

# IFOAM Guidance for CBs on EXTERNAL CONTROL of Group of Operators according to Reg. 2018/848

Guidance for CBs in Third Countries

Final, draft approved by the project working group and endorsed by the boards of IFOAM – Organics International, IFOAM – Organics Europe, and European Organic Certifiers Council (EOCC)



Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER State Secretariat for Economic Affairs SECO



# **ABOUT THIS GUIDANCE on Control of GoOs**





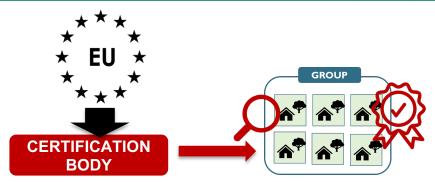




IFOAM Organics International, IFOAM Organics Europe and FiBL have collaborated since 2019 to analyse and provide guidance on the new EU requirements for certified groups in third countries.

The separate IFOAM "Guidance on Group Certification Requirements according to the new EU regulation" represents IFOAM's and FiBL current status of understanding of the EU requirements applied to GoOs (July 2022).

This additional "Guidance on the external Control of GoO" summarizes IFOAM's current understanding of control requirements for CBs (Status July 2022) with some guidance and recommendations based on IFOAM's past 20 years of experience. It is neither an accreditation standard nor official EU guidance!



Control Bodies in Third Countries need to be recognized by the EU in order to conduct organic certifications based on detailed policies & procedures to control the EU legal requirements,. Each CB needs to conduct its own analysis of the regulation text and ensure compliance with official guidance or feedback by the EU commission or other EU Bodies and will need to justify its control system.

Inspection and certification of GoO are always done according to each CB's recognised policies and procedures.

This guidance aims to provide CBs with an an easy-to-access guided summary of the new external control requirements for GoOs in third Countries in order to support Cbs in developing their own GoO control procedures and policies or for complementary additional training for GoO inspectors. It is recommended to be read in combination with the separate IFOAM&FiBL Guidance on Producer Group Certification Requirements.



- 1. Introduction & Overview Certification of Groups of Operators
- 2. The ICS Office Inspection & Verification of Documents
- 3. Farm Re-Inspections and Witness ICS Inspections
- 4. Inspection of Traceability & Purchase Centres
- 5. Evaluation and Certification of Groups of Operators

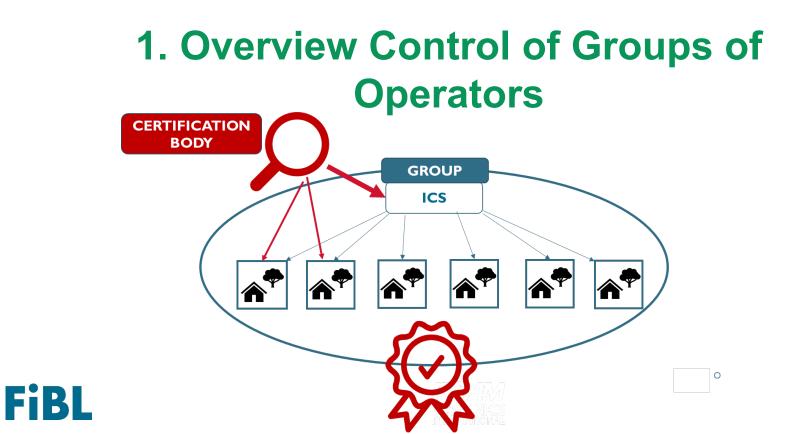
**NOTE: This summary of the External Control Process of Groups for Cbs is designed to be used in combination the separate IFOAM Guidance on Producert Group Certification for Groups and CBs**, which explains all new regulatory requirements that Groups of Operators are evaluated against.

**Disclaimer**: the present content represents IFOAM's and FiBL current status of understanding after detailed analysis and discussion with stakeholders (Jul 22). It is work in progress as a guided summary for CBs for certification on Groups of Operators according to 2018/848.

Please note that organic certification is based on each CB's approved EU control procedures and policies and their own interpretation of the regulatory texts as well as official EU guidance, if and when available.



