Global Certification and Monitoring Services

Organic Certification Procedure

QMS-03, version 5 Approved 2026/01/06

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GENERAL

This document was prepared by Global Certification and Monitoring Service Group (hereafter GCMS Group) and states the EU-Organic certification procedures for a third country (outside the EU) to audit and certify organic operators in accordance with EU organic regulations.

All certification activities are conducted in compliance with the following list of requirements:

- European Regulation **(EU) 2018/848** on organic production and labelling of organic products.
- European Regulation **(EU) 2021/1698** on 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.
- European Regulation **(EU) 2021/279** on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products.
- **ISO/IEC 17065: 2012** Conformity assessment — Requirements for bodies certifying products, processes and services.

1. Scope of Certification and Product Categories

The scope is defined following EU classification of organic products as defined in Regulation (EU) 2018/848. GCMS certifies operators that may be individual farms, processors of organic agricultural products, following the classification of the regulation:

(a) Unprocessed plants and plant products.

(d) Processed agricultural products.

GCMS Organic certification guarantees that operator of Unprocessed plant products and Processed Products, uses only permitted ingredients and processing aids, with at least 95% organic agricultural ingredients, no GMOs, and processing methods respecting organic principles. Segregation from non-organic products is maintained and cleaning measures are in place to prevent contamination.

2. Operator Application and Registration Process

2.1 Application Submission:

Potential organic operators must apply to the GCMS website for organic certification of their activities. GCMS provides an **Application Form** for applicants to fill in. This form captures essential information about the operator and serves as a signed declaration by the operator. The application form includes:

- **Operator Information:** Name of the operation (farm or company), legal status, address, contact details, and responsible person.
- **Scope of Activities:** Description of the operation's activities and facilities, including a description of the production unit(s). The operator details what they produce or process – e.g. types of processed foods– and whether any non-organic units exist in parallel. Maps or schematics of the production sites may be attached for farms or facilities.
- **Organic System Plan:** An overview of how the operator will ensure compliance. This includes the measures and procedures in place to meet the organic production rules. For example, the operator describes pest management strategies, input materials (fertilizers, additives, etc.), cleaning protocols for equipment, and how organic and non-organic products are kept separate. Precautionary measures to prevent contamination by prohibited substances are outlined.
- **Product Details:** A list of products or product categories for which certification is sought (e.g. "organic canned vegetables). For each, the operator may indicate if the product is already in conversion or fully organic, and the size/volume of production.
- **Previous Certification and History:** The operator must declare if they have previously been certified organic or if they are currently certified by another body for the same activities. Operators **cannot be certified by more than one control body for the same product category in the same country**, so any prior certification (including recent withdrawal or suspension) must be disclosed. If they had a previous certifier, they provide details and agree to allow transfer of their certification history.
- **Subcontracted Activities:** The operator lists any subcontractors (e.g. for processing or storage) and provides details of those facilities. They must indicate if those

subcontractors are certified under an equivalent organic standard or if the operator retains full responsibility for them.

- **Operator Declarations and Commitments:** The form contains declarations that the operator must sign, committing to the organic regulations. Key commitments include:
    - Abiding by Regulation (EU) 2018/848 and all applicable delegated/implementing rules for organic production.
    - **Access for Inspection:** The operator agrees to give GCMS' inspectors access to **all units, premises, and facilities**, including non-organic units, as well as to all records and accounts. This ensures GCMS can conduct thorough audits at any time.
    - **Information Provision:** The operator commits to provide any information deemed necessary for control purposes, such as purchasing records, input invoices, sales records, and internal quality test results.
    - **Notification of Irregularities:** The operator must immediately inform GCMS if they suspect a violation of organic rules or contamination in their operation or products. If a **suspicion of non-compliance** is substantiated or cannot be eliminated, or if a **proven non-compliance** affecting product integrity is found, the operator must notify GCMS and **inform buyers** of the product without undue delay. This transparency is required to protect the organic integrity through the supply chain.
    - **No Dual Certification:** A statement confirming the operator (or any member of a group, if applicable) is not individually certified by another control body for the same activities and products. This prevents duplicate certification for the same scope.
    - **Acceptance of Enforcement Actions:** The operator agrees to accept any enforcement of corrective measures or sanctions imposed by GCMS in case of non-compliance. This could include product decertification, increased inspection frequency, suspension pledge to maintain all required records (input/output records, invoices, batch records, etc.), or withdrawal of certification if necessary.

- **Record-Keeping and Traceability:** A and an internal traceability system that can trace organic products one step forward and back.
- **Changes and Updates:** The operator must inform GCMS of any significant changes (e.g. new products, new fields, changes in processing lines, changes of subcontractors) and any decision to discontinue organic certification (withdrawal). If withdrawing, they agree GCMS will keep their file for 5 years.
- **Transfer of Control File:** In case the operator switches to another control body or stops certification, they allow the transfer of their certification history (control file) to the new control body or retention by GCMS for the required period.
- **Subcontractor Agreement:** If some activities are subcontracted to third parties not certified by GCMS, the operator agrees to ensure those are either certified by an EU-recognized control body or that GCMS is allowed to inspect those subcontracted operations. The operator remains responsible for subcontracted activities unless those subcontractors are individually certified.

The document (CO01): "Commitment signed by Organic-EU operators", is a signed declaration required by GCMS prior accepting an operator into its certification system.

2.2 Application Review and Registration:

Upon receiving the completed application form and any supporting documents, the GCMS' certification staff performs an **initial document review**. In this step, GCMS verifies that:

- All required information and documents are provided (e.g. site maps, ingredient lists, input purchase records, previous certificates if any, etc.).
- The operator's described practices and inputs appear to be in line with organic requirements (no obvious non-compliances in the plan). For example, any fertilizers or additives listed are checked against approved inputs lists.
- The operator and product scope fall within GCMS accredited and recognized scope.

If the operator had prior certification, GCMS must request the **control file** from the previous control body (as per Article 21(5) of Reg 2021/1698). GCMS will examine the following information to be transmitted by the previous control authority or control body:

- 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.
- Reports of inspection carried out in the preceding 3 years.
- The list of non-compliances and the measures put in place to address them, and the fact that all non-compliances were addressed.
- Derogations granted or requests for derogation being processed by the previous control authority or control body past inspection reports, non-compliance history, and certification status before proceeding.

If the previous control body does not transmit the file or if there are unresolved doubts (e.g. outstanding non-compliances), GCMS will **not issue certification** until those doubts are resolved. Operators whose certification was withdrawn for cause in the last 2 years by another control body are **not accepted** for certification, unless the previous CB's EU recognition was itself withdrawn by the Commission. This precaution prevents operators with a recent history of critical non-compliance from hopping between certifiers.

- GCMS also checks that the operator is not listed in any EU or CB-internal registry of prohibited operators (e.g. due to fraud).

If the application is complete and satisfactory, GCMS registers the operator in its system. The operator is assigned a unique **registration/code number** under GCMS (often used on certificates and labels). At this stage, the operator is considered "in-conversion" or "applicant" status – not yet certified – until the initial on-site inspection and certification decision are successfully completed. GCMS enters the operator's details into the appropriate database/tracking system and schedules the **initial inspection**.

GCMS also conducts an **initial risk assessment** based on the application (see Section 5) to inform the planning of the first inspection. An **inspection plan** is then drawn up, and an inspector is assigned. The operator is informed of the next steps, including the timeline for inspection. In the case of crop production, the inspection will typically be timed to allow viewing the crops in the field if possible (to verify practices during production).

