

















The ITC Guide to the New EU Organic Regulation

Part I: The new EU Organic Production Rules

I.I Introduction and Key Changes for Organic Operations in Third Countries

Author: FiBL Research Institute for Organic Agriculture Updated Version for ITC 30.10.2023

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Content of this Chapter I: Introduction and Key **Changes for Organic Operators in Third Countries**

- 1.1.1 The new EU Organic Regulation
- 1.1.2 Key Changes for Producer Groups
- 1.1.3. Key Changes for Farm Production and Handling of Organic **Products**
- 1.1.4 Key Changes for the Organic Control System

About this Guide

This ITC guide was written by experts of FiBL, the Research Institute for Organic Agriculture, based on careful analysis of regulatory texts. The new regulation is not yet applied in Third Countries and, as any summary or guidance on the new legislation, it represents the current understanding of requirements (Status: July 2023). Interpretation of regulators' requirements will evolve as the new regulation is being applied in the EU and third countries, and the guide may need to be updated accordingly.

The EU Organic Regulation is a legal act, embedded in the EU's wider regulatory framework. It continues to be supplemented by secondary acts, additional measures or rulings by the EU and member states.

Certification decisions are always taken by the CB, based on its application of the legal texts and according to its recognised policies and procedures



This guide aims to summarize & explain the new requirements in a simplified way to operators, certification bodies, experts and competent authorities in Thailand and other Third Countries.

It is not a certification standard nor an official EU Guidance or official interpretation of the Regulation by the EU.

I.I.I.The New EU Regulation



The New EU Organic Regulation

The new organic regulation (EU) 2018/848 and its more than 25 "secondary acts" came into force on I January 2022.

The new Regulation:

- Aims to strengthen the organic integrity of production, especially for imported products
- **Sets the same production rules** for operators in EU & worldwide.
- Rules for group certification are completely re-defined – and integrated fully in the Regulation
- Fundamentally changes the control system in "third countries" outside the EU.



Timeline for Application of the New Regulation

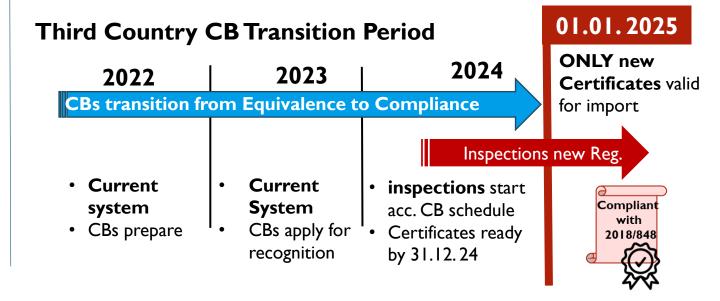
The Regulation is applicable for operators and groups of operators in the EU since:



January 2022

BUT there is a transition period for recognized equivalent Control Bodies (CBs) in Third Countries until 31.12.2024.

- Third Country CBs have to apply for recognition under the new rules The first list of recognized CB is expected from mid till end of 2024.
- Operators should contact their CB to learn about the detailed program and time frame for the switching to the new regulation.
- New certificates can be issued once the CB is listed for compliance and the operator has been inspected according to the new regime.



The Regulatory Framework New EU regulation

The Regulation (EU) N° 2018/848 (Consolidated Version)

The "Consolidated Version" is available in multiple languages. To find the latest version, search for 2018/848 and follow link to "current consolidated version" in www.eurlex.eu;



Regulations are easy to find on EURO-

LEX by searching in browser by

number, e.g. "EU 2021/279"

ADDITIONAL KEY SECONDARY ACTS for organic production in Third Countries outside the EU



2021/279: Measures ensuring traceability & compliance (incl. groups)

2021/771: Documentary accounts & control of groups of operators

2021/1698: Recognition of CBs & control procedures in Third countries

2021/1165 List of Authorized Substances (in organic production)

EU Commission: Frequently Asked Questions on organic rules (V 13.06.2023)



The new regulatory framework on organic production is complex, as the Organic Regulation (EU) 2018/848 is amended and complemented by many "secondary acts" as well as interlinked with other EU legislation. See also section 2.1 for a more complete overview of secondary acts.

This Guide summarizes the most relevant requirements for "groups of operators" and "operators" in Third Countries and provides references to the relevant sections in the Consolidated Version of Regulation (EU) 2018/848 and/or to relevant "secondary" or other EU regulations to find the detailed legal texts.

For example:

§ 2018/848:Art 36.1 (h) 2021/279, Art 5

CONSOLIDATED Version of Regulation (EU) 2018/848

The Most Fundamental Change for Third countries





«Compliance» instead of equivalence»

- Currently, in most Third countries, such as e.g. Thailand, organic operators and Groups are certified according to their certifiers' «equivalent organic standards» with some consideration of local conditions.
- With the new regulation Operators in «Third Countries» will need to comply with to the same (very detailed and prescriptive) rules as EU operators.





Applicable new rules to comply with: Guide Sections 1.2 -1.4

1.2 New rules for smallholder groups

1.3 Summary of new organic production rules for plant production in Third Countries 1.4: Brief overview livestock, apiculture and aquaculture in third countries

Organic Production in "Third Countries"



This guide focusses mainly on the applicable relevant requirements of the new regulation for organic production in "Third countries" such as Thailand, which are not recognized as "equivalent Third Country" by the EU.

If this Guide refers to rules in "Third Countries", it refers all countries outside the EU except USA, Australia, New Zealand, Canada, Switzerland, UK, Israel, Argentina, Costa Rica, Chile, India, Korea, Tunisia and Japan (Status June 2022)



Certified Organic Operators in Third Countries for export to the EU

In most countries organic farms are primarily certified in groups.

>99% Plant production minimal honey & aquaculture, hardly any livestock

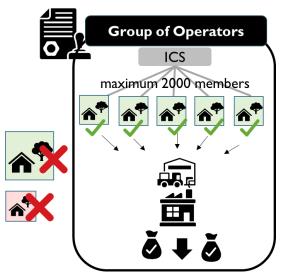


For details on the current and future EU import and third country recognition system, see Guide Section 2.1 for overview and Section 2.3 for details on country recognition & trade agreements

I.I.2. Key Changes for Producer Groups



Fundamental Changes for Groups in Third countries



The Regulation defines in Art 36.1 the new concept of a "Groups of Operators"

- ✓ Legal entity composed only of organic or in-conversion farmers
- ✓ all under a new maximum farm size/organic turnover limit and
- ✓ Up to a maximum of 2000 members
- ✓ Joint marketing, Internal Control System, Geographic proximity



Only some currently certified producer groups meet the EU's "Group of Operator" definition of Art 36.1, and can be certified as GoO in their current form.



The majority of currently certified groups will need to set up new legal group entities and/or change organisational set-up for future EU group certification.

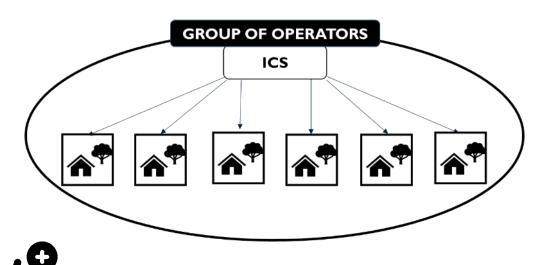
This includes all "contract production groups" organised by a trader and farmers organisations with non-organic or "too large" statutory members.