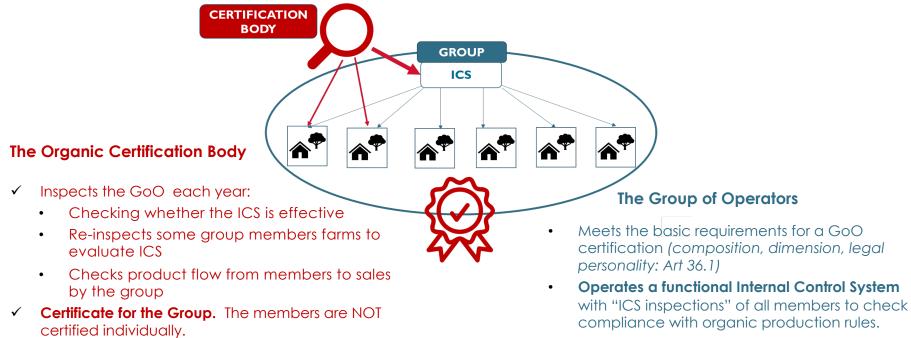






## **Principles of Group Certification**





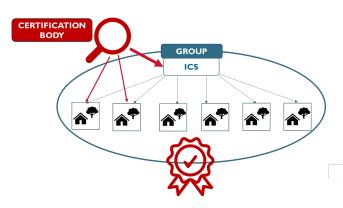
Markets the members' organic products as a group.



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## **Overview Regulatory Requirements: Control of GoOs**





Reg. 2018/848: Art. 35 & 38 Reg. 2021/1698 Art 9-12 Reg. 2021/279: Art. 7 & Annex Reg. 2021/771, Art 1 & 2

**Reg 2018/848** (Consolidated version Jan 2022)

- Art 38: GoO in third countries: physical on-the-spot inspection "at least once a year" Art 35 GoO Certificate to be issued in TRACES data base

## <u>Reg 2021/1698 CB recognition & Control in Third Countries:</u>

- Art 9. General provisions Control of Operators & GoOs in Third Countries
- Art 10 Checks for the certification of GoOs and Operators
- Art 11 Methods and Techniques of Control
- Art 12 Sampling Methods

### Rea. 2021/279:

minimum 10 % of GoO without prior notice every year;

"Re-inspection" of a minimum of 5% of members of a GoO (min 10 members) every year

Minimum 2 % of members of each GoO shall be "subject to sampling"

## Rea 2021/771:

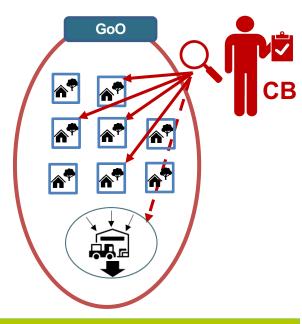
- Art 1. Traceability check & mass balance check
- Art 2 ICS Evaluation





## **External Control of Groups of Operators**





Reg. 2021/1698 Art 8, 9 & 12 Reg. 2018/848: Art. 35, 38, Reg. 2021/279: Art. 7

- 2021/1698 Art 9 :Physical Inspection of the GoO "at least once a year
  > plus every year at least 10 % of additional controls of Operators & GoOs
  > 10 % of all physical on-the-spot inspections shall be without prior notice
  > EU will define list of high risk products in implementing Act (art 8) that will need to be inspected twice a year (Art 9.8)
- ✓ The certifier needs to re-inspect 5% of the total number of GoO members each year (not less than 10)

➤ NOTE: if for risk products (2021/1698 Art 8) 2 physical inspections will be required per year, It still means a minimum of 5% re-inspection per year in total,. e.g. regular GoO visit 4% re-inspection, 2<sup>nd</sup> unannounced inspection: remaining 1% reinspections. The 5% re-inspection shall be completed before issuing certificate.

✓ Minimum 2% of Members shall be subject to sampling

### ✓ Control of Purchase Centres & Units

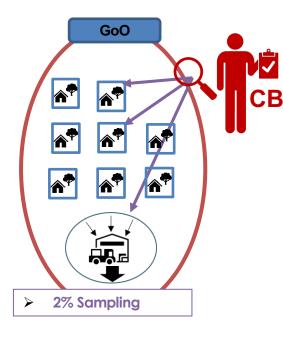
➢ GoO purchase centres, that handles the certified product also in nonorganic quality, need to be inspected each year (2021/1698 Art 9.9)





## **External Control: 2% Sampling for Analysis**





2021/1698, Art 12 (Control in Third Countries)

# CB needs to carry out sampling of at least 2% of the members of each GoO per year.

#### **Regulation 2021/1698**

Art 12.1. The CB shall take and analyse samples for

- detecting the use of non-authorised products and substances for organic production,
- for checking production techniques not in compliance with the organic production rules
- Or for detecting possible contamination by non-authorised products and substances for organic production

Art 12.3. **Samples shall be taken based on the CB's risk assessment** (...), taking into account all stages of production, preparation and distribution."