3. Risk-Based Planning of Inspections

GCMS employs a risk-based approach to plan and prioritize inspections in accordance with EU requirements. Regulation (EU) 2018/848 and Delegated Regulation (EU) 2021/1698 mandate that controls be carried out regularly **"on a risk basis and with appropriate frequency"**. Each operator is evaluated for the likelihood of non-compliance, and this risk assessment guides the intensity and frequency of surveillance.

3.1 Risk Assessment Procedure:

GCMS has a documented risk assessment procedure (often an Excel-based **Risk Assessment Template**) used to assign a risk level to each operator. The risk assessment considers multiple criteria as outlined by the regulation, including:

- **Nature and Complexity of Operations:** The type of activities (e.g. simple farm vs. complex processor), the number of product lines, and whether both organic and non-organic production are carried out on-site. Operations where organic and non-organic products are handled in the same facility are higher risk due to possible commingling or contamination.
- **Size and Structure:** The scale of the operation (land area, volume of output, number of sites) and organizational structure. Large or spread-out operations or groups with many members are evaluated for complexity.
- **Internal controls of the group of operators:** in the case of a group of operators, the results of the internal inspections carried out in accordance with the documented procedures of the system.
- **Product's description:** The type, quantity and value of products.
- **Experience in Organic Production:** How long the operator has been involved in organic production. New entrants may be assigned higher risk until they demonstrate compliance over time.
- **Previous Compliance Record:** Results of prior inspections and any history of non-compliances. Operators with past major non-compliances or repeated issues are higher risk. A clean compliance history lowers risk.

- **Product Risk Profile:** The type of products produced and their susceptibility to fraud or contamination. Certain products (sometimes designated by the Commission as "high-risk products") require extra scrutiny. For example, products like organic spices, exotic ingredients, or high-value commodities known to have fraud incidents are higher risk. The **risk of fraud or substitution** is considered.
- **Potential for Contamination:** The environment and location – e.g. farms in areas with intensive conventional farming might have higher risk of pesticide drift; processors handling allergenic or chemical inputs might have contamination risks. The operator's precautionary measures (cleaning procedures, testing of inputs, etc.) are factored in.
- **Mix of Production (Parallel Production):** If the operator has non-organic units or parallel conventional production of the same product, risk is higher. Complete organic operations are generally lower risk in this aspect.
- **Use of Derogations/Exceptions:** If the operator uses any authorized exceptions such as non-organic seeds due to unavailability, can elevate risk as they require careful management.

  As per article 25 of (EU) 2021/1698, before granting authorizations for the use of non-organic plant reproductive material, GCMS must assess the following information and draw up a justification for each derogation granted: Scientific and common name (common and Latin name); Variety; Total weight of seeds or number of plants concerned; The availability of organic or in-conversion plant reproductive material; and Documentation or a statement from the operator proving that the requirements set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848 have been fulfilled. Each authorization for the use of non-organic plant reproductive material, GCMS will include the relevant information in the annual report.
- **Subcontracting:** If critical steps are subcontracted to entities not directly certified by GCMS, risk increases due to less direct oversight.
- **Changes in Certification Status:** If the operator **recently changed control bodies** or joined after another CB's withdrawal, the CB treats this as a risk factor and reviews past issues carefully.
- **Supply Chain Complexity:** For processors/traders, the complexity of sourcing (many suppliers, imported raw materials, etc.) and whether there have been alerts about

suppliers or regions. Any information suggesting the **possibility of consumer deception or mislabeling** raises risk.

Using the above factors, the CB assigns a **Risk Score or Level** (e.g. Low, Medium, High). The **Risk Assessment Template** typically includes a scoring matrix for each factor, with weighted scores. For example, an operation might score points for having parallel production, for a history of non-compliance, for being new, etc., and the total score corresponds to a risk category.

3.2 Inspection Frequency and Intensity:

Based on the risk category, GCMS plans the inspection regime:

- **Annual Inspection: Every operator is inspected on-site at least once per year as required by EU law**. The annual inspection is a full **physical on-the-spot inspection** covering all aspects of the operation. This is mandatory regardless of risk level (even low-risk operators must get a yearly inspection).
- **Additional Inspections:** Higher-risk operators will receive **additional control visits** beyond the annual visit. **At minimum, 10% of all operators are subject to one or more additional inspections each year** (these may be follow-up or unannounced visits). The selection of who gets additional inspections is guided by the risk ranking: typically, all High-risk and some Medium-risk operators would get an extra visit. This fulfills the requirement that at least 10% of controls are extra controls beyond the basic annual checks.
- **Unannounced Visits: At least 10% of all inspections are conducted without prior notice**. Unannounced inspections are a critical tool to detect non-compliance when the operator is not expecting an auditor. GCMS uses risk assessment to decide which operators get unannounced inspections (e.g. high-risk operators, or as spot-checks among lower risk ones). An unannounced visit may target specific times (like during harvest or processing) or specific issues. Operators are informed at registration that unannounced inspections can occur at any time.
- **High-Risk Products:** If the operator produces a product that the EU has listed as high-risk (due to past fraud cases or residue issues), the CB will implement the enhanced frequency required by regulation. **For high-risk product operators, at least two**

inspections per year are conducted, one of which is unannounced doubling of inspection frequency provides closer oversight on those supply chains.

- **Sampling Frequency:** The risk level also influences sampling (detailed in Section 7), where higher-risk operators or products will have more frequent sampling of products for laboratory testing.

The outcome of the risk-based planning is an **Annual Control Plan** that schedules each operator's annual inspection and indicates any additional or unannounced inspections. This plan is reviewed periodically (e.g. mid-year) to incorporate new information (such as if an operator has a serious non-compliance, their risk may be upgraded leading to an extra check). The plan also ensures coverage of **at least 10% unannounced and 10% additional checks** across the CB's operator portfolio every year. These minimum percentages are tracked to meet the EU's control intensity requirements.

The risk assessment is updated **at least annually** for each operator (usually during the post-inspection review and preparation for the next year). If an operator's circumstances change significantly (e.g. expansion, a contamination incident, etc.), the CB will re-assess risk promptly and adjust the control measures accordingly.

4. Conducting Inspections (Audit Procedures)

The on-site inspection (audit) is the core activity to verify operator compliance. GCMS follows a structured inspection process covering preparation, execution, reporting, and follow-up. Inspections are conducted by qualified organic inspectors employed or contracted by GCMS, who are trained on the EU organic standards and GCMS procedures. An **Audit/Inspection Checklist** is used to ensure all relevant points are evaluated consistently.

4.1 Preparation for Inspection:

For announced annual inspections, GCMS inspector contacts the operator to agree on a date. (Unannounced inspections obviously have no prior warning; the inspector arrives on site and announces him/herself upon arrival.)

The preparation period of the inspection is fixed for two weeks minimum before the inspection date, all GCMS group inspectors must follow this rule to allow sufficient time for evaluating the operator's application dossier and collecting the necessary documents from the operator. The mandatory list of documents to be collected are mentioned below:

- **Farm map**
- **Product specification**
- **Label layout**
- **GMO-free declaration**
- **Facility map**
- **Organic system plan**

Inspectors review the operator's file beforehand, including the application details, product profiles, past inspection reports, and any prior non-compliances. This helps focus the inspection on key risk areas (e.g. if last year an issue with buffers was noted, the inspector will re-check that specifically).

The inspector prepares any equipment needed (e.g. sample containers, camera, measuring devices) and ensures he or she has the latest checklist and relevant regulatory references.

4.2 Opening Meeting:

Upon arrival, the inspector holds an opening meeting with the operator's representative. They confirm the scope of the inspection (facilities to visit, products to cover) and request an overview of any changes since the application or last inspection (new fields, new ingredients, new machinery, etc.). The inspector presents identification and explains the inspection plan for the day. If the inspection is unannounced and the needed personnel are not on-site, the inspector will proceed with whatever staff are available; the operator is obliged to allow the inspection whenever it occurs. The opening meeting sets the cooperative tone and clarifies that the inspection will cover documents and physical verification.