For details on the new rules for organic farmer groups, see Guide Section 1.2

Detailed Rules for the Internal Control System (ICS)

The regulation sets detailed requirements for the "Internal Control System" in a "group of operators" which ensures effective internal control of 100% of group members



- The rules are in line with well established best practice guidance on ICS, e.g. by IFOAM
- ✓ Having ICS rules included in the regulation may help to harmonize practices and implementation

Documented Procedures

ICS Documents & Records

ICS manager & **ICS** inspectors

Internal inspection

Managing Non-Compliances

Traceability

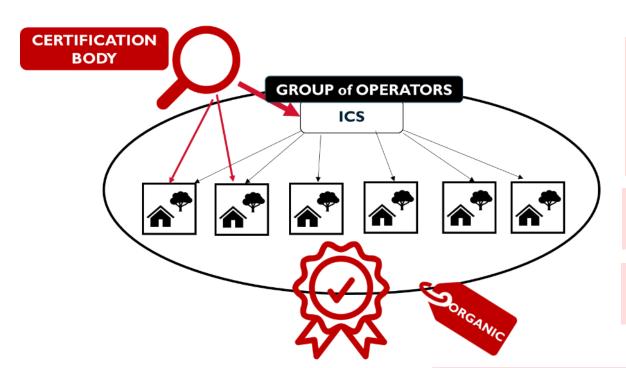
Farmers Training

2018/848: Art 36.1.g & h 2021/279, Art 5&6



For details see Guide Section 1.2

Key Changes: External Control of Groups



- ✓ At least 5% of members need to be re-inspected by the CB each year.
 - = considerably higher control rates for larger groups.
- Sampling of at least 2% of members each year.
- Stricter rules for control of traceability
- ✓ Overall stricter control of the ICS and its efficiency to determine "compliance" with the detailed new EU requirements of the Regulation.



I.I.3. Overview Key Changes Organic Production Rules



Key Changes Agricultural Production: Compliance

The rules for organic plant production have been tightened but not changed that much from the previous Regulation 834/2007. For livestock production, apiculture and aquaculture there are slightly more technical changes.

But most importantly, farms in third countries have so far been certified according to their certifier's EU-approved "equivalent standards".



Under the new "compliance system, every farm in Third countries will need to comply with all detailed EU organic production rules (no longer in an equivalent way).

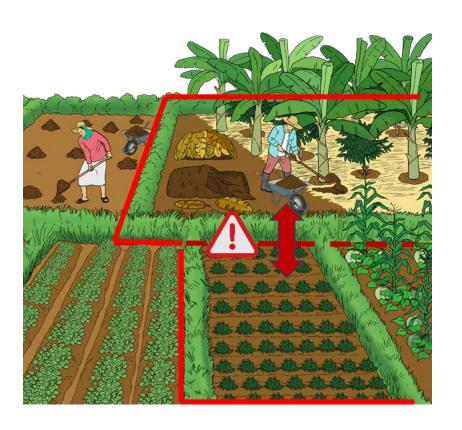
This will be the most significant change and mean stricter rules for most farms and **groups** in Third countries

The following slides summarize key changes for organic **plant production**.



Guide Section 1.3 summarizes the applicable organic production rules for Third Countries **Guide section 1.4.** provides a brief overview of rules for livestock, aquaculture and apiculture

Key Changes Farming: Land & Planting Materials



Requirements for separation in case of mixed production on the farm:

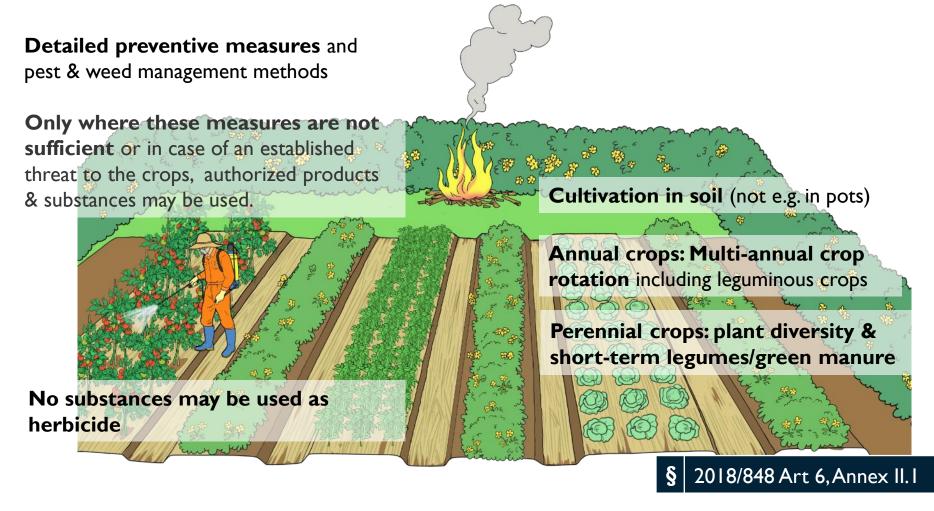
- E.g. documentation & separation of organic and non-organic production units, also for smallholder farms in groups
- stricter restrictions and conditions for parallel production

Clearer & stricter procedures for authorising exceptions e.g.

- for use of non-organic seeds & planting materials
- or retroactive recognition of the conversion period.



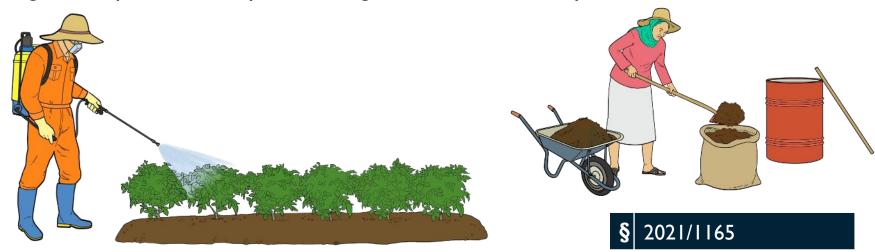
Key Changes Soil Management, Pest/Weed Control



New List of Authorized Substances: Reg. 2021/1165

Only the products and substances listed in Regulation 2021/1165 may be used

- Many substances have very specific conditions or restrictions.
- For Pest control (Annex I) the substance (even plant extracts, bacteria, etc.) must be additionally authorized for agricultural use in the EU.
- New list for substances permitted for cleaning & disinfection (from 2024)
- → Careful re-evaluation of farm-inputs will be necessary
- → This is likely to mean less flexibility than current "equivalence approach" e.g. for adaptation to tropical farming conditions and locally available substances



Key Changes Preparation / Processing



- More detailed /specific requirements to ensure separation and prevent contamination for collection, storage and transport to other units (in Annex III)
- Only specified products for cleaning & disinfection in processing and storage from 2024 (will be included in Reg. 2021/1165;)
- **Detailed requirements for producing** "processed food" and measures in case a unit handles organic and non-organic products.
- Some new restrictions for ingredients or processing aids; ban of nano-particles

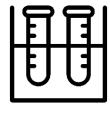
Key Changes for all Operators in Third Countries



Strong focus on (documented) precautionary measures to prevent contamination & commingling of organic products (including prior identification of critical points)