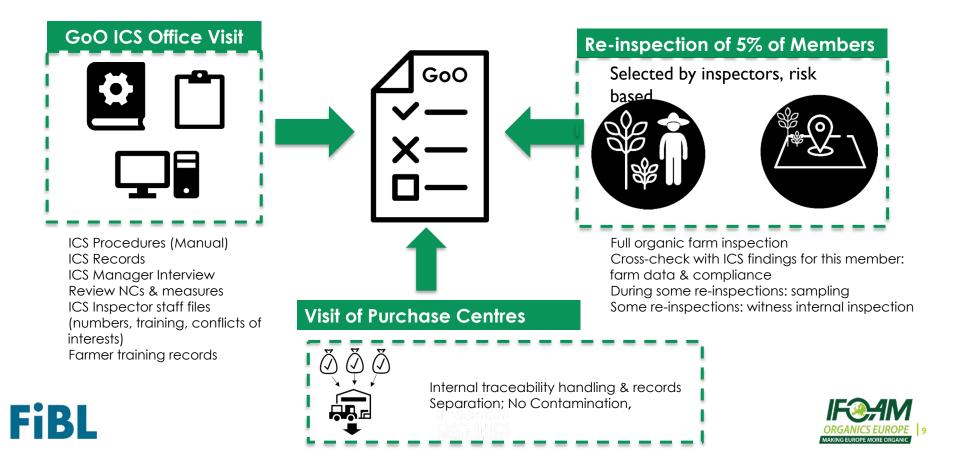
Art 12.5. For the high-risk products referred to in Article 8, the control authority or control body shall take, in addition to the 2% sampling rate, at least one field sample of the crop each year. That sample shall be taken from crops in the field, at the most appropriate moment to detect potential use of non-authorised substances according to the assessment of the control body.

**Art 13:** 1 (c): (the CB shall have ) a sampling strategy, procedures and methodology, control methods and techniques, including laboratory analysis, testing and interpretation and evaluation of results and consequent decisions + (e) a procedure for risk assessment and for carrying out sampling (...)

Note: The topic of sampling is being discussed in other working groups and not dealt with further in detail in this guidance.











# FiBL







Inspection of a GoO and evaluation of an ICS is demanding & complex task. The inspector needs to evaluate a quality management system and combine findings from many days of inspection and compliance assessment activities anaginst many sections of the EU Regulation.



- Inspection of organic agricultural production AND
- Inspection of basic preparation activities AND
- Specific training and practical experience in GoO and ICS evaluation

Note: For inspections of large groups with a high number of field reinspection days, an experienced GoO inspector could lead an team of more junior inspectors focussing on farm re-inspections.







# 2. ICS Office Visit & Evaluation of ICS Records



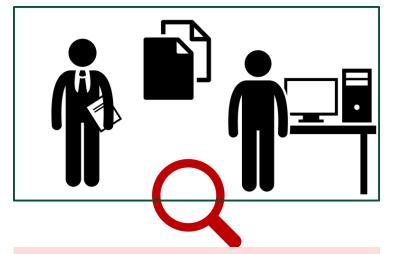






## ICS Office Visit & Evaluation of ICS Records





The ICS evaluation often starts during the ICS office visit but all information is evaluated and cross-checked throughout also entire GoO audit, especially also during re-inspection visits! Interview with ICS Manager

**Review ICS Manual / Procedures** 

**Overview project sites and purchase centres;** planning re-inspections.

### **Review Members list**

**Review ICS files for members:** agreements, basic farm data information

### Check of ICS staff files

- Appointments of ICS manager & inspectors
- ICS inspector training records
- Conflicts of interest declarations

Farmer training procedures & records





## **Guidance Evaluation ICS Procedures & Member list**



Reg 2021/771 Art 2: For the purpose of evaluating the set-up, functioning and maintaining of the ICS of a group of operators, the CB shall determine at least that:

(a) the documented procedures of the ICS that have been put in place comply with the requirements of (EU) 2018/848 (→ listed in Art 36.1.h!)