4.3 On-Site Inspection Activities:

The inspector uses the **Audit/Inspection Checklist** to systematically evaluate compliance. The checklist is usually divided into sections covering general information and specific organic rule requirements. Key areas include:

- **Operator Details and Certificate Scope:** Verify the basic information – legal name, addresses of sites, and that all sites/units are listed in the certification scope. Check that the operator has a valid *certificate of compliance* from the CB for the current period (for already certified operators). Ensure any changes (like new production unit) have been reported.
- **Previous Non-compliances:** Review the status of any corrective actions from the last inspection or any outstanding issues. Confirm that the operator addressed prior **non-compliances** adequately (e.g. if they were required to install a storage separation barrier or update a record-keeping procedure, verify that it has been done).
- **Inputs and Materials:** Check all inputs used or stored on the premises. This includes seeds/planting stock, fertilizers, soil amendments, pest control substances for crop production, processing ingredients, additives, and cleaning agents for processed products. The inspector cross-verifies that all inputs are permitted under organic rules (using approved input lists or the regulation Annexes). For example, no synthetic fertilizers or prohibited pesticides are present on an organic farm, and only authorized processing aids appear in a processor's inventory. Lot numbers and purchase records of critical inputs may be examined to ensure they match what was declared.

- **Production Practices:** Observe and evaluate the actual practices in the field or facility:
    - For crop production: Check crop rotation plans, soil fertility management (compost, manure use), weed and pest management practices, and whether any **non-organic units** exist on the farm. If both organic and non-organic crops are grown, verify clear separation in space or time and proper buffers between organic fields and conventional fields. Inspectors will verify that organic fields are clearly marked and that prohibited substances haven't been used (they may look for evidence like chemical containers or application equipment residues). They also verify adherence to conversion periods for new organic fields.
    - For processing (food): Examine the processing facility to ensure no commingling of organic and non-organic product. There should be clear labeling of organic raw materials, dedicated or properly cleaned equipment, and procedures to prevent cross-contamination. The inspector checks that **production runs of organic products are adequately separated in time or**

space from non-organic runs and that cleaning logs demonstrate equipment was purged or cleaned. All ingredients in an organic product recipe should be organic (or listed as allowed non-organic ingredients within the 5% limit, if applicable), and any flavorings, additives, or processing aids must comply with the organic regulation allowances.

- **Traceability and Records:** Conduct a **traceability audit** and **mass balance** to ensure the operator's records support the organic claims:
    - **Mass Balance:** The inspector picks a representative period or product and checks input vs output quantities. The goal is to detect any unexplained losses or excess (which could indicate fraud or commingling).
    - **Traceability:** Select a batch of finished product and trace back through records to the inputs and their sources. For instance, take a lot of organic product produced and verify there are purchase invoices for all ingredients showing they were organic certified. The inspector ensures that the operator's record-keeping allows full traceability from incoming raw materials to outgoing organic products. All records (production logs, inventory records, sales invoices, transport documents) are reviewed for accuracy and completeness.
    - Check that the operator keeps records as required by the regulation (field logs, processing batch records, etc.) and retains them for at least 5 years.
    - As mentioned in the Article 1 of the regulation EU 2021/771, 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 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.

- 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 or group of operators 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.

- **Product Labelling and Claims:** Inspect labels and any packaging of organic products. Verify that labels meet the EU organic labeling requirements: use of terms "organic" or equivalent, the code number of GCMS, the EU organic logo (if applicable), and

indication of origin (e.g. “Non-EU Agriculture” for products from third countries) are correctly applied. No prohibited claims (like “100% organic” for multi-ingredient products) and no use of organic logo on in-conversion products. For bulk product shipping, verify the operator knows to obtain a **certificate of inspection** (for export to EU) and uses the TRACES system as required.

- **Facility Check:** Observe storage areas, production lines, equipment, and surroundings. Ensure organic products are clearly identified and separated. Look for any potential contamination sources (for instance, check if pest control in a warehouse uses only allowed methods, or if cleaning agents are adequately flushed out). If the operator also handles non-organic products, verify that **organic products are stored separately or clearly distinguished** to prevent mixing. Also check that containers, silos, or packaging are properly labeled as organic.
- **Interviews and Worker Practices:** The inspector may interview staff (those in charge of quality, warehouse, field workers) to gauge their understanding of organic procedures. Do they know what to do if there’s a contamination risk? Are they following the organic system plan?
- **Unannounced Specific Checks:** If the visit is unannounced or if specific risk flags exist, the inspector might perform spot checks such as taking inventory counts and comparing to records on the spot or checking for unauthorized substances in storage. Unannounced audits often emphasize **surprise checks** (e.g. asking to see a section of the farm not initially planned or testing whether product in the conventional section is being misrepresented).

Throughout the inspection, the inspector collects evidence: notes, photographs of fields or labels, copies or samples of records, and possibly samples for lab testing (see Section 7 for sampling). All observations of non-conformities are noted in the checklist or inspection report.

4.4 Group of operators

- **Internal Control System (for groups, if any):** If the operator is a group of producers (in some third countries small farmers can be certified as a group), then GCMS will also audit the Internal Control System (ICS) of the group. This involves checking a sample of group members and the effectiveness of internal inspections. (This manual’s

primary scope is individual operators, but if group certification is in scope for crops, the CB follows group certification rules as per Reg. 2018/848 and Reg. 2021/1698).

According to the article 4 and 5 from the regulation (EU) 2021/279, the following applies in case of group pf operators:

A member of a group of operators shall register to only one group of operators for a given product, also where the operator is engaged in different activities related to that product. The maximum size of a group of operators shall be **2 000 members.** The group of operators shall keep the following documents and records for the purposes of the system for internal controls (ICS):

_The list of members of the group of operators based on their registration of each member and consisting of the following elements for each member of the group of operators: name and identification (code number); contact details; date of registration; total land surface under the management of the member and whether it is part of an organic, in-conversion or non-organic production unit; information on each production unit and/or activity: size, location, including a map where available, product, date of the beginning of the conversion period and yield estimates; date of the last internal inspection with the name of the ICS inspector; date of the last official control performed by the competent authority or, where appropriate, control authority or control body with the name of the inspector; date and version of the list;

_The signed membership agreements between the member and the group of operators as legal person, which shall include the rights and responsibilities of the member.

_The internal inspection reports signed by the ICS inspector and the inspected member of the group of operators and including at least the following elements: the name of the member and the location of the production unit or premises, including purchase and collection centers where the activities referred to in Article 36(1)(a) of Regulation (EU) 2018/848 subject to the inspection take place; the date and starting and ending hour of the internal inspection; the findings of the inspection; the audit scope/perimeter; the date of issue of the report; the name of the internal inspector.

_The training records of the ICS inspectors consisting of the dates of the training; the subject matter of the training; the name of the trainer; the signature of the trainee; where appropriate, an assessment of the knowledge acquired.

_The training records of the members of the group of operators.

_The records of the measures taken in case of non-compliance by the ICS manager, which shall include: the members subject to measures in case of non-compliance, including those suspended, withdrawn or required to comply with a new conversion period; documentation of identified non-compliance; documentation of follow-up of the measures.

_The traceability records, including information on the quantities, on the following activities, where relevant: purchase and distribution of farm inputs including plant reproductive material by the group; production including harvest; storing; preparation; delivery of products from each member to the joint marketing system; placing on the market of products by the group of operators.

_The written agreements and contracts between the group of operators and subcontractors including information on the nature of the subcontracted activities.