Focus on product traceability & mass balance documentation and verification



Blocking products while investigating in case of suspected or confirmed presence of non-authorized substances

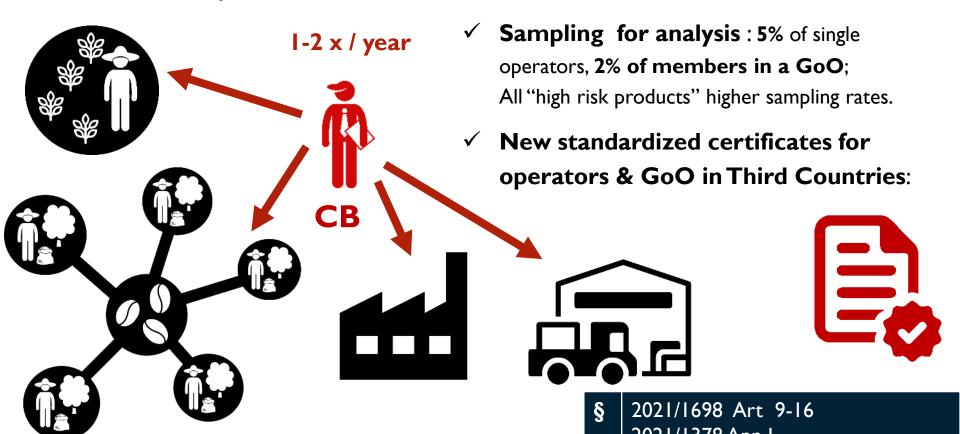
The EU will define "High Risk products" in Third Countries which will be subject to control twice a year and more intense sampling (each year). 2021/1698, Art 8

I.I.4 . Key Changes
Organic Control Process



General Changes for all Operators in Third Countries

- ✓ Physical Inspection "at least" once a year
 - > For future EU-defined "high-risk products": 2 inspections / year
 - > 10% of operators & GoO: additional unannounced control



Other key changes of the EU Control System for **Organic Imports**



The new worldwide compliance system will apply to the majority of countries exporting to the EU

- Third Country CBs need to become recognized to perform "compliant" certification according to Reg. 2018/848.
- The EU regulation must be complied with in the EU and outside the EU, with only some minor adaptations for Third countries, especially for control aspects.

Changes Organic Country Legislation Equivalence System:

- Currently the EU recognizes 14 Third Country organic legislations as equivalent: Argentina, Australia, Canada, Chile, Costa Rica, India, Israel, Japan, the Republic of Korea, Switzerland, Tunisia, United Kingdom, the United States of America and New Zealand;
- This system is discontinued. All countries that are currently recognised as equivalent have to renegotiate the terms for trade agreements or change to compliance.



For details on the new Compliance Control System see Guide Section 2.2 For the country equivalence recognition and trade contracts system, see Guide Section 2.3

For Group Certification: The new EU Rules will be different to other Organic and Sustainability Standards



- New NOP sections on group certification drafted; not yet final
- External Control rate proposed: 1.4 x Square root (members)
- USDA is considering maximum number of members/group; but not proposed yet.



- External Control Rate = square root
- No maximum number of members → Large can be certified as one legal unit.



Since a wide harmonisation process on certification of smallholder producer groups in the early 2000s, all organic standards as well as various voluntary sustainability standards (e.g Rainforest Alliance, GLOBAL G.A.P, FSC and others) applied the same underlying principles to group certification, with an external control rate based on a square root re-inspection approach. The EU regulation's new rules change will mean that external control according to multiple standards will become more complex for both the certified groups and the external control body.



















The ITC Guide to the New EU Organic Regulation

Part I: The new EU Organic Production Rules

1.2 The New Rules for Smallholder Group Certification

Author: FiBL Research Institute for Organic Agriculture

Updated Version for ITC, 31.10.2023

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Content ITC Guide Chapter I.2

1.2 : The New Rules for Smallholder Group Certification

- 1.2.1 Group of Operators Definition
- 1.2.2 Implications for Certified Producer Groups
- 1.2.3 Overview ICS Requirements
- 1.2.4 Overview External Control of Groups of Operators

Acknowledgement: the content in this section is based on the IFOAM Guidance on the new EU regulation for Producer groups (Final Version June 2023), which has been developed jointly by IFOAM Organics International, IFOAM Organics Europe and FiBL.

Note: The IFOAM guidance has been developed to explain the regulatory changes to certified organic producer groups in Third countries. It is not official an official interpretation by the EU., but includes reference to some EU Commissions FAQ on Groups of Operators.



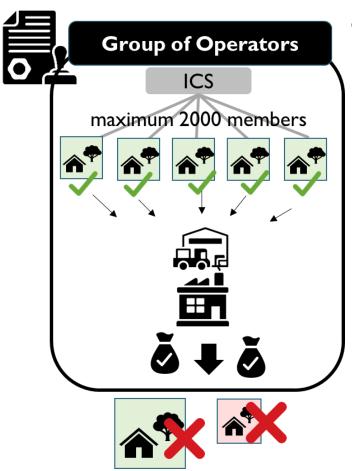




I.2.I Group of Operators: Composition, Dimension and Legal Personality



Basic requirements for "Group of Operators"



The Group of Operator (GoO)



is composed of members

- ✓ who are farmers committed to organic production
- under the maximum size/turnover limit (< 5 ha total land, OR < 25'000€ organic turnover).



Max. 2000 members



has "legal personality"



operates an Internal Control System (ICS)



has a system of joint marketing



Members shall be in geographic proximity. and shall register only for ONE GoO for a given product.

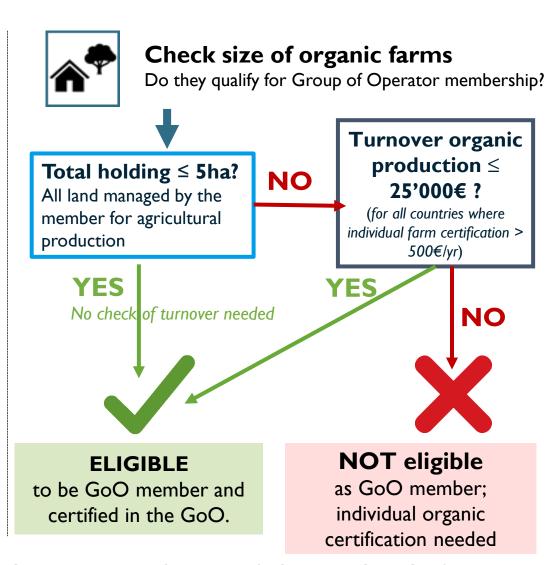
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Maximum Farm Size / Turnover of GoO Members



GoO Member is farmer with \leq 5ha total land OR ≤ 25'000€ organic turnover*

* Simplified summary; valid in all countries where the cost of organic certification for a single farm of that size would be more than 500€/year, i.e. almost all countries worldwide.