### Additional Guidance Evaluation ICS Procedures/ Manual:

All required ICS procedures available (listed in Art 36.1(g)

#### Verify that procedures (as written) comply with regulation

Important to ensure corect "translation" of complex EU rules into ICS procedures internal organic production rule summary for members (if any) procedures to register & apoprove new members & handle conversion in practice procedures to maintain & update farm data for the member list internal inspection guidance/protocol traceability, purchase and handling Risk management & precautionary measures

## Check that ICS documented procedures are known to ICS staff and effectively implemented

e.g. avaliable in local language of ICS inspectors? relevant details known by the staff who should implement?







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Reg 2021/771 Art 2: s, the CB shall determine at least that:
(b) the list of members with the required information for each member is continuously updated and aligned with the scope of the certificate;
(c) all members of the group of operators comply with the eligibility criteria or in Article 36(1)(a), (b) and (e) throughout their participation in the GoO



### IFOAM Additional Guidance Verification of GoO Members List:

all data avaliable for each member as per Reg. 2021/279: Art 5 (a)

Consistency check across members (e.g. similar harvest estimate for similar crop acreage; sums across memebers consistent;

Understand internal process for updating members list after internal inspection

### <u>Member Eligibility</u>: see separate IFOAM Guidance on Group Certification Section 2 on Composition of GoO !

- All members < 5ha TOTAL land  $\rightarrow$  OK
- For all members > 5 ha total land → check turnover /organic sales to the group < 25'000€: if more → not eligible</li>





## **Guidance ICS Evaluation of ICS inspectors**



**Reg 2021/771 Art 2:** (d) the number, training and competence of ICS inspectors are proportionate and adequate and ICS inspectors are without conflicts of interest;

**Reg 2018/848 Art 36.1 (g) (viii)** ICS manager shall verify the conflict of interest statements of ICS inspectors ICS inspector shall (iii) submit written & signed conflict of interest statement and update it annually. Art 36.1.h: Compulsory record: Appointments of ICS inspectors



# IFOAM Additional Guidance Evaluation ICS Staff Number, training & competence of ICS inspectors:

<u>Number</u>: ICS should prove that it has a sufficient number for at least 1 thorough inspection of each member per year including travel time & reporting, follow up as well as other office and field extension or training duties.

<u>Training</u>: at least 1 /year (&recorded), all new inspectors need to be more carefully trained, shorter update training ok for experienced inspectors!

CB needs to verify the ICS information and will need to present a justifed system how it assesses that the number, training and compentence of ICS inspectors is sufficient.

 Check that ICS inspections are free of conflicts of interest Annually updated Conflict of interest statements ICS inspectors.

Statements are verified by ICS manager & considered in inspection scheduling Also very important that ICS manager has no Conflicts of interest!!!!!

#### IFOAM Guidance: What constitutes a "Conflict of Interest" in an ICS:



Providing Training & extension to farmers is NOT per se a conflict of interest Relevant conflicts of interest : any relationship that can jeopardize an objective control. e.g. family ties, close friendships, business relations to the inspected/sanctioned member.



## **Checking Internal Inspections Schedule & Progress**



**Reg 2021/771 Art 2:** (e) the internal inspections of all members of the group of operators and their activities and production units or premises including purchase and collection centres have been carried out at least annually and are documented;.





### IFOAM Additional Guidance 100% Internal inspection

Best Practice would be to schedule internal inspections risk-based, at different times of the production season (not just once a year, before external inspection & harvest). For crops with defined harvest season, it is also important that each harvest is controlled, i.e. that 100% inspections take place between one harvest and the next.

- → IFOAM recommends that CBs adapt their external verification approach of "100% ICS inspection" in a sensible way for GoOs that apply a risk-based ICS schedule approach:
   a) ICS manager has a defined schedule to do 100% internal inspection for the current year and can present reasonable progress against schedule. CB should be informed of schedule.
   b) Verify that 100% of farmers were ICS inspected in past 12 months or last calendar year, ensuring effectively "100% annual inspection"
- c) Additional risk evaluation by CB to decide when GoO certificate can be issued/ new harvest "released" (e.g. new GoO or weak ICS management → after 100% inspection confirmed)

Example 1 : Inspection in Jun, Harvest in Aug, critical period to check herbicide use: Dec during rains  $\rightarrow$  100% inspection between Aug last year and Aug this year?