_The appointment of the ICS manager.

_The appointment of the ICS inspectors as well as the list of ICS inspectors.

To evaluate the set-up, functioning and maintaining of the ICS of a group of operators, the competent authority or, where appropriate, GCMS shall determine at least that:

_A documented procedures of the ICS that have been put in place comply with the requirements established in Regulation (EU) 2018/848.

_List of members of the group of operators with the required information for each member is continuously updated and aligned with the scope of the certificate.

_All members of the group of operators comply with the criteria set out in Article 36(1)(a), (b) and (e) of Regulation (EU) 2018/848 throughout their participation in the group of operators.

GCMS applies risk assessment to select the sample of the members of the group of operators for the re-inspections in accordance with Article 38(4)(d) of Regulation (EU) 2018/848.

GCMS allocates reasonable time for the control of a group of operators, proportional to the type, structure, size, the products, the activities and output of organic production of the group of operators.

GCMS carry out witness audits to verify the competence and knowledge of ICS inspectors.

GCMS assess whether there is a failure of the ICS based on the number of non-compliances undetected by the ICS inspectors and the result of the investigation of the cause and the nature of the non-compliances.

4.5 Closing Meeting:

After the site tour and records review, the inspector holds a closing meeting with the operator's management. The inspector presents findings and gives the operator an opportunity to clarify any issues. Any non-compliances identified are discussed. The inspector distinguishes between observations (minor issues) and serious non-compliances. For each non-compliance, the inspector explains the nature of the issue, referencing the specific organic regulation clause that is violated. The operator is informed of required corrective actions and given a timeline for correction. For example, if a minor record-keeping gap was found, the operator might need to submit updated records within 30 days. If a major issue (like use of a prohibited input) is found, the inspector will explain that this product cannot be sold as organic and that the CB will determine sanctions (e.g. product downgrade or certificate suspension) after further review.

The inspector and the operator's representative both sign the **inspection report** or checklist to acknowledge that the inspection took place, and the findings were reviewed. The operator receives a copy of the signed report for their records. The report includes a summary of what was checked and the initial classification of any non-compliances, along with deadlines for corrective actions. The operator's signature is not an admission of fault, but a confirmation of receipt of the findings.

Finally, the inspector reminds the operator that the certification decision is not made on-site by the inspector, but by an independent decision-maker, after reviewing the report. The operator is told that they will be informed of the certification decision (and any imposed sanctions or requests) within a specified timeframe after the inspection.

4.6 Audit Checklist and Forms:

GCMS **Audit/Inspection Checklist** (Excel template) is used by inspectors to ensure all aspects are covered. The checklist is structured as follows:

- *Section 1: General Information* – Operator name, code, date/time of inspection, type (announced/unannounced), inspector name, persons interviewed, sites visited, summary of activities.
- *Section 2: Changes and Updates* – Have there been changes in operations, products, staff responsible, new fields, new suppliers, etc. since last year?
- *Section 3: Inputs and Materials* – List of inputs (seeds, fertilizers, ingredients, etc.) and check of their approval status; storage and handling of inputs.
- *Section 4: Production Practices* – Crop management (or processing steps as applicable). Series of checkpoints like "No prohibited substances used on crops" (Yes/No), "Buffer zones respected (if parallel production)" (Y/N), "Cleaning procedures between organic and non-organic runs documented" (Y/N), etc. The inspector notes evidence for each.
- *Section 5: Records and Traceability* – Verification of organic purchase and sales records, lot numbering system, trace-back test results, mass balance calculation.
- *Section 6: Organic Integrity Measures* – Separation in storage, proper labeling of organic status on containers, pest control methods used (with a checklist point for "only allowed pest control methods on-site" (Y/N)).
- *Section 7: Labelling and Claims* – Check product labels for required info (logo, code, term "organic"), review any advertising or website claims for accuracy.
- *Section 8: Previous Non-compliances Follow-up* – List any prior issues and whether they have been resolved (Y/N and comments).
- *Section 9: Findings and Non-compliances* – A table where any deviations are recorded with description, regulatory reference, severity classification (minor/major/critical), and corrective action required.
- *Section 10: Sampling* – Note if samples were taken, what for, and sample IDs (this also links to the Sampling Template for lab analysis).
- *Section 11: Concluding Summary* – Overall compliance assessment by inspector (recommended outcome, e.g. "compliant with minor corrections" or "serious non-compliance – review needed"). This is a recommendation only; final decision is by the certification officer.

- *Signatures* – Inspector and Operator representative, date.

The checklist ensures consistency and completeness. It exists in Excel for ease of use and data entry, but the signed copy is saved as PDF or printed for records.
After the inspection, the inspector submits the completed checklist/report and any collected documents or samples to the CB's certification office for the **certification decision stage**.

5. Sampling and Laboratory Testing

Sampling of products and soil/water (if needed) is an important part of the control regime to detect residues of prohibited substances or verify product integrity. GCMS has a sampling plan in line with regulatory requirements. According to Reg. 2021/1698, the control body **shall take samples for analysis on at least 5% of the operators each year**. GCMS policy is to exceed this minimum when risk indicates.

5.1 When Sampling is Done:

- **Random/Risk-Based Sampling:** As part of the annual control plan, GCMS ensures that at least 5% of operators are sampled annually. Operators with higher risk (as determined in Section 4) are more likely to be selected for sampling. The selection of who to sample is based on risk factors such as a history of residues, the type of crop (e.g. those prone to pesticide drift), or suspicion of adulteration. The goal is to both randomly check a portion of operators and also target those where sampling would be most informative.
- **Mandatory Suspect Sampling: Whenever the inspector suspects the use of a non-authorized substance or a method not in compliance, a sample is taken** for analysis. For example, if an inspector observes unexplained crop vigor suggesting possible fertilizer use, or finds unapproved substances on-site, they will sample crop tissue, soil, or product to test for prohibited substances. Similarly, if a residue alert from a buyer or authority is reported, GCMS will initiate sampling.
- **High-Risk Products:** For any product categorized as high-risk by the EU, GCMS will perform **at least one sample test per year of the relevant crop or product** in addition to regular sampling. For instance, if chili powder is on the high-risk list due to past

adulteration, every operator producing organic chili powder under GCMS control will have at least an annual lab test for residues or authenticity.

- **Types of Samples:** The inspector may take samples of final product (for residue or authenticity testing), raw material (to verify it's organic, e.g. detecting prohibited treatment), soil or foliage (for detecting persistent substances in fields), or swabs of equipment (if contamination is a concern).

5.2 Sampling Procedure:

The inspector follows a documented procedure for sampling to ensure integrity and chain of custody:

- Use clean sampling tools and containers (often provided by the accredited laboratory or CB kit). Avoid any cross-contamination.
- Samples are sealed and labeled with a unique sample code, date, operator, and sampled lot identification. Both inspector and operator usually sign or initial the sample labels or sampling form.
- The quantity taken is according to lab requirements (e.g. 1kg product, or a composite of plant tissue from multiple spots in a field).
- If relevant, a **"control sample"** might be taken (for example, a non-organic reference from next door field if investigating drift, or duplicate samples for second testing).
- The sampling is documented in the **Sampling Template** (Excel form) noting the reason for sampling, the description of sample, and intended analyses. The operator receives a copy of the sampling record.

The samples are sent under secure chain of custody to an **independent accredited laboratory**. GCMS uses labs that **meet ISO/IEC 17025 accreditation** for the relevant tests. These labs are accredited for comprehensive pesticide residue screening or other necessary analyses, and they participate in proficiency tests to ensure quality. The lab must be accredited by an ILAC-MRA signatory body, guaranteeing international recognition of results.