2018/848: Art 36. I b

Analysis: Maximum Size of GoO Members



Regulation Art 36.1.(b)

(The Group of Operators shall...) only be composed of members

- (i) of which the individual certification cost represents more than 2 % of each member's turnover or standard output of organic production and whose annual turnover of organic production is not more than EUR 25 000 or whose standard output of organic ← production is not more than EUR 15 000 per year; **OR**
- (ii) who have each holdings of maximum five hectares, 0,5 hectares, in the case of greenhouses, or 15 hectares, exclusively in the case of permanent grassland;

Condition (i) to be GoO Member:

If the cost of an individual farm's annual certification in the country is more than 500€/yr (almost all countries worldwide), the 25'000€/yr maximum turnover from organic production becomes the relevant restriction for farms > 5ha. In the few countries with farm certification cost < 500€/yr, the 2 % rule is relevant: e.g. certification cost 400€/yr → maximum organic turnover: 20'000€.

Example: Farm with 20 ha total land, thereof 7 ha coffee. Certification cost single medium farm in the country 1200€/yr; Turnover from organic coffee sales to the cooperative: 50'400€. \rightarrow 2% rule would be met (1200€ certification cost is more than 2% of organic turnover (=1008€) → BUT Organic TURNOVER = coffee sales to the group > 25'000 € → Too big to be GoO member; needs individual certification

"Standard output of organic production". The "standard output" (SO) is an EU-wide reference value calculated by EUROSTAT by region, product & reference period based on EU farm surveys. There are no defined "SO" values for third countries. In third countries, it is not useful to apply the SO rule instead of the easy to determine (and higher) 25'000€ turnover threshold. The SO may be useful to apply for GoOs in the EU.

GoO members must meet EITHER condition (i) OR (ii) - not **both!** \rightarrow a farm with up to 5ha total land can always be an GoO member. There is not need to check turnover.

Condition (ii) to be GoO Member: holding of farmer < 5ha

"Holding" = all land managed by the farmer for agricultural production. This includes all organic as well as non-organic land (with any type crops, pasture for livestock or fallow land).

EU COM FAQ: Requirements to be GoO member



EU Commission FAQ N° 12: What are the requirements for an operator to become a member of a group of operators?

In order to become a member of a group of operators, an operator must comply with the requirements of Article 36 of Regulation (EU) No 2018/848.

First, Article 36(1), point (a), defines the type of operators that can be members of a group of operators and the activities that members of a group of operators can perform: "Each group of operators shall: (a) only be composed of members who are farmers or operators that produce algae or aquaculture animals and who in addition may be engaged in processing, preparation or placing on the market of food or feed;".

Second, Article 36(1), point (b), requires the members of a group of operators to meet one of three alternative criteria in terms of turnover or holding size in order to be eligible to be part of group of operators:

- "only be composed of members (...) of which the individual certification cost represents more than 2 % of each member's turnover or standard output of organic production and whose annual turnover of organic production is not more than EUR 25 000":
- "only be composed of members (...) whose standard output of organic production is not more than EUR 15 000 per year"; or
- "only be composed of members (...) who have each holdings of maximum:
 - five hectares.
 - 0.5 hectares, in the case of greenhouses, or
 - 15 hectares, exclusively in the case of permanent grassland".

Third, Article 36(1), point (e), requires that a "group of operators shall only be composed of members whose production activities or possible additional activities referred to in point (a) take place in geographical proximity to each other in the same Member State or in the same third country".

EU Commission FAQ on organic rules, Version 13 Jun 2023

Maximum Farm Size of GoO members

Holding = all production units operated by the member for the purpose of producing live or unprocessed agricultural products, including products originating from aquaculture and beekeeping



Does the 5 ha size refer only to the member's organic plots?

- No, the 5 ha holding limit refers to the farmers "holding" = total land operated by the member for agricultural production
- i.e. organic fields as well as non-organic or fallow land for rotation
- This includes plots with other crops than the organic export crop and any leased/rented plots cultivated by the member
- Forest plots are not included, unless used for beekeeping

The "total land surface under the management of the member " = compulsory element in GoO member list. It must be registered by the ICS & kept up to date for each member.

Maximum Turnover of Organic Production



What is the GoO member's "turnover from organic production"?

= The member's annual value of organic sales to the group

- Accumulated total sales per accounting year in local currency (past year)
- Based on the price for products as actually paid to the member
- **Subsidies** do not count as turnover



Question: What about significant sudden fluctuations in sales volumes, prices and exchange rates?

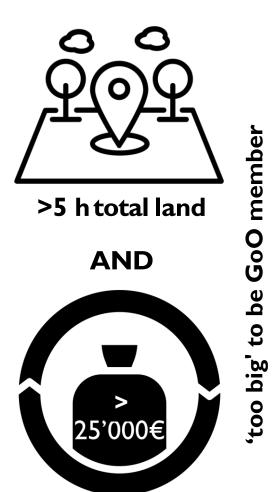
Answer: It is up to the ICS to define rules & procedures to ensure member eligibility is met.

→ The ICS procedures need to be reviewed & approved by the certification body.

FIBL & IFOAM additional considerations

- Intention = continuity in GoO membership; not annual in/out
- **Annual average currency conversion** to € is normal EU practice e.g. EU's InforEuro converter 12 months value
- Groups are advised to manage compliance with the turnover rules carefully and apply a safety margin in their membership rules

Larger Farms in a Farmers Association



If the farm is > 5ha AND its organic turnover is > 25'000€/yr it can't be GoO member.

- To sell as organic, the farms needs to be certified as an organic farm by a CB
- The farmer can NOT remain statutory member of the GoO group entity.
 - → either the larger farm is excluded from statutory membership.
 - → OR the cooperative forms a new legal GoO entity for just the "small" farmers, see next section

EU COM FAQ: Members no longer eligible



EU Commission FAQ N° (10): When members of a certified group of operators no longer comply with the requirements set out in Article 36(1)(a) and (b) of Regulation (EU) No 2018/848 can they remain a member of the group of operators?

No. Article 36(1) of Regulation 2018/848 provides that each group of operators "shall only be composed of members" fulfilling, among other requirements, the conditions set out in points (a) and (b).

Consequently, an operator who does not fulfil the **requirements** of Article 36(1), points (a) and/or (b) of Regulation 2018/848 cannot be a member of the group of operators if that group is intended to be controlled and certified as a group of operators within the meaning of Article 36 of Regulation (EU) No 2018/848.

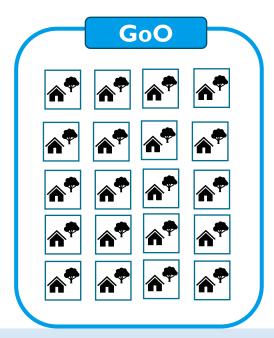
Art 36.1.(a) \rightarrow be a farmer or algue/aquaculture operator; comply with organic rules.

Art 36.1.(b) \rightarrow under the farm size or organic turnover limit.

Can not remain statutory (legal) member in the legal entity to be certified as GoO.

EU Commission FAQ on organic rules, Version 13 Jun 2023

Maximum Dimension of a Group of Operators



Max. 2000 members per Group of Operators

An GoO may have a maximum of 2000 Members

- → Groups with > 2000 certified members will need to set up new smaller legal entities for EU certification as GoO.
 - Each new smaller GoO unit will need "legal personality" and be composed of only organic or inconversion farmers
 - It is not acceptable that subunits (< 2000 members) of a cooperative share the legal personality of the cooperative. Each GoO must have own legal personality.

Already certified producer groups have a transition period until 1/2025 to comply with this new size rule.

EU COM FAQ: Cooperative with > 2000 members



EU Commission FAQ (9): In an example of a cooperative that has more than 2000 members, can this cooperative have groups of operators as sub-units of the cooperative, which are certified as groups of operators but which remain under the cooperative or share the same legal personality as it?