Example 2: Inspection in Mar, Harvest season Apr:  $\rightarrow$  check 100% inspection in the previous calendar year and that the inspections in current year have taken place according to schedule.



## Checking GoO's Registration of New Farmers/Activities



**Reg 2021/771 Art 2** (f) new members or new production units and new activities of existing members, including new purchase and collection centres, have been accepted only after they have been approved by the ICS manager on the basis of the internal inspection report according to the ICS documented procedures that have been put in place;



**Procedures for new members or new added units/activities** of existing members in line with new requirements for retrospective recognition?

Verify conversion status as proposed by ICS manager

If any cases of retroactive recognition of part of the conversion period\_ → spot checks & in depth verification of these members & their ICS files

Authorisation on any retroactive recognition only by the CB!

New GoO members and activities are approved by the ICS manager, but they are only "<u>certified</u>" after the next CB certification of the GoO, i.e. once they are listed on the CB's GoO certificate!

New requirements for retroactive approval applied to GoO: → see IFOAM Guidance Section 5



## Checking the ICS' Measures in case of NCs



**Reg 2021/771 Art 2:** (g) the ICS manager takes appropriate measures in case of non-compliance, including their follow up, according to the ICS documented procedures that have been put in place; (h) the ICS manager's notifications to the CB, are appropriate and sufficient; **Reg 2018/848 Art 36.1 g:** The ICS shall comprise (vii) the measures in cases of non-compliance detected during the internal inspections, including their follow-up;

**Reg. 2021/279 Art 1:** Procedures to follow in case of suspicion of non-compliance due to presence of non-authorised products or substances. **Art 5.(f)** records of measures taken in case of NC, including those suspended, withdrawn or required to comply with a new conversion period;

Reg. 2021/1698 Annex IV: Classification of Non-Compliances into Minor, Major & Critical



### **IFOAM Additional Guidance Measures & Notifications:**

Verify records of members "subject to measures

Check ICS documentation of NCs, Measures taken, and follow up. Were the measures alligned with the severity of the NC especially for any Major/Critical NC?

Critical to check internal follow-up of sanctions, in particular if a farmer was suspended or de-certified. Was the sanction known at purchase and no product bought from the sanctioned member

Timely notification to the CB in case of all major and Critical NCs?

Timely (=prompt) notifications by the ICS manager are required in case of any NCs which lead to suspension, withdrawals or re-set of the conversion period of members or products lots as the integrity of the certified products may be affected.









# 3. Re-Inspection of Members;



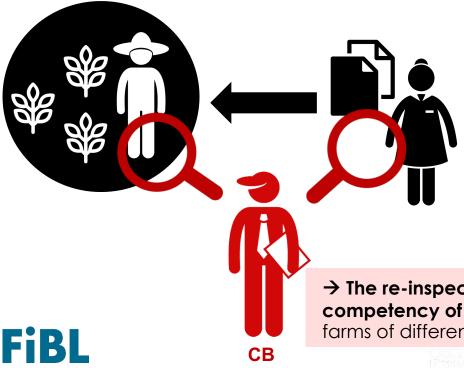








The MAIN OBJECTIVE of re-inspection visits is to evaluate the quality and effective functioning of the ICS



**Full organic farm inspection** against the organic production rules, incl. Post harvest handling & storage

**Cross-Check external findings** against the ICS's findings & measures for this farmer

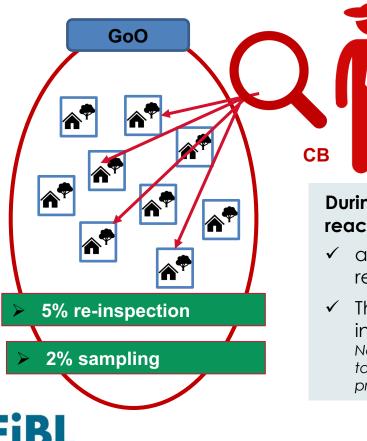
**Cross-Check ICS Data for this farm** (in ICS file and member list): Farm size, units, crops, harvest estimates

→ The re-inspection serves to assess the competency of ICS inspectors by sampling the farms of different ICS staff members



## **EU Requirements Member Re-inspection?**





Each year, at least 5% of members shall be subject to re-inspection by the external inspector

# During some of these re-inspections, samples shall be taken to reach at least 2% sampling per Year in TOTAL

- ✓ according to the CB's sampling procedere for GoOs; to reach 2% member sampling IN TOTAL
- ✓ Thus, samples will be taken at less than 40% of all reinspected farms.

