



## OP 5: INSPECTION PROCEDURE

### Part 1: Relevant definitions

#### EU 178/2002 Article 2

**Definition of 'food':** For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products within the meaning of Council Directives 65/65/EEC ( 1 ) and 92/73/EEC ( 2 );
- (e) cosmetics within the meaning of Council Directive 76/768/EEC ( 3 );
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC ( 4 );
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- (h) residues and contaminants;
- (i) medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council ( 5 ).

#### EU 178/2002 Article 3

**'feed' (or 'feeding stuff')** means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

#### Regulation (EC) No 767/2009 article 3 (2)

**(g) 'feed materials'** means products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether

or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures.

**(EC) No 852/2004 Article 2(1)**

**(m) ‘processing’** means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;

**(n) ‘unprocessed products’** means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;

**(o) ‘processed products’** means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

**EU 2018/848 article 3 (49) ‘traceability’** means the ability to trace and follow food, feed or any product referred to in Article 2(1), and any substance intended or expected to be incorporated into food, feed or any product referred to in Article 2(1), through all stages of production, preparation and distribution.

**Inspection Procedure:**

**Part 2: General:**

For food or feed processors, inspections will be scheduled when organic product &/or process can be verified. For first time applicants, procedures and facilities should be verified in order to assess their preparedness for organic certification.

High risk operations or operations with high-risk product as determined by GCS in its risk policy or risk assessment matrix must receive two or more audits per year (see Additional and unannounced audits).

**Part 3: Inspection Process (This applies to all inspections including for first time applicant and annual re-inspection(s))**

**Part 3.1 Procedure - Opening Meeting:**

Inspector shall conduct an opening meeting before initiating the inspection and confirm the audit plan with the operator. Signatures of all members, client and audit team, shall be taken on Opening meeting.

An opening meeting is an opportunity to discuss followings, but is not limited to:

1. Introductions



2. Purpose of the Audit
3. Scope of the Audit
4. Audit Criteria
5. Audit Plan Overview
6. Expected Outputs (Non-conformities (NCs), Observations, Opportunities for improvement, Final report timeline, closing meeting time etc.)
8. Rules and Expectations (Freedom to access locations, documents and personnel, Permission for photos, if required, Health and safety requirements of the site, No interference with the audit, etc.)
9. Confidentiality & Impartiality Statement
10. Questions & Confirmation

The inspection action is the means by which the field visit or organic production plant is carried out in order to verify the content of the application, production records and evaluation of the entire operation; and to assess that the information provided by the operator conforms to the standards, accurately, truthfully and completely.

Inspection shall take into account the requirements for EU 2018/848 and its delegated acts and that the operators comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation.

GCS maintains records of the selected inspector to conduct on-site inspection. No inspector will inspect the same operation for more than two consecutive years.

The procedure for an initial operator is that GCS will make a first inspection if the application proves that the operator appears to meet or will be able to meet the requirements.

GCS's inspectors while inspection shall apply the following control methods and techniques:

(a) Verification that the maps or sketches, including cardinal directions and geo-location of production units and premises to be physically inspected, as provided by operators, are up-to-date.

(b) Inspection of the following, as appropriate: (i) Production units, equipment, means of transport, premises, and other places, including units used for non-organic products, under the control of the operator. (ii) Goods (including semi-finished goods), raw materials, ingredients, processing aids, and other products used for preparation and production of goods, or for feeding or treating animals, including substances authorized for use in organic production. (iii) Traceability, labelling, presentation, advertising, and relevant packaging materials.

- (c) Examination of documents, traceability records, and other relevant records, practices, and procedures for assessing compliance with Regulation (EU) 2018/848, including documents accompanying food, feed, and substances entering or leaving an establishment.
- (d) Interviews with operators and their staff.
- (e) Sampling and laboratory analysis. (min. sampling rate- 5% of all operators)
- (f) Examination of the control systems implemented by operators, including an evaluation of their effectiveness.
- (g) Review of non-compliances identified in previous inspections and the corrective measures taken by operators.
- (h) Any other actions necessary to identify cases of non-compliance.