No. On the one hand, in the context of this example, the sub-units mentioned are groups of operators for the purpose of organic certification in accordance with Article 36(1), point (d) of Regulation (EU) No 2018/848, which provides as follows: "Each group of operators shall (...) have legal personality". Therefore, the mentioned sub-units cannot share the legal personality with other sub-units and/or cooperatives.

On the other hand, Regulation (EU) No 2018/848 does not prevent a group of operators from participating in the membership of other types of farmers associations or arrangements such as a cooperative subject to the respect of all applicable provisions. Finally, as set out in Article 4 of Regulation (EU) No 2021/279, the size of a group of operators cannot exceed 2000 members.

EU Commission FAQ on organic rules, Version 13 Jun 2023

The Group of Operators shall have "legal personality"

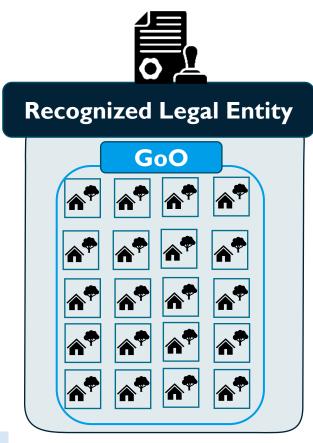


Art 36.1.(d) The Group of Operators shall have "legal personality":

EU Commission FAQ (13): Legal personality

FAQ (N°13): «Legal personality» is not defined by Reg. 2018/848, but refers to entities recognized by national law as having distinct identity, as well as legal rights and duties, and are thus able to do things in law that a natural person can do (e.g. own property, enter into contracts etc) according to the laws of that country.

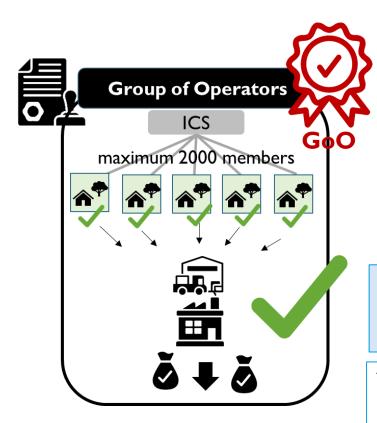
Note: Additionally, Art 36.1.(a) requires the GoO to be "composed for members who are farmers" \rightarrow the GoO entity can have any legal form but it shall be "composed of farmers".



Legal Personality

2018/848:Art 36. I d

Preparation Activities in a Group of Operators



Farmers organizations usually perform some preparation activities after collecting the product **from members**, e.g. sorting, mixing, packaging, sometimes also "processing" (e.g. drying).

The definition in Art 36.1, however, only states that members shall be farmers (...) who may in addition be "engaged in preparation and processing '

EU Commission FAQ (N°II): Can the group of operators perform preparation activities on the products that it receives from its members?

Yes. A group of operators certified as organic in the EU, or a group of operators certified as organic in the third countries can perform any activity, including "preparation", under the group's certification.

I.2.2. Implications for Currently Certified Producer Groups



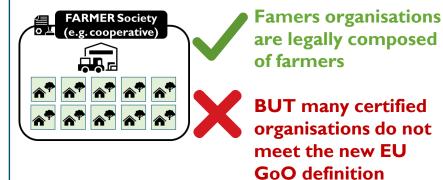
Important Implications for certified organic groups



Art 36.1 defines a "Group of Operators" as an new "concept".

- > Only some currently certified organic smallholder groups meet the new definition in its current legal and organisationalset-up.
- Many smallholder supply chains will need to set up new legal entities as "GoOs", or identify existing eligible entities to be certified as GoO.



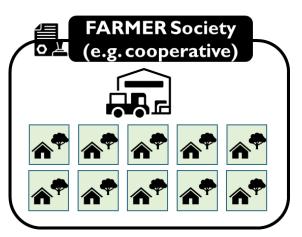


B. Processor/Exporter Organized Group ("Contract Production")



NOT in line with Art 36.1 as the legal entity is not composed of farmers

Implications for Farmers' Cooperatives or Associations



A registered farmers' organisation, e.g. a cooperative or farmers' association, is composed of farmers and can be certified as a "group of operators" if it has less than 2000 members...

BUT ONLY IF the farmer organisation is...



legally composed only of farmers committed to compliance with **EU** organic rules = organic and/or in-conversion statutory members (including farmers in first 12 months of conversion).



who are all farmers under the new farm size/turnover limit

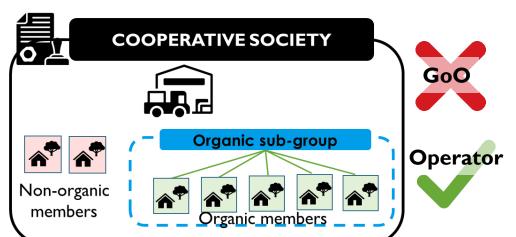


and it is registered under national law (e.g. cooperative, society, association, farmer community enterprise, self-help group, etc.).

Farmers' Cooperative with non-organic members

Question: Can a certified organic cooperative with organic as well as non-organic statutory members become certified as group of Operators?

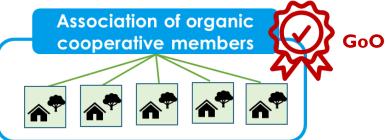
Answer: No. According to the EU interpretation, Art 36.1 implies that statutory members of a legal GoO entity must meet all eligibility criteria of Art 36.1. (farmers, comply with organic rules, under maximum farm size/turnover limit, in geographic proximity)



This cooperative can NOT be certified as GoO

It can be certified as operator for preparation & export of organic products from certified GoO(s) or other operators.

The sub-group of small organic farmers could be certified as GoO IF it had «legal **personality**» as a registered sub-group (e.g. association) or separate legal entity.



EU COM FAQ: Non-organic members in a GoO



EU Commission FAQ (8): Can a group of operators certified as organic (Regulation (EU) No 2018/848) consist of members who are not organic farmers or organic operators that produce algae or aquaculture animals?

No. Group of operators can only be composed of members who are farmers or operators that produce algae or aquaculture animals and who in addition may be engaged in processing, preparation or placing on the market of food and feed. Moreover, farmers or operators that do not comply with Regulation (EU) No 2018/848 cannot be members of a group of operators certified as organic.

First, Article 36(1), point (a), defines the type of operators that can be members of a group of operators and the activities that members of a group of operators can perform: "Each group of operators shall: (a) only be composed of members who are farmers or operators that produce algae or aquaculture animals and who in addition may be engaged in processing, preparation or placing on the market of food or feed;".

Second, the following provisions of Regulation (EU) No 2018/848 are also relevant:

- Article 3, point (13), which provides the following definition of "operator": "Operator means the natural or legal person responsible for ensuring that this Regulation is complied with every stage of production, preparation and distribution that are under that person's control"; and
- Article 36(1), point (g), which provides as follows: "Each group of operators shall [...] establish a system for internal controls comprising a documented set of control activities and procedures in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group."

EU Commission FAQ on organic rules, Version 13 Jun 2023

Can Unions of Cooperatives be certified as GoO?