Note: 40% of all reinspection = 2% of all members, i.e. if all samples would be taken at farm leve; more likley some samples also drawn at later stages (e.g. pruchase and preparation).

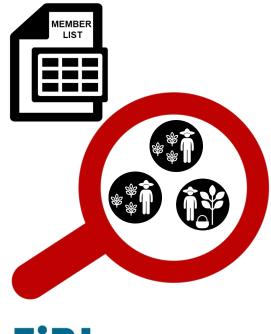




## **Selection of Members to Re-Inspect**



**2021/771 Art 2.3:** The control body, shall apply risk assessment to select the sample of the members of the group of operators for the re-inspections (...). In doing so, it shall take into account at least the volume and the value of the production and the assessment of the likelihood of non-compliance with (...) the Regulation. Re-inspections shall be carried out physically on the spot with the presence of the members selected.



The inspector selects the members to be re-inspected according to the CB's GoO control procedures and risk assessment.

IFOAM recommends considering the following GoO specific criteria in the risk based re-inspection sampling process:

- ✓ Size of farm & estimated volumes of certified products
- Heterogeneity of production risks within the GoO, e.g. if some high-risk crops or methods are relevant on some but not all GoO member farms.
- ✓ Sampling sub-groups: Many groups have regional subgroups/project centers → important to sample different sub-groups New stricter rules of inspection of purchase centers that handle also non-organic products mean that ALL project areas may need to be inspected every year.
- ✓ Some re-inspected members (e.g. 15%) should be the same as during previous CB inspection in order to check that NCs have been resolved
- Sampling different ICS Staff' work : if the ICS team is split in regions / teams, important to sample the work of different teams





## What to check during Member Re-inspection?

### Physical Organic Farm Inspection Focus

- Interview with farmer
- Visit of organic/Conversion fields & crops. Spotcheck of also nonorganic unit
- Check all organic plant production rules in the organic/covnersion unit
- Assessment of contamination risks & precautionary measures
- Check Storage of input, Post harvest activities & product storage
- Assess compliance/noncompliance & report the findings





### **ICS Records & data Evaluation Focus**

- Review ICS file for this farmers (agreement, inspection reports, maps or basic data forms if any)
- Member list: crosscheck data on this farmer in Members list
- Check yield estimates and basic farm data (e.g. fields, crops & activities)





## Member Re-inspection: Evaluation of Competencies



During farm-inspections it is advisable to have also ICS staff present and use the time to assess competencies. Witness inspections are required and very useful!

### Evaluating ICS Inspector's Competencies during Re-Inspection

- Test knowledge of organic production rules & ICS procedures
- ✓ Cross-check trainings received
- Evaluate inspection techniques and technical skills
- Check ICS inspector's numbers of inspection / year & other duties in order to assess whether number of ICS inspectors is sufficient & realistic for 100% internal physical inspection



### Witness Internal Inspection

- Some re-inspections should be witness audits, i.e. ICS inspector conducts the inspection and the external inspector observes; but adds checks/questions if required.
- Shows inspection techniques & whether ICS inspector follows the protocol
- Insights on how ICS inspections are normally conducted , e.g. field visits & an interview always done or not)

CB will be expected to have a defined system to evaluate competencies, e.g. minimum number of witness inspections and procedure how competencies are assessed during farm re-inspections



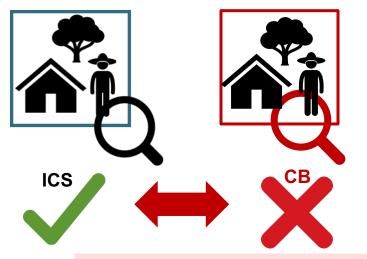




## **Dealing with Deviations Internal-External Inspection**



If during a re-inspection the inspector comes to a different finding than the ICS, it is very important to evaluate the case according to the CBs procedures, in order to assess whether/to what extent this indicates an ICS deficiency that could affect the integrity of organic products.