5.3 Types of Analysis:

Common analyses include multi-residue screening for over 500 pesticides, testing for synthetic fertilizers (nitrates levels, etc.), GMO presence in seed, prohibited processing aids, or checking if a product matches its description (like detecting cheaper non-organic ingredients in a processed product). The CB specifies the tests based on the suspicion or risk: e.g. for leafy vegetables, a full pesticide screen; for a product like olive oil, possibly an authenticity test to ensure no non-organic oil blending.

5.4 Actions on Lab Results:

- If results come back **clean (no residues or issues detected)**, GCMS informs the operator (usually these results are also reviewed at the next inspection). The negative result is filed. If it was a random test, no further action needed.
- If a **residue or non-compliance** is detected (e.g. a pesticide above a certain threshold, or GMO DNA in an organic maize sample), GCMS immediately initiates a **non-compliance investigation**. In line with Article 22 of Reg 2021/1698, GCMS treats this as suspicion of non-compliance affecting integrity and will **investigate promptly**. The product in question is typically put on hold – not allowed to be sold as organic – until the investigation is concluded. The operator may be asked for an explanation (e.g. source of contamination, records of pesticide applications in region, etc.). GCMS may do confirmatory re-tests if needed. According to EU rules, if the investigation finds no intentional use or no violation, and the residue is explained (for example environmental contamination below certain levels), the product can remain organic. However, if a non-compliance is confirmed, GCMS will take action (downgrade the product to conventional and possibly sanction the operator as per Section 9).
- GCMS will report any serious residue findings to authorities via OFIS if required (see Section 12 on reporting).

5.5 Laboratory Selection and Quality:

GCMS maintains a list of approved laboratories that meet the criteria of Article 12(6) of Reg 2021/1698. These labs are accredited for the relevant methods and *specifically for pesticide residue analysis, they have GC/MS and LC/MS capabilities covering the EU coordinated multi-*

annual control program's pesticide list. This ensures the lab can detect a wide range of substances at low levels. The CB periodically evaluates lab performance (checking their accreditation status annually, reviewing turnaround times and result quality). GCMS may also participate in any proficiency tests indirectly via the labs.

All sampling records and lab results are kept in the operator's file. Results are also summarized in the GCMS annual report to the Commission (number of samples taken, and any non-compliances detected).

6. Certification Decision and Compliance Evaluation

After the inspection and receipt of any sample analyses, GCMS conducts the certification decision process. This is a critical control point where GCMS decides if the operator is compliant with the organic standards and what certification status or actions should result.

6.1 Inspection Report Review:

A **Certification decision-maker** (separate from the inspector to maintain impartiality) reviews the inspector's report, checklist, findings, and any other relevant information (lab results, operator's file, previous history). The officer verifies that the inspection was thorough and that evidence supports the findings. If clarifications from the inspector are needed, the officer communicates internally.

6.2 Evaluation of Non-Compliances:

Each non-compliance noted by the inspector is evaluated for its severity (minor, major, critical) in line with the CB's sanction policy (which is based on the EU's guidance for categorizing non-compliances). The definitions generally are:

- *Minor Non-Compliance:* A small deviation that does not directly compromise organic integrity (e.g. incomplete record, slight delay in updating a document, minor labeling error that doesn't mislead).
- *Major Non-Compliance:* A significant issue that could affect organic integrity or traceability, but product might still be salvaged as organic after correction (e.g. missing documentation for an input, or inadequate separation that *could* lead to mixing, use of a non-certified subcontractor without approval, etc.).

- *Critical Non-Compliance:* A violation that **jeopardizes the organic status** of products or shows a serious failure of the system (e.g. use of prohibited substances, intentional fraud or false records, selling non-organic product as organic).

GCMS internal **Catalogue of Sanctions** maps typical non-compliance scenarios to these categories and to corresponding actions. This catalogue follows the framework set by Annex IV Part B from the regulation (EU) 2021/1698. it includes a list of possible non-compliances with references to the rules violated, classification into minor/major/critical based on criteria like the impact on product integrity, extent of deviation, and repetition. It also pre-defines measures for each category.

List of cases of non-compliance and the corresponding classification mandatory to be included in the catalogue of measures

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

6.3 Decision Outcomes:

Based on the evaluation, the CB decides one of the following for the operator:

- **Grant/Renew Certification:** If the operator fully complies (only minor issues or none, at all), the certification is granted (for new operators) or continued (for renewals). Minor non-compliances will be communicated as conditions or recommendations but do not block certification. The certificate of compliance is issued or updated accordingly.
- **Certification with Conditions:** If there are major non-compliances that need correction, the CB may issue certification on the condition that corrective actions are taken by a deadline. In such cases, the operator is certified but must, for example, submit proof of corrected labels or improved procedures within, say, 30 or 60 days. Follow-up may be a desk review or an additional inspection. Failure to comply by the deadline could escalate sanctions.
- **Suspension or Withholding Certification:** For critical issues, GCMS will suspend certification (for existing operators) or withhold initial certification (for applicants). Suspension means the operator is temporarily not allowed to market products as organic pending corrective measures. For example, if a prohibited insecticide was found in use, the certification is suspended immediately. The operator must correct the issue (e.g. undergo a new conversion period for affected fields or otherwise resolve the integrity breach) and only after satisfactory evidence can the suspension be lifted. In extreme cases, or if the operator cannot correct the issue, this leads to withdrawal.
- **Product Downgrading:** As an immediate measure for certain non-compliances, GCMS can require that specific lots or products be **downgraded** to conventional status. For instance, if a residue is found in one batch of product, GCMS may allow the operator to remain certified, but that batch must not be sold as organic. The certification decision will note that those products lose organic status. This is often combined with further investigation into the cause.
- **Certificate Withdrawal:** In case of egregious or uncorrectable non-compliance (fraud, refusal to allow inspection, or repeated critical violations), GCMS will withdraw the operator's certification entirely. This means the operator is no longer certified organic under GCMS, and they must cease marketing any products under organic status.

Withdrawal is typically accompanied by notification to authorities and a minimum period before the operator can re-apply.

GCMS ensures decisions are made consistently and fairly, referencing the **CB's catalogue of measures** which covers at least the items suggested by the EU (list of non-compliances, classification, and actions). Operators are treated uniformly for similar infractions.

All certification decisions are made in a timely manner, usually within a few weeks of the inspection (depending on waiting for lab results). GCMS documents the rationale for the decision, especially if deviating from an inspector's recommendation.

6.4 Communication of Decision:

The CB communicates the decision to the operator in writing. If compliant, a **Certificate of Compliance** is issued (see Section 8). If conditions or sanctions apply, the operator receives a **Certification Report/Letter** detailing:

- The decision (e.g. certification granted, or suspended, etc.).
- Any non-compliances found and their category (minor/major/critical).
- Required corrective actions and deadlines.
- Any sanctions imposed (e.g. product cannot be sold as organic, certificate suspension details).
- The operator's right to appeal the decision (the CB's procedure typically allows an operator to appeal or present additional info if they disagree).

GCMS may use standardized letter templates for this communication. A copy of this decision letter and certificate (if issued) is kept in the operator file.

Only after this official notification can an operator know the definitive status of their products. Operators with suspended or withdrawn status are also flagged in GCMS records and, if required, communicated via OFIS to the EU Commission and other control bodies, particularly if products were exported or interlinked with other supply chains (to prevent falsely labeled goods on the market).

7. Issuing Certificates of Compliance

Upon a positive certification decision (initial or annual renewal), the CB issues a **Certificate of Compliance** to the operator, as required by Article 35 of Regulation (EU) 2018/848. This certificate is the documentary evidence that the operator and their products comply with organic regulations, and it is a prerequisite for marketing products as organic. For third-country operators under Article 46, the certificate confirms compliance equivalently to EU standards so that their products can be accepted for import.