**Inspections should verify as a minimum:**

- (a) Verification of the application of preventive and precautionary measures at all stages of production, preparation, and distribution.
- (b) For holdings with non-organic or in-conversion production units, GCS verifies records and ensures effective separation between organic, in-conversion, and non-organic production units. This includes checking parcels retroactively recognized as part of the conversion period and inspecting non-organic units.
- (c) Where organic, in-conversion, and non-organic products are handled simultaneously, GCS verifies that procedures ensure separation by time or place, suitable cleaning measures are implemented, and traceability is maintained from land parcels to collection centres.

Inspections shall include a traceability check and a mass balance check of operators. These checks will be conducted through a review of documentary accounts and any other relevant elements deemed necessary by GCS.

Traceability and mass balance checks, exclusively for EU 2018/848 and as per EU 2021/1698 & EU 2021/771:

- 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.
- The formula for the number of products to be picked up for traceability is the square-root of the number of products transacted within the last certification cycle, rounded off to the nearest whole integral number. For example, if 10 different products are transacted/ sold as organic, at least '3' products will be picked up for the traceability exercise.



- The time required for traceability and mass balance exercise shall be considered under the audit planning.
  - If there is a high-risk product which is transacted within the last certification cycle, it will be given priority to be picked up for traceability.
  - Where the number of total products transacted in the last certification cycle is equal to or less than 6, one sample can be picked up for the traceability checks.
- The traceability check shall cover at least the following elements justified by appropriate documents including stock and financial records:
  - The name and address of the supplier and, where different, of the owner or the seller, or the exporter of the products.
  - The name and address of the consignee and, where different, of the buyer or importer of the products.
  - The certificate of the supplier in accordance with Article 35(6) of Regulation (EU) 2018/848.
  - The information referred to in the first paragraph of point 2.1 of Annex III to Regulation (EU) 2018/848.
  - The appropriate lot identification.
  - For processors, the necessary information to allow internal traceability and guarantee the organic status of ingredients

Where relevant\*, the mass balance check shall cover at least the following elements justified by appropriate documents including stock and financial records:

\*Mass balance might not be required for warehouse operations which does not have ownership of the product.

- 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.
- The nature and the quantities of products held in storage at the premises.
- The nature and the quantities of the products that have left the unit of operator to the consignee's premises or storage facilities.
- 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
- The yield of the products obtained, collected or harvested over the previous year.



- The actual yield of the products obtained, collected or harvested over the current year.
- The number and/or weight in case of livestock managed over the current and previous year.
- Any losses, increase or decrease in quantity of products at any stage of production, preparation and distribution.
- Organic or in-conversion products that are sold on the market as non-organic.

The field inspection focuses on the production, processing and marketing phase, with emphasis on technical, administrative and organizational aspects. It verifies the operation's compliance or ability to comply with specific regulations; that the information, including the application for the organic production system, accurately reflects the practices used or to be used by the applicant; that no prohibited substances have been applied and are not being applied to the operation.

In addition, on the basis of risk assessment, samples of soil, water, vegetative tissue, waste, seeds and fertilizers may be taken for laboratory analysis, if warranted (refer: Sampling Policy and Procedure - GCS\_EU\_069). Sample may also be taken if inspector is suspicious of any activities at the operator's site. Reason of sampling should be documented.

For a new applicant, the first inspection gives an outcome of an opinion that specifies the production and processing and establishes the missing conversion period and corrective actions to be taken before certification as organic.

### **Part 3.2 Multiple Production Units**

If operators manage multiple production units, including purchase and collection centres, all units are subject to inspection, including any unit handling in-conversion or non-organic products within the same holding.

### **Part 3.3 Procedure - Closing Meeting**

At the end of the inspection, a closing meeting is held with the operator or legal representative and the inspector to confirm the accuracy and completeness of the scope of the inspection observations and information gathered during the production unit inspection.

The inspector should also address the need for additional information as well as any issues of concern along with clear rime line to submit the response or a corrective action by the operator and any consequence of not submitting the corrective actions in given time frames.

Sanctions and measures should also be discussed in brief, with clear description on different kind of non-compliances (minor/ major/ critical/ OFI).

The operator should sign the inspection report for acceptance and take appropriate corrective action and submit a time-bound compliance schedule.

**Note for maintenance of certification/ re-inspection:** GCS mandates at least one annual inspection for each client to ensure ongoing compliance. It is required that clients initiate the certification renewal process at least three months before certificate expiry. Delays beyond certificate expiry are not acceptable.