### **Evaluate ICS's staff reaction & context**

Is the problem found one that the ICS is clearly aware off and has detected in other cases (but missed in this case)?

### Try to further qualify and quantify the NC in other reinspections:

- Similar problems at other farms inspected by same ICS inspector?
  Ainly one weak ICS inspector?
- Problem across ICS inspectors in an area / across all project subsites?
- The problem across crops / production system or only in a few selected (unusual) production situations?

In any case of Major NCs found on farm level  $\rightarrow$  check if products from this member have been bought  $\rightarrow$  traceability check whether products can be localized or not .



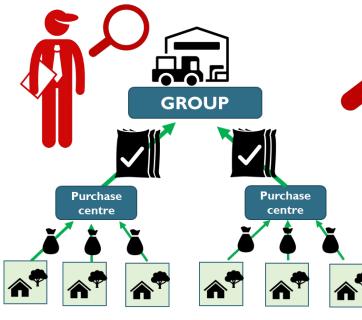


## 4. Checking Purchase & Traceability in the GoO GROUP Pr **Purchase** hase centre centre CB FiBL



## Inspection of Traceability & Product Flow

To ensure organic product integrity, the organic inspection needs to carefully check the entire product flow from members (farms) into the joint marketing system and then all product handling within the GoO's internal units (e.g. purchase centres).







## Critical traceability risks to check at farm level

- Product Substitution (members selling other farmers' products as organic to the GoO)
- Contamination of organic products at farm level (during preparation or storage)
  - Commingling with non-organic products during member's processing activities (e.g. joint processing with neighbours)







## **Inspection of Purchase Centres**





The GoO inspection shall always include the checking of purchase centres and traceability

<u>Reg. 2021/1698, Art 9.9:</u> All purchase centres that handle the certified product also in non-organic quality need to be annually inspected by the CB!

### Most critical risks to check at purchase centres

Purchase procedures do not guarantee a correct check of the member's organic status and/or crosscheck of harvest estimates by purchase staff

Purchase centre

- Conflicts of Interest of purchase staff, e.g. Independent purchase officers who collect/buy products from members and sell to the GoO
- Traceability system is not applied consistently
- Contamination of organic products during storage (e.g. facility pest control))
- Commingling with non-organic products during product handling (e.g. quality grading, packing, storage)





# **Overall Traceability Check Joint Marketing System**





2021/1698 Art 11.2: The annual physical on-the-spot inspection shall include a traceability check and a mass balance check of the groups of operators, carried out by means of checks of documentary accounts and of any other relevant element deemed necessary by the CB.

Relevant traceability related aspects to check in most GoOs:

- Check the functionality and consistent application of the traceability system by tracing some sales lots throughout all stages back to members
- □ Mass balance check according to CB's protocol
- Check that all organic production rules are met during transport between internal units (e.g. from purchase centre to central warehouse), preparation, storage and export according to CB's inspection protocol for these activities.
- **Subcontracted processes**, e.g. subcontracted processors

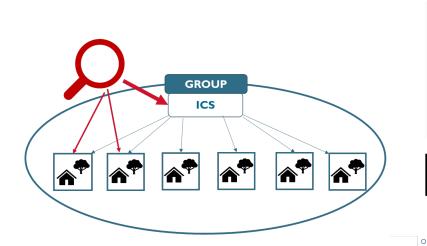








# 5. Evaluating Compliance and Certification of a GoO



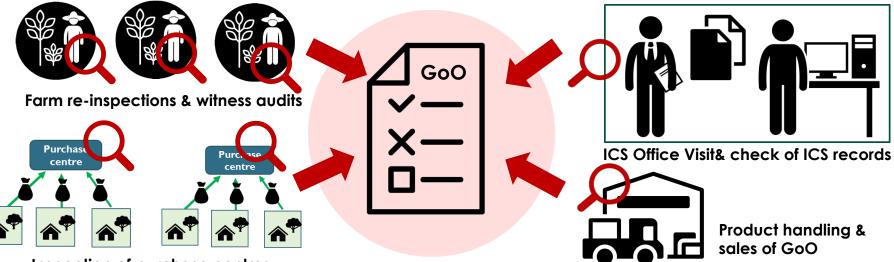


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# **Compiling the Findings of the GoO Inspection**

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In a large group inspection, and with the new even higher number of farm re-inspections it is a complex task to compile the overall findings after many days of GoO inspection.