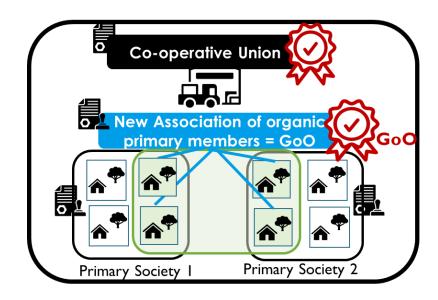
Answer: Most certified Unions or Associations (2nd or 3rd degree farmers societies) are unlikely to meet the new GoO definition as they have also non-organic farmers as (primary society) members and /or have > 2000 members.

A Union could be certified as "operator" marketing the products from GoO entities that meet EU definition:

e.g. GoO= certified primary societies

or GoO = new legally recognized group of organic primary society members

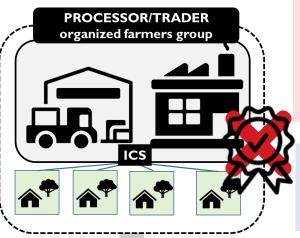
Note: There may be unions that meet the new GoO definition, e.g. if small organic cooperatives associate for the purpose of forming a larger GoO unit according to EU GoO specifications for joint exports



Adaption Example: New registered «association» with eligible organic primary society farmers as GoO members

Implications for Processor/Exporter Organized Groups

Now



Processors are usually neither composed of farmers nor farmers who are group members and engaged in processing.

A processing company can therefore be certified as a processing "operator", but not as a "Group of Operators".

For certification as group of operators farmers must be organized in a separate "farmer group entity" composed of eligible organic or in-conversion farmers, with legal personality.

New regulation:



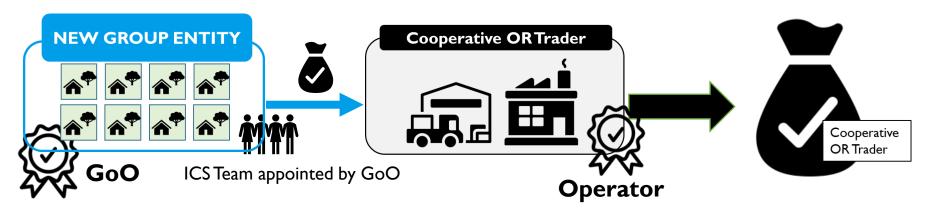


(New) Separate GoO Entities

The majority certified organic groups do not meet the EU definition of GoO and will need to change their organisational & legal set up for group certification to the EU.

- All "Contract production" groups organized by trader
- All farmer organisations that not meet the new EU GoO composition or size rules

Future Set-up: GoO certification for new group entities + operator certification (for preparation and export) for currently certified cooperative or trader



- The separately certified processing company or cooperative) as "operator" can still buy, process & sell products from the GoO entity/entities. It can provide services as "subcontractor" to the GoO.
- The company or cooperative could continue to operate the ICS on behalf of the new GoO to ensure continued quality, if the new GoO "appoints" the processor's ICS manager and ICS inspectors.

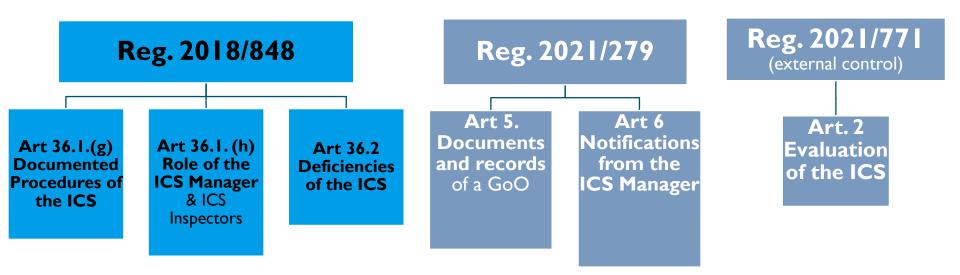
I.2.3. Overview ICS Requirements



Overview ICS Requirements in the Regulation



In the regulatory texts, the applicable new requirements and rules for the Internal Control System are defined in the following structure & regulatory acts:



Overview ICS Requirements





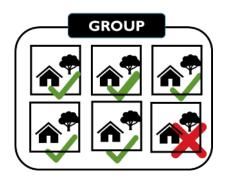


ICS Documents & Records

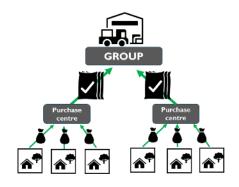


ICS Manager & ICS inspectors

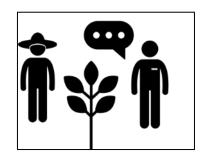




Managing Non-Compliances & notice to CB



Traceability & **Product flow records**



Farmers Training



The new regulatory requirements for a System of Internal Control (ICS) are more detailed than previous import guidelines, but overall in line with quality ICS Guidance, e.g. by IFOAM since almost 20 years

Documented ICS Procedures



An ICS shall operate according to defined procedures, as set by the ICS manager. The ICS procedures are often documented in an "ICS Manual"

Art 36.1 (g) The ICS shall have documented procedures on:

- (i) Registration of **GoO** members
- (ii) Internal inspection of all group members
- (iii) Approval of new members or new units/activties
- (iv) Training of ICS **Inspectors**

- (v) Training of GoO members
- (vi) The control of documents & records
- (vii) Measures in case of non-compliances
- (vii) Internal traceability of products



It is recommended to read the list ICS of procedures in Art 36.1 (g) and (h) as they contain many relevant details on the required ICS procedures. The list of responsibilities of the ICS manager is relevant too, as it also contains details on some core ICS processes (e.g. GoO member agreements)

2018/848: Art 36. I. g & h

ICS Documents & Records



→ Full list of required records with details in Reg. 2021/279 Art 5



- **List of Members** (see next slide)
- **Signed "membership" agreements** (→ Art 36.1 (g))
- **Internal Inspection reports**
- **Measures** taken in case of non-compliance

Note many ICS keep also other records in their ICS farm files, e.g. farm registration / field history of new fields, maps





- √ (Annual) Training records of ICS inspectors
- ✓ Annual Conflict of Interest statement of ICS inspectors
- ✓ Appointments of ICS manager & ICS Inspectors
- **Training records** of members



- **Traceability records:** purchase and distribution of farm inputs, records on production/harvest, storing & preparation and on delivery of the products into the joint marketing system
- **Subcontracting agreements**

2021/279: Art 5

ICS List of Members



The GoO Members List (shall have date & Version)

Name of farmer, identification, contact, date of registration



Total land surface managed by member and whether part of organic, conversion, nonorganic production unit

Information on each production unit, e.g. organic unit & non-organic unit: Size (of unit = fields), location* crops, start of conversion, yield estimate (recommended: yield estimate per ha & total yield estimate per production unti).

Date of the last internal inspection & name of ICS inspector

* Location of Production units shall be shown on map "where available"



The up to date members list is the most important ICS document, and also acts as a summary of all internal inspections, documenting also the results of the internal approval & sanction process. Managing the collection and updating of farm data and inspection results into members list is a challenging task for most producer groups and requires careful procedures, qualified staff and suitable IT equipment.

2018/279: Art 5

The ICS Manager



The ICS manager's role requires a senior position in the organisation with the authority, management & technical skills to manage compliance.