7.1 Certificate Format and Content:

The certificate is issued in GCMS secure format (often as a PDF or printed document with signatures and/or digital seal) and conforms to the EU model (Annex VI of Reg. 2018/848). Key elements included are:

- **Certificate Title:** Typically, "Certificate of Compliance" with reference to organic production. It may explicitly state "Certificate confirming compliance with Regulation (EU) 2018/848" as per Article 45(1)(b)(i).
- **Certification Body Details:** Name, address, and the code number of the CB. For example, the code might be in the format **"UZ-BIO-XXX**" as assigned in the official list of recognized control bodies.
- **Operator Identification:** Name and address of the certified operator (and operator code number in the CB's system). If the operator is a group, the list of group members can be referenced or attached.
- **Scope of Certification:** The **categories of products** and/or specific products the operator is certified for. For clarity, the certificate will list categories such as:
    - **(a)** "Unprocessed plant products
    - **(d)** "Processed agricultural products for use as food" – for food processors.
- **Validity Period:** The certificate indicates its **date of issue** and the period of validity or the ongoing nature of validity subject to annual updates. In practice, GCMS certificate according to Organic-EU scheme is **valid for 2 years**. (EU) 2018/848 model allows listing the date of the control/inspection and a validity based on continued compliance.
- **Standards and Regulations:** A statement that the operator **"complies with Regulation (EU) 2018/848 on organic production"** for the listed scope. It may also reference

compliance with applicable delegated and implementing acts (like 2021/1698 and 2021/279) or simply state compliance with the organic regulation in general.

- **Certificate Number:** A unique certificate number or identifier for verification.
- **Date of First Certification:** Many certificates list the initial certification date (useful to show how long the operator has been organic).
- **Signature and Seal:** The certificate is signed by an authorized person of the CB (or digitally signed) and carries the CB's official seal or logo. It may also contain a note about authenticity (like a QR code or instructions to verify the certificate on the CB's website or database).
- **Annex or Product List (if needed):** If the operator has many products, an annex might detail each product and its status (organic/in-conversion). For seeds, details like species and varieties might be listed.

The certificate is preferably issued **electronically** (as per the regulation's encouragement to use electronic form), but the operator can obtain a printed copy if required for documentation (especially to accompany export shipments).

7.2 Distribution and Use:

GCMS provides the certificate to the operator and maintains a copy. The operator may need to show this certificate to importers, trade partners, or authorities. Notably, **for import into the EU**, the operator's certificate details are used in the TRACES system to issue the **Certificate of Inspection (COI)** for each consignment. Article 45 of Reg. 2018/848 requires that all such operators and exporters have this compliance certificate, and importers in the EU must verify that their suppliers are certified by an EU-recognized CB. The certificate information (operator name, product categories, etc.) also gets uploaded or referenced in the EU's electronic systems so that EU Member State authorities can confirm the legitimacy of the operator.

7.3 Certificate Updates and Maintenance:

The certificate remains valid as long as the operator continues to comply and maintains certification annually. Each year after the annual inspection and certification renewal, GCMS issues an **updated certificate** (or reaffirms the existing one with a new issue date). If an operator **suspends or withdraws** from certification, or if GCMS withdraws their certification,

the certificate is no longer valid. GCMS in such cases will update its records and notify the necessary parties (so the operator cannot continue to use the old certificate). Operators are not allowed to hold multiple certificates for the same scope, ensuring one certificate per operator per scope. GCMS procedures ensure that if an operator is caught trying to double-certify with another body, action is taken.

The format of the certificate issued by GCMS follows the standard EU model and thus is easily recognized by authorities. It includes the language(s) as required (English in this case, being the manual's language; sometimes bilingual certificates are issued depending on region).

Certificate Template (Excel): GCMS maintains an Excel template for generating certificates, which pulls in operator data, scope, etc. But the final output is a controlled PDF/printed document to prevent tampering. The template ensures consistency in including all required elements (like categories, validity, etc.).

In summary, the certificate of compliance is the operator's proof of organic certification under EU-equivalent standards, and its issuance is based strictly on the positive outcome of the inspection and review. It is tied to Article 45(1)(b)(i) conditions for import, thereby allowing the operator's products to be exported to the EU as organic.

8. Follow-Up and Surveillance Audits

Organic certification is an ongoing process. Beyond the routine annual inspection, GCMS carries out follow-up and surveillance measures to ensure continuous compliance throughout the year.

8.1 Implementation of Corrective Actions:

If an operator had any non-compliances that required corrective action (as identified in the inspection report or certification decision), GCMS follows up on these. The operator must submit evidence of correction by the deadline given (e.g. new labels, purchase documents for approved inputs to replace unapproved ones, training records for staff, etc.). The certification staff reviews these submissions. In some cases, a **follow-up visit** may be warranted – for example, if a major structural issue was found (like needing to construct a wall to segregate organic from non-organic storage), an inspector might revisit to confirm the fix. Follow-up inspections can be announced or unannounced depending on nature. These follow-ups are part of surveillance to close out non-compliances.

8.2 Unannounced Inspections:

As noted, GCMS conducts unannounced inspections on at least 10% of operators yearly. These are a form of surveillance audit. GCMS internal schedule ensures that over time, all operators will eventually receive unannounced checks, with high-risk ones potentially more frequently. Unannounced visits might target specific seasonal activities (like planting or harvest time for farms, or peak production season in a processor) to observe operations in their normal state. Inspectors during unannounced audits verify that day-to-day practices match what was described at the annual inspection. They may perform quick traceability tests and physical inspection focusing on known risk points for that operator. Results of unannounced inspections are documented just like regular ones and can lead to non-compliances if issues are found.

8.3 Increased Surveillance for Risk:

If an operator is classified as **high risk**, GCMS increases surveillance accordingly. For example, as per 2021/1698 rules, high-risk product operators get two inspections a year (one unannounced). Also, if an operator has a history of non-compliances, GCMS might conduct an extra audit or more frequent sampling until the operator rebuilds a record of compliance. These could be considered "surveillance audits." GCMS keeps a log of which operators are scheduled for multiple audits and ensures execution.

8.4 Sampling as Surveillance:

In addition to routine inspections, GCMS treats **sampling** (Section 6) as part of surveillance. Surprise sampling (e.g. buying a product from the market and testing it or taking a sample at an unannounced visit) can be done to check integrity. The results may trigger further action if problems are found.

8.5 Surveillance of Subcontractors:

If operators subcontract processing or packing to facilities not regularly inspected by GCMS (but under the operator's responsibility), GCMS may choose to inspect those subcontractor

premises as part of surveillance, especially if they pose a risk to organic integrity. The operator's agreement (from the application stage) allows GCMS to do this and coordinates with any other control bodies if needed to exchange information about subcontracted operations.

8.6 Ongoing Monitoring:

GCMS also monitors external information that could prompt follow-up: e.g. **complaints** from buyers or whistleblowers about an operator, **alerts from authorities** (via OFIS) about residues or fraud involving an operator's products, or media reports. If such information arises, GCMS will initiate an investigation which may include an **unplanned inspection** or targeted record audit of the operator. This aligns with Article 22 of Reg 2021/1698, requiring immediate investigation if an import-bound product is suspected not to comply.

All surveillance activities are recorded in the operator's file. The cumulative findings from surveillance feed back into the risk assessment (Section 4) for future planning. A consistent pattern of compliance might lower an operator's risk category over time, whereas issues will keep it high or elevate it.

