASURES

1.1. Concerned products

The reassessment of the risk of occurrence of non-compliances² has led to the conclusion that additional control measures will have to be applied. This means that from 1 January 2025 until 31 December 2025 at least the following increased control measures as regards products originating in and imported directly from one of the countries below or via another third country are necessary to ensure compliance of products with Article 45 of Regulation (EU) No 2018/848.

These control measures are without prejudice to the basic obligations to carry out a minimum percentage of additional controls and take a minimum number of samples based on a risk assessment.

These additional control measures have to be applied exclusively to the following products and the operators producing, preparing, trading, storing or exporting organic food and feed with the following CN-codes:

Country	Product	CN-code	Taric subheadings (where applicable)	Sampling percentages
China	Ginger	0910 11 00 – Neither crushed nor ground 2006 00 10 – Ginger, preserved by sugar		10%
China	Peanuts	1202 42 00 – Shelled,		10%

		whether or not broken		
China	Pumpkin seeds	ex1207 99 96 – pumpkin seeds, whether or not broken ex1209 91 80 - pumpking seeds, of a kind used for sowing ex1212 99 95 - pumpkin seeds, fit for human consumption	10	10
China	soy	2304 00 00 - Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of soya-bean oil		10%
China	Tea	0902 10 00 – Green tea (not fermented) in immediate packings of a content not exceeding 3 kg 0902 20 00 – Other green tea (not fermented) 0902 40 00 – Other black tea (fermented) and other partly fermented tea		20%

1.2 Sampling percentages

For the products defined in section 1.1, the control authorities and control bodies should carry out additional sampling for consignments applying the minimum sampling percentages as stipulated in the table above, for the products in the abovementioned list.

2. NATURE OF THE ADDITIONAL CONTROL MEASURES

2.1. Sampling and analysing for presence of non-authorised substances

For consignments of products sampled according to the percentages defined in section 1, the control body should take at least one representative sample of the consignment. Sampling should be done by using the methods as described in Commission Regulation (EU) No 691/2013 on the sampling methods to be used for official control of feed and Commission Directive 2002/63/EC establishing

Community methods of sampling for the official control of non-authorised substances in and on products of plant and animal origin. These samples should be analysed for the presence of non-authorised substances in a laboratory accredited to the analytical methods used. The analytical methods to be used should cover all the relevant non-authorised substances, including ethylene oxide, as defined by expert knowledge. This implies that, inter alia, the appropriate specific analytical methods – including single-residue methods where relevant – should be applied to detect non-authorised substances. The results of the analysis or the tests carried out on the samples taken should be included in the sampling report and contain the identification of the consignment: lot number and, when available, number of the certificate of inspection (COI). The control body shall not issue the certificate of inspection before it has received and assessed the result of these analyses. The sampling report of a consignment should be introduced in TRACES. Please bear in mind that, according to Article 5(2) of Regulation 2021/2306, sampling results have to be uploaded in TRACES along with commercial and transport documents. This information, among the information to be submitted in the Annual Report mentioned below, will be used for the supervision by DG AGRI.

2.2. Controls

a. The control body or control authority should carry out 2 physical inspections per year of each operator involved in producing, preparing, trading, storing or exporting organic products listed under section 1 it intends to certify. One of these inspections shall be unannounced.

b. On a farm that is certified for the first time, the control authority or control body should carry out the first inspection of each parcel before cultivation measures on that parcel in order to be able to certify the product.

c. The control body or control authority should take at least one field crop sample each year at each operator as defined in point a. The sample shall be taken from crops in the field, at the most appropriate moment to detect the potential use of non-authorised substances according to expert knowledge. The sample should be analysed as set out in point 2.1. For operators not growing crops, a relevant sample of incoming raw material, intermediate product or processed product should be taken.

d. The control body or control authority should pay utmost attention to the verification of the product flows and traceability established by each operator as defined point a. It should also verify the quantities harvested and/or prepared, the means of storage and transport of the goods, including the possible application of non-authorised substances at these stages.

e. The control body or control authority should analyse in depth the

bookkeeping and financial documentation of each operator as defined in point a, for which it intends to certify products. The control body or control authority must systematically verify the destination of all the products harvested and/or prepared at the farm it certifies, regardless whether these crops are sold as organic or not or are exported or not. This includes the quantities and the names of the buyers.

f. As stipulated in article 4 of Delegated regulation (EU) 2021/2306. The control body or control authority shall issue the certificate of inspection before the shipment leaves the third country of origin or of export.

g. Before issuing the certificate of inspection, the control body or control authority shall carry out systematic documentary checks in accordance with Article 3 of Delegated Regulation (EU) 2021/2306 verifying:

- a) the traceability of the products and ingredients;
- b) that the volume of the products included in the consignment is in line with the mass balance checks of the respective operators according to the assessment carried out by the control authority or control body;
- c) the relevant transport documents and commercial documents (including invoices) of the products;

At simple request, the control body or control authority shall send this traceability documentation to the control body of the importer concerned and to the Competent Authorities of the importing country. In case of a complex supply chain a transparent flow chart shall be added to that documentation unequivocally presenting both the flow of the goods and the financial flow.

At least points a) and c) should also be applied to new and other operators who cultivate fields that are in conversion to organic farming.

3. EXCHANGE OF INFORMATION

Where operators and/or their subcontractors change their control body, the new control body shall verify and ensure that non-conformities noted in the control file forwarded by the previous control body have been completely and effectively addressed by the operator.

The control bodies have to carefully evaluate the situation where a certification decision on such an operator has to be made. DG AGRI will take all necessary supervisory actions to ensure that control bodies have done this effectively.

4. REPORTING

In accordance with Article 3 of Commission Delegated Regulation 2021/1698 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with procedural requirements for the recognition of control authorities and

control bodies that are competent to carry out controls on operators and groups of operators certified organic and on organic products in third countries and with rules on their supervision and the controls and other actions to be performed by those control authorities and control bodies(14), the Commission services request the implementation of these recommendations to be documented and made available in a report.

This report shall be included in the annual report referred to in Article 4 of Delegated Regulation 2021/1698 and include at least the following information:

1. The list of the operators under your control in the countries mentioned above.
2. For each operator and for the period starting on 1 January 2025 and ending on 31 December 2025:
 - a. the inspections carried out, indicating the date of each inspection;
 - b. the sampling and analyses carried out;
 - c. the non-compliances found;
 - d. the corrective measures and/or sanctions applied;
 - e. the Certificates of Inspection signed;
 - f. for each operator who changed its control body, the corrective measures and/or sanctions applied if non-conformities were noted in the report of the previous control body.
3. As regards consignments subject to the additional official controls in accordance with this letter:
 - a. COI reference for imported consignments;
 - b. overview of sampling analysis results which indicate presence of non-authorised substances, if any;
 - c. investigations and follow-up measures taken by the control body in case of non-authorised substances found in the consignment, including the decision concerning the consignment e.g. downgrading the consignment to conventional, not issuing a COI etc., as well as confirmation that the operator has taken corrective measures.