### Part 3.4 Risk-based Controls

Along with the annual controls and minimum controls, GCS conducts additional controls like additional inspection, unannounced inspection and additional sampling based on the risk assessment of operators.

Controls are conducted regularly on a risk basis and with appropriate frequency throughout all production, preparation, and distribution stages. Factors determining the likelihood of non-compliance include:

- a. Type, size, and structure of the operators, including newly added land parcels.
- b. Location and complexity of operations.
- c. The duration of the operator's involvement in organic activities.
- d. Results of previous inspections and compliance records.
- e. Whether the holding includes non-organic or in-conversion units.
- f. Type, quantity, and value of products handled.
- g. Risk of product commingling or contamination with non-authorized substances.
- h. Application of derogations or exceptions to the rules by operators.
- i. Identification of critical points for non-compliance at any stage.
- j. Subcontracting of activities.
- k. Changes in certifying authority by operators.
- l. Potential for misleading consumers.
- m. Any indications of non-compliance with Regulation (EU) 2018/848.
- n. Risk based traceability and mass balance checks
- o. OFIS cases
- p. history of derogations
- q. High-risk products
- r. History of non-compliance

### Project risk calculation methodology:

- i. If all risk factors are in low category than overall risk category of operation is low.
- ii. If 1 or 1 – 15 risk factors are in medium category than overall risk category of operation is medium.
- iii. If more than 15 risk factors are in medium risk category than overall risk category of operation is high.
- iv. If 1 – 5 risk factors are in high-risk category than overall risk category of operation is medium
- v. If more than 5 high-risk factors, then overall risk category is high

For risk category of consignments, please refer GCS\_EU\_020 - Traces and Controls on Consignment-EU.

Certification delivery or renewal will be based on the results of GCS's compliance verification as outlined in this procedure. Any other controls like additional inspections/ unannounced inspections/ investigation inspections/ follow-up inspections/ sampling are also reviewed by GCS and the certification is continued only if the results are in compliance with EU 2018/848 and its delegated acts.

### **Part 3.4.1 Additional Controls**

#### **Criteria:**

GCS must conduct additional or unannounced inspections considering risks identified by GCS inspectors.

Also. Before issuing COI, GCS verifies that whether there is a bulk transaction or high-risk product or where there are several operators involved in the distribution chain of the products who do not store or physically handle organic products, or any other criteria deemed relevant. And if answer of any of these is yes, GCS conducts a physical verification of the consignment. Please refer GCS\_EU\_020 - Traces and Controls on Consignment-EU for detailed checks on consignments and issuance of COI.

#### **Additional & unannounced inspection:**

GCS uses a risk-based approach for selecting operators for unannounced inspections, assigning risk scores (High, Medium or Low). An on-site assessment is conducted, with duration depending on the identified risk.

For projects with high-risk products, GCS performs at least two on-site inspections annually, one of which is unannounced.



An Unannounced inspection should not include prior notification of the inspector's arrival. Inspectors should not enter private property without explicit permission from the operation. It is recommended that they have proper identification and an inspection warrant to show that they are acting on behalf of GCS.

Unannounced inspections are considered annually during the period of validity of a certificate for both operators applying for certification for the first time and operators applying for recertification.

## Important Notes

- All operators are subject to annual inspections to verify compliance.
- Follow-up inspections for non-compliance do not count towards additional or unannounced inspection requirements.
- Any deviations found during additional or unannounced inspections are addressed similarly to those discovered during annual inspections, with non-conformance raised as needed.
- Presence during Inspections: All on-site inspections must be conducted when an authorized representative with knowledge of the operation is present. Inspections and sampling are timed to coincide with critical activities demonstrating compliance with organic standards, except in the case of unannounced inspections.
- Of the total number of operators with high risk, 100% will be selected even if more than 10% of operators exceed 10% for additional inspections.
- The 10% of operators at risk will be distributed between the 2 categories (High and Medium) mentioned above, starting with High-risk operations.
- In the absence of operators with high or medium risk factors, at least 10% of the organic operator population will be randomly selected for additional inspection.

GCS conducts additional inspections for 10% of certified operators annually.

Of all physical on-the-spot inspections carried out by the control authority or control body, at least 10 % shall be without prior notice. (unannounced).

For instance, if there are 100 certified operators, there will be 100 annual inspections, 10 additional inspections, and at least 11 unannounced inspections based on risk.