GCMS quality system ensures that surveillance measures are not neglected: a calendar or tracking system is used to make sure the required percentage of unannounced and additional audits are completed each year. If, near year-end, the target hasn't been met, GCMS will schedule extra unannounced visits to fulfill the requirement. This is reported in the annual report (number of unannounced done, etc.).

9. Non-compliance Handling and Sanctioning

Despite preventive measures, non-compliances (violations of organic standards) may occur. GCMS has a clear procedure for handling such cases, aiming for transparency, fairness, and maintaining organic integrity. The approach is aligned with Article 41 of Reg. 2018/848 and further detailed rules in Implementing Reg. 2021/279 and Delegated Reg. 2021/1698 regarding actions in case of non-compliance.

9.1 Identification and Classification:

When a non-compliance is detected (either during inspection, via testing, or reported by the operator or third parties), GCMS first assesses its nature and severity. The **internal sanctions catalogue** (or measures catalogue) is used to classify the non-compliance as **minor, major, or critical**. The classification criteria include: the impact on the integrity of the organic product, the extent of deviation from the rules, whether it's a one-time mistake or a systemic issue, and whether it was intentional or a repeat offense. For example:

- Minor: e.g. an overdue record or slight labeling oversight with no product integrity impact.
- Major: e.g. use of a non-listed cleaning agent that didn't contact product, or incomplete documentation that raises concern but no evidence of conventional product mixing.
- Critical: e.g. detected use of prohibited pesticide on organic crop, evidence of deliberate mislabeling, failure to allow access to inspection, or any issue that directly compromises organic status of product (integrity breach) or trust.

9.2 Imposition of Measures (Sanctions):

Depending on the classification, GCMS imposes measures, as per its catalogue of measures:

- **Corrective Action Request:** For minor issues, typically the "sanction" is simply to correct the issue by a deadline and possibly a warning letter. The operator remains certified, but the issue is noted.
- **Warning or Notice of Non-Compliance:** For a first-time major non-compliance that doesn't require product withdrawal, GCMS may issue a formal warning and require corrective action. This is a step short of affecting certification status but indicates seriousness.
- **Product Downgrading / Sale Prohibition:** If a specific product or batch is affected, GCMS will **prohibit that product from being sold as organic.** For instance, if a forbidden treatment was given to a certain field, the harvest from that field loses organic status. The operator must remove organic labeling from that batch (downgrade to conventional) and inform any buyers. This measure protects consumers and organic

markets from non-compliant goods. GCMS records this in the sanctions register and will verify that the operator indeed did not sell the product as organic (through inventory checks or requiring proof of disposal or relabeling).

- **Increased Inspection Frequency:** As a remedial measure, GCMS can place the operator on a heightened surveillance regime. For example, after a major non-compliance, the operator might get an extra unannounced inspection next year, or additional sampling at operator's cost, until confidence is restored.
- **Suspension of Certification:** For critical non-compliances, GCMS may **suspend the operator's certification** entirely or for specific product categories. Suspension is often immediate if continuing to certify the operator would allow potentially non-compliant product to be sold as organic. Under suspension, the operator cannot sell any products as organic (everything must be treated as non-organic) until the suspension is lifted. GCMS will outline what corrective actions are needed and perhaps a minimum time for suspension. For example, if an organic herd was given a prohibited treatment, those products may need to undergo a new conversion period – until then, certification is suspended.
- **Certification Withdrawal:** If the situation is irredeemable or the operator is unresponsive, GCMS will **terminate (withdraw) certification**. This is effectively a cancellation of the contract: the operator loses organic status for all products and must start over (with potential new conversion) if they ever wish to return. Withdrawal is used for severe cases like fraud or if an operator repeatedly violates rules or ignores suspensions. After withdrawal, GCMS informs the Commission and other control bodies to prevent the operator from simply moving operations without addressing the issue (and as noted, an operator withdrawn for non-compliance cannot be certified by another body for 2 years unless special circumstances).

GCMS measures are **proportionate and incremental**, meaning minor issues don't receive harsh penalties, but critical issues receive strong sanctions to protect organic integrity.

9.3 Communication of Non-compliance and Sanctions:

GCMS communicates all decisions regarding non-compliance to the operator in writing. If a product must not be sold as organic, the operator is instructed to immediately inform all affected buyers (this aligns with the operator's commitment in the application to inform buyers

in case of issues). GCMS may also directly alert the importers or other relevant parties if needed, especially for products already shipped or on the market.

In cases affecting import shipments, GCMS will update the status in TRACES (for example, if a Certificate of Inspection was issued but later a problem is found, GCMS would inform authorities to possibly cancel the COI or refuse endorsement at entry).

For group certifications (if applicable), a severe non-compliance by the ICS or many members could lead GCMS to withdraw the whole group's certificate. For a single member's issue, that member can be expelled from the group and their products denied organic status.

9.4 Sanctions Register:

GCMS maintains a **Sanctions Register** (Excel log) to track all non-compliances and actions taken. This is important for internal management and also for reporting. The sanctions register typically has columns for:

- Operator Name / Code
- Date of detection of non-compliance
- Description of the issue (with reference to rule violated, e.g. "Use of non-authorized fertilizer – Article X of Reg 2018/848")
- Category (Minor/Major/Critical)
- Actions/Sanctions imposed (e.g. "Product lot ABC downgraded; Warning issued; Extra inspection next quarter")
- Deadline for corrective action
- Date of resolution (when the operator completed the action or when suspension was lifted)
- Remarks (any additional notes, e.g. if authorities notified via OFIS, or if operator appealed, etc.)

This sanctions register is kept up to date by the certification department. It allows GCMS to ensure consistency (by reviewing how similar cases were handled) and to monitor if an operator accumulates multiple issues over time. It also feeds into the annual report to the Commission, where GCMS must summarize cases of non-compliance and measures taken.

9.5 Notification to Authorities (OFIS):

For serious cases, especially those **affecting products already exported or likely to be exported**, GCMS will use the Organic Farming Information System (OFIS) to notify the European Commission and EU Member States. For example, if GCMS finds that a shipment of "organic" product destined to the EU is contaminated or fraudulent, it must send an OFIS notification (or respond to one initiated by an EU member). Implementing Reg. 2021/279 specifies that when a suspected non-compliance could affect the integrity of organic products in another country, an alert should be raised. The CB in third countries, upon such findings, shares information immediately with the Commission, other CBs, and competent authorities. They also must respond to any requests following an OFIS notification within 30 days with the investigation results.

9.6 Appeals and Disputes:

The manual includes a note that operators have the right to appeal decisions. GCMS procedure for appeals is separate from the immediate handling of non-compliance (i.e. sanctions are applied without delay to protect organic integrity, but the operator can contest through a formal process). During an appeal review, GCMS might temporarily keep a suspension in place until resolved, for caution.

In all cases, the highest priority is ensuring that any product sold as organic truly meets the requirements. Thus, GCMS sanctioning policy is strict on preventing suspect product from being called organic while investigations are ongoing. The credibility of the certification scheme relies on swift and appropriate action on non-compliances.

10. Reporting and Use of Electronic Systems (OFIS & TRACES)

The Certification Body operates within a larger framework of oversight and information exchange that involves EU authorities and databases. Two key systems used are **OFIS (Organic Farming Information System)** and **TRACES (Trade Control and Expert System)**. Additionally, the CB must fulfill reporting obligations to the European Commission.

10.1 Annual Reporting to the Commission:

As a recognized third-country control body, GCMS is required to submit an **annual report** to the European Commission by 28 February each year. This report (submitted in English) details GCMS activities and compliance with organic rules over the previous year.