The "ICS manager" has the responsibility to:

- verify eligibility & approve GoO members, new units, etc.
- develop ICS procedures & forms; ensure records are up to date
- **Schedule internal inspections** and ensure adequate implementation
- be liaison to the CB: decide on notifications to the **CB**
- ensure annual trainings of ICS inspectors & assessment of their competencies
- decide on measures in case of non-compliances
- decide on subcontracting activities and sign agreements



The role of the ICS manager and the ICS inspector cannot be combined. The GoO can "appoint" an external ICS Manager and external ICS inspectors. The "Appointment" of the ICS manager and all ICS inspectors are compulsory ICS records to have on file.

2018/848: Art 36. I. h

Role of the ICS Inspectors

The GoO needs to appoint a sufficient number of ICS inspectors for annual inspection of all GoO members and ensure that they are competent.

Conduct the annual physical **inspection** of each GoO member farmer according to schedule and procedure set by the ICS manager

Need to be trained each year in organic production rules, ICS procedures and inspection techniques. Training records compulsory



Need to speak the local language of farmers and be able to read and write.

Note: ICS inspectors are often the main contact link between group & farmers

ICS inspectors may not have Conflicts of Interest that can jeopardize integrity of the internal control (e.g. family ties, business interests). Annual conflict of interest declaration compulsory.

2018/848:Art 36. I. h



Many groups have field advisors who visit and advise the organic farmers regularly. Once a year they conduct the internal inspection, preferably in another subgroup of farmer to avoid conflicts of interest due to close relationship to farmers. Please note that giving advice on organic farming is not per se considered a conflict of interest for an ICS inspection, but close personal ties to a farmer is a conflict as it can affect the assessment.

The ICS Inspection



100% of GoO members must be physically inspected by the ICS each year. The results of the inspection are recorded in an ICS inspector report, and dates of ICS inspection indicated in members' list

Farmer Interview (Compulsory!)

Identification of risks and prevention of contamination (e.g. buffer zones, tools)

Check post harvest activities & product storage

Visit of organic & conversion fields Spot-check of non-organic fields

Check use & storage of inputs

ICS farm data and details correct?

Yield Estimate

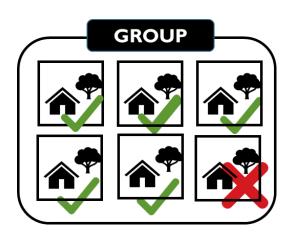


ICS Inspection report (Reg 2021/279, Art 5)

- Details of member & collection/purchase centre
- Audit scope / perimeter, starting & ending hour;
- signed by farmers & internal inspector

Best Practice: Inspections should be scheduled for different times to cover risks throughout the production season, e.g. 10% early season, 20% mid season, 70% in the 2 months before harvest.

ICS Approval Measures in Case of Non-Compliances:



Art 36.1 (g): ICS shall comprise documented procedures on

- measures in cases of non-compliance detected during the internal inspections, including their follow-up
- (internal) approval of new members or (...) new units/activities (..) by the ICS manager on the basis of the internal inspection report;







Records of measures taken by ICS manager in case of Non-Compliance (Reg 2021/279, Art 5f)

- ✓ **Members subject to measures**, including those suspended, withdrawn or required to undergo new conversion
- ✓ **Documentation of identified non-compliance**, e.g description of problem in ICS report, pictures, follow-up investigation / assessment of severity
- **Documentation of (implemented) follow-up of measures**, e.g. information to the member; information to purchase centre; notification to CB if required, training of members, scheduling more frequent ICS visits

Reg 2018/848: Art 36. I. g & h. Reg 2021/299 Art. 5

Managing Any Major & Critical Non-Compliances:



2021/279 Art 6: Notifications by the ICS manager

The ICS manager shall immediately notify the control body of:

- a) any suspicion of major and critical non-compliance;
- b) any suspension or withdrawal of a member or a production unit, including purchase centres.
- c) any prohibitions of placing certain product lots on the market as "organic"

manager

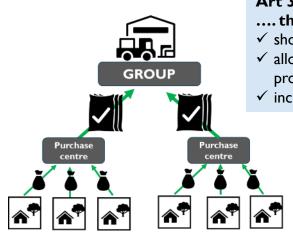


All Third Country CBs shall develop catalogue of measures with 3 new non-compliance categories (Annex IV of Reg. 2021/1698). These categories and the CB's will also be relevant for ICS Managers to be aware of for defining the ICS list of measures on how to deal with common non-conformities according the new Regulation

New EU Categories of Non-Compliances (→ see Annex IV of Regulation 2021/1698)

Non-Compliance	Classification criteria (simplified for ICS context)	Measures
MINOR	Organic product integrity not affected; sufficient precautionary measures, affected lots are traceable	Corrective action plan with time limit
MAJOR	NC affects the organic product integrity, but affected products / lots are traceable & can be located.	Affected product (lots) downgraded to non-organic; new conversion period
CRITICAL	NC affects organic product integrity + affected product lot cannot be located /separated	Affected products are non-organic, new conversion, suspension or de-certification

ICS is responsible for Traceability of Organic Products



Art 36.1 (g): ICS shall comprise documented procedures on

- the internal traceability, which
- ✓ shows the origin of the products in the joint marketing system and
- ✓ allows the tracing of all products of all members throughout all stages, such as production, processing, preparation or export
- ✓ include estimation and cross-checking the yields of each member

Reg. 2021/771, Art 2: Annual ICS of all purchase centres.

Note: the new requirements extend the ICS responsibility beyond the delivery to purchase centres - ICS responsible for traceability until sales!



- At purchase, member deliveries must be added up to cross-check with yield estimates
- A consistent lot identification system from point of purchase through preparation & storage up to final sales is very important! In case of Non-Compliances that affect the organic product integrity (e.g. farmer who sprayed herbicide) it is essential to be able to locate the affected lot and separate it from other lots
- Prevention of mixing with non-organic product and prevention contamination at all times!



Traceability Records (Reg 2021/279, Art 5g)

- **Joint Purchase & distribution of farm inputs** (incl. seeds or planting material to members)
- Records on delivery of products from each member to the joint marketing system
- GoO production, storing (in & out) & preparation records
- Sales of products by the group



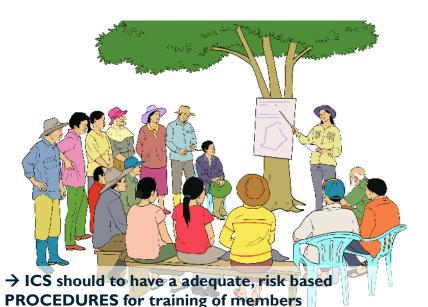
ICS training of Members



Farmers' training as new EU Requirement (Art 36.1 g)

- ICS shall have a procedure for "training of GoO members on ICS procedures and the requirements of the EU organic Regulation"
- Training of members shall be "recorded".

2018/848: Art 36.1.g



- to make sure they understand the organic production rules and the internal control system.
- e.g. in-depth initial training for all new members
- regular update trainings on changes as well as topics that ICS had found to need extra attention.



The regulation allows for all forms of farmers training, including field demonstration, training by extension visits (as long as training is recorded)

Field practice and explanation of production rules with practical examples in the field always works best to ensure that farmers understand the rules & how to meet them!