### **Part 3.4.2 Additional Sampling requirements:**

Inspector should do sampling as required by the regulation.

Annual sampling rate is at least 5% of its all operators, based on the risks of the operators. 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.

In addition to the minimum sampling rate set above, GCS shall take and analyse samples in each case where the use of non-authorized products and substances or techniques for organic production is suspected, unless it considers that sufficient evidence is available without sampling.

For the high-risk products referred to in article 8 of Regulation (EU) 2021/1698, GCS shall take, in addition to the 5 % sampling rate a relevant sample of incoming raw material or intermediate product or processed product shall be taken.

For EU 2018/848, these additional control measures have to be applied exclusively to the products and the operators producing, preparing, trading, storing or exporting organic food and feed with the following CN codes\*:

Country	Product	CN-code	Sampling percentages

\*the list to be updated based on the 'Letter to control bodies and authorities on the import of organic products from certain countries' updated by DG Agri time to time [here](#).

Follow-up of the Analysis carried out by the Inspector.

**Part 3.5 Investigation inspections**

GCS carries out inspections and investigative audits immediately after receiving confirmed information or suspicions of non-compliances or about the presence of prohibited products or substances in organic production from other certification agencies, competent authorities or operators, or when the presence of unauthorized substances has been detected during residue analysis carried out by GCS.



An announced or unannounced inspection of the suspect area is performed by an experienced inspector, other than the one who performed the last inspection. This is determined by the quality manager/ certification manager.

GCS during the investigation period, which must be reasonable and taking into account the durability of the product and the complexity of the case, will provisionally prohibit the marketing of the product in question and its export until it has the results of the investigation.

In the event that the results of the investigation do not reveal any non-compliance affecting the integrity of the organic or in-conversion products, the use and labelling of such products as organic or in-conversion products shall be permitted.

In the event that the operator has been found to have used prohibited products or substances, failed to take the necessary preventive measures and/or failed to take corrective action in response to previous non-compliance, the product shall NOT be marketed as organic or in-conversion or used in organic production.

GCS will document the results of the investigations in the Operator's file. The results will be shared with the operator and the operator will be given the opportunity to comment, and if necessary, the operator will be required to take the necessary corrective actions and respond to the non-compliance finding.

The inspector will follow the procedure for investigative inspections and submit the report following the normal procedures, which will be evaluated by an assessor, or if necessary and depending on the complexity of the case, by GCS's technical team.

GCS will ensure to respond and follow up with the inspection bodies and/or inspection authorities concerned by the non-compliance. Likewise, the Organic Farming Information System (OFIS) will be used for the exchange of information with the Commission, with other control authorities and other control bodies, as well as with the competent authorities of the Member States and third countries concerned to notify the results of the investigation.

### **Part 3.6 Non-Conformance**

GCS can raise a non-conformance at any stage of certification, including but not limited to, while annual inspection, additional inspection, unannounced inspection, investigation inspection, result of OFIS notices, etc. A non-conformance can also be raised as a result of sampling and testing.

Operator is required to submit corrective actions in given timeframe which are subject to be reviewed by GCS.

Certification delivery, renewal, and validity depend on the results of any of the above controls activity.

**Relevant Documents:**

- Procedure - Opening Meeting - GCS\_EU\_049
- Procedure - Closing Meeting - GCS\_EU\_050
- Sampling Policy and Procedure - GCS\_EU\_069
- Procedure - Catalogue of Measures - GCS\_EU\_071
- Audit Plan - GCS\_EU\_048
- Sample Slip - GCS\_EU\_070
- Opening & Closing Meeting Attendance - GCS\_EU\_051
- Inspection Checklist - Category D (Processed Food) - GCS\_EU\_055
- Inspection Checklist - Category E (Livestock Feed) - GCS\_EU\_056
- Inspection Checklist – observation sheet (Cat D, Cat E) - GCS\_EU\_056a
- Risk Assessment Checklist Processing (Food & Feed) - GCS\_EU\_060
- Investigation Report Format - GCS\_EU\_083
- Procedure - Mass Balance and Traceability - GCS\_EU\_061
- Mass Balance & Traceability – Production - GCS\_EU\_062
- Mass Balance Verification Sheet - EU Processing & Handling - GCS\_EU\_063
- Traceability Audit Sheet - EU Processing & Handling - GCS\_EU\_064