It includes:

- Updates to GCMS technical dossier (any changes in legal status, accreditation, key personnel, etc.)
- The list of countries and product categories under GCMS control and number of operators in each.
- Summary of inspections carried out, including total number of operators, number of inspections, number of unannounced visits (to show the ≥10% rule was met), number of samples taken (showing the ≥5% sampling was met)
- Results of oversight: statistics on non-compliances and sanctions. Specifically, **the number of OFIS notifications of suspected or established non-compliance** GCMS dealt with, and the measures taken. Also, the annual report will indicate how many operators were suspended or certificates withdrawn, etc.
- Any noteworthy issues or improvements, training of staff, and how GCMS addressed Commission feedback from the previous year.
- It also covers **witness audits** and internal audit findings (GCMS must perform internal audits and witness inspections on its inspectors as part of quality control, per Reg. 2021/1698).

The annual report essentially demonstrates GCMS performance and enforcement of organic rules, enabling the Commission to supervise GCMS recognition. GCMS compiles this information continuously (e.g. via the sanctions register, inspection logs) to ensure accurate reporting.

10.2 Organic Farming Information System (OFIS):

OFIS is the platform for exchange of information on organic irregularities and breaches among EU Member States, the Commission, and control bodies. GCMS is **required to use OFIS for timely information exchange**. Key uses:

- **Notification of Irregularities:** If the CB detects a suspected or established non-compliance on a product that **could affect trade** (especially exports to the EU or products from another CB), it uses OFIS to notify authorities. For example, if a pesticide residue is found in an organic product batch intended for export, GCMS would create an OFIS notification so that the importing country's authorities are aware to hold or check the product. The notification includes details of the operator, product, issue, and actions being taken.
- **Responding to Notifications:** GCMS also might receive notifications via OFIS if a Member State finds a problem in a product certified by GCMS (e.g. at border control or on the market). In such cases, the Commission forwards the info to GCMS. GCMS must investigate and respond through OFIS within 30 days, detailing what they found and what actions were taken. GCMS uses the standard templates (Annex III of Reg. 2021/1698) to reply to these international non-compliance notifications.
- **General Exchange:** GCMS uses OFIS to communicate with other control bodies or authorities if an operator is switching CBs (ensuring the control file is passed on as required) or if they discover an operator under their control had dealings with another CB's operator in a fraudulent way, etc. Essentially, OFIS is the secure channel recognized by the EU for these exchanges.

GCMS has internal procedures to ensure any staff member handling OFIS notifications does so quickly. There are documented processes for investigation triggered by an OFIS case (including possibly extra inspections or sampling).

10.3 TRACES (Trade Control and Expert System):

TRACES is the EU's online platform for sanitary and phytosanitary certifications, including organic import certificates. GCMS responsibilities with TRACES include:

- **Certificates of Inspection (COI):** For each consignment of organic products that the operator exports to the EU, GCMS must issue a **Certificate of Inspection** through TRACES. The COI attests that the product is certified organic and complies with Reg. 2018/848. The process is:
    - The operator/exporter notifies GCMS of a planned shipment, providing details (product, quantities, destination, importer, etc.).

- GCMS verifies the product is indeed certified and traceable to the operator's certified production. If all is in order, GCMS fills out the electronic COI on TRACES, including reference to the operator's certificate of compliance, lot numbers, transport details, etc.
- GCMS inspector or authorized certifier will sign off the COI (often electronically with a digital certificate) **before the consignment leaves the third country**. This COI travels with the shipment (electronically accessible) and EU border control posts will check it upon import.
- If the consignment is bulk and involves multiple stages in transit, GCMS also, as required by Article 16(5) of Reg. 2021/1698, **draws up a travel plan in TRACES** detailing all the premises and points the shipment will pass through from origin to EU. This ensures traceability during long transport routes (for example, bulk grain going through various warehouses).
- GCMS only validates the COI if everything is compliant. If there were any issues (like pending lab results or suspicion), GCMS would not issue or would cancel the COI, effectively blocking the organic import until resolved.

- **Operator Registration (if applicable):** TRACES has a module for listing organic operators and control bodies. GCMS ensures that all certified operators intended to export are registered in TRACES with their valid certificate info. This helps EU importers to select the correct operator from a drop-down and link the COI.
- **Using TRACES Data:** GCMS monitors the COIs it issues via TRACES to ensure all exports are accounted for. TRACES provides an audit trail. If an issue arises with a consignment, GCMS can use TRACES to see who approved the COI and what notes were included (or if any part of the shipment was split or modified en route, since TRACES handles that).

10.4 Other Reporting:

- GCMS informs the Commission of any significant changes such as changes in accreditation scope, key personnel, or if it wishes to extend its scope to new product categories or countries (such requests are made via formal channels, often requiring updated dossiers as per Delegated Reg. 2021/1698).

- If GCMS ever has to suspend or terminate an operator's certificate, and that operator had products in transit to the EU, GCMS will proactively alert the relevant border control post or national authority via OFIS or direct communication, to prevent the product from being sold as organic. This ties into both reporting and non-compliance handling.

10.5 Record-keeping of Communications:

GCMS keeps copies/records of all OFIS notifications sent or received, TRACES COIs issued, and annual reports submitted. These may be audited by the Commission during their supervision audits of GCMS. GCMS use of these electronic systems is itself subject to evaluation by EU auditors to ensure proper implementation.

10.6 Data Protection and Access:

All electronic exchanges comply with data protection laws. Only authorized GCMS personnel have access to OFIS and TRACES for the CB's scope. They use secure logins and follow the EU's guidelines for these systems.

By fulfilling these reporting and electronic system obligations, GCMS contributes to the overall integrity and traceability of organic products from the third country to the EU market. It ensures that information flows efficiently: any **suspected non-compliance is quickly shared via OFIS** and every **certified organic shipment is transparently documented in TRACES** for scrutiny.

11. DEROGATIONS FROM REGULATION (EU) 2018/848 IN CATASTROPHIC CIRCUMSTANCES

11.1 Recognition of catastrophic circumstances

As mentioned in the article 28 of the regulation (EU) 2021/1698, exceptional production rules may apply, as referred to in Articles 22(1) and 45(3) of Regulation (EU) 2018/848, in case of situation qualified as catastrophic circumstances. This situation is deriving from an 'adverse climatic event', an 'environmental incident', a 'natural disaster' or a 'catastrophic event', as well as any comparable situation, GCMS may recognize a situation as catastrophic circumstances based on a statement issued by the relevant authorities of the third country in which the situation occurs, where available. If such a statement is not available, any such

recognition by GCMS will be based on data provided by official organizations justifying the catastrophic circumstances.

11.2 Conditions for derogations

As mentioned in the article 29 of the regulation (EU) 2021/1698, derogations shall apply:

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

The application of the derogations referred to in paragraph 1 shall be without prejudice to the validity of the certificates, during the period where the derogations apply, provided that the operator or operators concerned fulfil the conditions under which derogations were granted.

GCMS immediately notify the Commission, the Member States and, their accreditation body, of the derogations granted by them pursuant to this Regulation via the system by indicating the name of the operator or operators concerned, the time period for the derogation, the type of production or, where relevant, land parcels, the justification for the derogation and include a statement from the relevant authority of the third country as referred to in Article 28.

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

12. DOCUMENT HISTORY

Version number	Description	Date
01	First release	2025-04-18
02	Added requirements related to the catalog of sanctions and derogations from regulation in catastrophic circumstances.	2025-10-29
03	Added history of the document.	2025-12-02
04	Updated chapter “4.1 Preparation for Inspection” with requirements of preparation timeframe and the list of documents to be collected from the operator before the inspection.	2025-12-10
05	Removed the term “Organic Management plan” and replace it with the term “Organic system plan” to avoid misleading. Removed the scopes that not covered by GCMS accreditation with EGAC.	2026-01-06