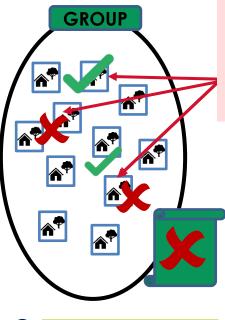


#### Inspection of purchase centres

Note: The system how findings are combined into the Final GoO inspection report will depending on the CB's Standard Control procedures and inspection report for GoOs

## **ICS** Deficiencies





**Reg 2018/848 Art 36.2** (added by 2021/715)

2018/848, Art 36.2: CBs shall withdraw the certificate (...) for the whole group where deficiencies in the set-up or functioning of the ICS, in particular as regards failures to detect or address non-compliance by individual members of the group of operators, affect the integrity of organic and in-conversion products.

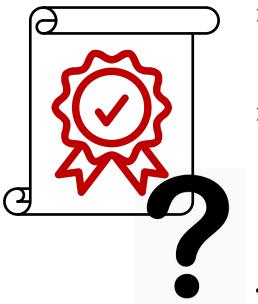
36.2. (continued): At least the following situations shall be considered "ICS deficiencies":

- Serious deviations between findings of internal/external inspections
- serious deficiencies in imposing appropriate measures in case of NCs
- processing/selling products from suspended or withdrawn members;
- Adding new members (or units) to the list without following procedures,
- Failing to indicate suspended/withdrawn members in lists
- Not carrying out annual physical internal inspections of 100% of members
- Inadequate number or competency of internal inspectors











**eg 2018/848 Art 36.2** added by 2021/715)

### **IFOAM Guidance ICS Deficiencies :**

- Group certification is based on the existence of an effective ICS, i.e. an internal system that guarantees compliance and organic product integrity for 100% of members (although only min. 5% are re-inspected by CB).
- If an ICS is systemically too weak / deficient to guarantee the organic product integrity for 100% of members, the certification of the entire GoO needs to be at least suspended until the ICS is effective.

Note: If findings between internal and external inspection differ considerably, this should not just result in the CB de-certifying the few non-compliant re-inspected members. However, in some cases the identified problems may indeed be very localized and can be swiftly corrected and may not affect the entire groups certification

• It is up to the CB's evaluation and approved procedures incl. catalogue of measures if the identified "ICS deficiencies "affect the organic product integrity" and lead to withdrawal /suspension.







## The new EU Certificate for GoOs in Third Countries



The new EU certificate indicates certified ACTIVITIES & certified PRODUCT CATEGORIES. The same template applies for GoO as well as operators; in the GoO certificate template there is a section for listing the GoOs members. Certificate will be issued in Traces.

IMPORTANT: The decision on certified activities & product categories is done by each CB according to its approved procedures.

#### Certified ACTIVITIES of GoOs, Operators & Exporters

**Production** (crop production, livestock, aquaculture, apiculture)

#### Preparation which includes:

- Operations of "Preserving"
- Operations of "Processing" = any action that substantially alters the initial product, e.g. heating, curing, extracting, marinating, drying e.g. GoO member curing cocoa beans on the farm
- Operations carried out on an unprocessed product without altering initial product (e.g. cleaning, milling)
- Packaging & Labelling
- □ Storage
- Export

□ Import and Distribution (business to business in same country)



#### **Certified Product Categories**

**A - Unprocessed plants & plant products** (incl. seeds and plant reproductive material)

# D - Processed Agricultural Products, including aquaculture products, for use as food

B- Livestock and unprocessed livestock productsC- Algae & unprocessed aquaculture productsE- Feed F- Wine G- other specified products

## Most operators (= legal entity) likely to be certified for more than one activity and product category.

e.g. a diary farm in the EU that processes some of its milk into cheese for sales on the local market will be certified for production, preparation, storage and distribution of B unprocessed livestock products (milk) and D- Processed agricultural products.