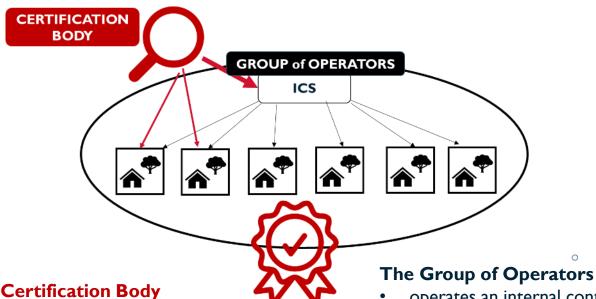


Farmer Training must be recorded (Reg 2021/279, Art 5)

1.2.3. Overview External Control of Groups of Operators



Introduction Organic Group Certification



The Organic Certification Body

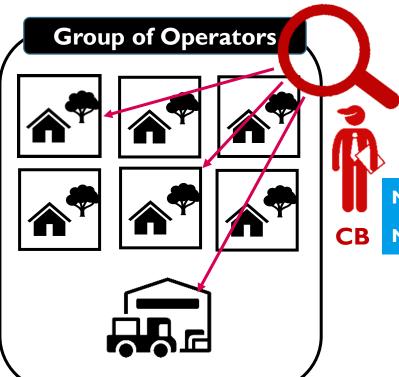
- Evaluates the functionality of the groups ICS
- To evaluate the ICS, the CB re-inspects a certain number of group members
- The CB issues ONE certificate for the group.

- operates an internal control system that ensures compliance of all GoO members
- markets member's organic products as a group
- farmers are certified as group members and cannot individually sell as certified organic.



Group Certification is different to the standard organic control system, which requires annual control and certification of each farm by control body. A certified farm can sell its organic products to any certified buyer. As this certification system is not accessible for smallholder farmers in developing countries, the EU has accepted group certification in developing countries for imports since more than 20 years. With the new EU regulation, «group of operator» certification is for the first time embedded directly in a major organic regulation and permitted anywhere in the world, including the EU.

New Rules for External Control of Groups of Operators



Physical GoO Inspection AT LEAST once a year

- + unannounced checks (10% of CB's Operators & GoOs)
- EU will define list of high risk products which will need to be physically **inspected twice** a year

2021/1698 Art 8 & 9

Min 5% of GoO members to be re-inspected each year.

Min. 2% of GoO members are subject to sampling

2021/279 & 2021/1698 Art 9

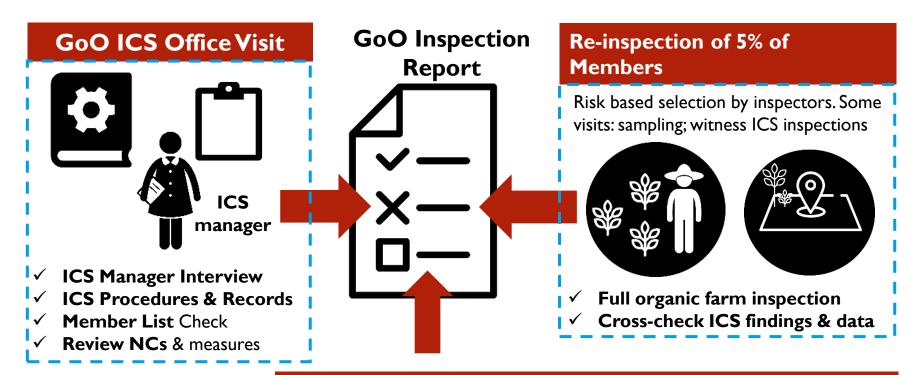
Purchase centres – all purchase centres that handle also non-organic products need to be inspected each year

2021/1698 Art 9.9



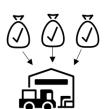
The new Regulation defines stricter control requirements for groups in Third Countries compared to the current import guidelines. The 5 % re-inspection rate will mean significantly higher control rates for larger groups, compared to the current system based on the square root of members times a risk factor. For products and origins that will be defined by the EU as «high risk products» in the future, two physical inspections per year will be required.

External Inspection of a Group of Operators



2021/1698 Art. 9-13 2021/279 Art. 2

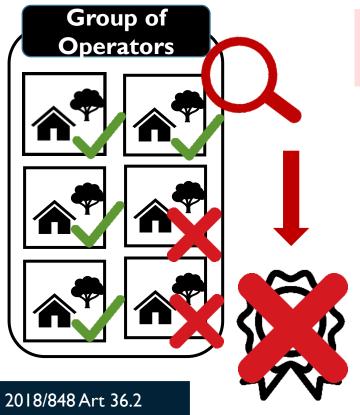
Inspection of Traceability



Inspection of Purchase centres

- **Traceability records** of delivery from members and combination into lots
- **Separation; No Contamination Inspection of all activities** until sales by the GoO, including traceability checks and mass balance checks

ICS Deficiencies



If the external inspection finds that ICS deficiencies affect the integrity of organic and in-conversion products, the group's certificate shall be withdrawn.

New regulation includes a list of "ICS deficiencies" e.g.

- Not carrying out 100% physical internal inspections each year
- 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,
- Inadequate number or competency of internal inspectors



Group certification is based on a functional internal control system. If the ICS is systematically «deficient», to the extent that the organic integrity of products cannot be guaranteed for all farmers, the entire group's certificate may need to be suspended, e.g. if the ICS is systemically failing to detect major non-compliances at members' farms or fails to impose appropriate measures in such cases.



















The ITC Guide to the New EU Organic Regulation

Part I: The new EU Organic Production Rules in Third Countries

I.3 Rules for production, collection, preparation and trade of organic plant products

Author: FiBL Research Institute for Organic Agriculture

Final Technical Version for ITC, 31.10.2022; Updated 31.10.2023

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Content ITC Guide Chapter I.3

Rules for production, preparation and trade of organic plant products

- 1.3.1 Overview & general organic production rules
- 1.3.2 Organic plant production rules
- 1.3.3 Rules for preparation, processing, storage & export
- 1.3.3 Important other rules for all types of operators

1.3.1 Overview & General Production Rules



Key Organic Production Rules in the Regulation

Key production rules for all organic operators in Third Countries

Regulation (EU) 2018/848 (consolidated version | an 22 including amending secondary acts like the 2022/474 Art 9: General production rules

- Art 27: Obligations and actions in the event of suspicion of non-compliance
- Art 28: Precautionary Measures to avoid the presence of non-authorised products & substances
- Art 29: Measures to be taken in the event of presence of non-authorised products or substances

Regulation (EU) 2021/1165 on authorised substances

Reg. (EU) 2021/1698 on recognition of CBs in Third Countries and Control Procedures especially Art 9-16

Specific sections plant production

Reg 2018/848 (consolidated version)

- Art 5 & 6 (Principles)
- Art 10 (conversion)
- Art I2 → Annex II Part I: Plant Production Rules

Reg 2021/1165 Annex I & II Authorised substances

Reg 2021/1698: especially Art 10 & 24 on exceptions

Specific sections handling

Reg 2018/848

- Art 23: Collection, packaging, transport & storage → Annex III
- Art 16 + Annex II Part IV production of "processed products"



Reading the EU regulatory texts as an operator in a "third country" outside the EU is complex. Some specific rules/procedures apply only to operations in EU member states or to EU authorities. Some include a specific section applicable to "Third countries", whereas for others, relevant rules for "compliant" application in Third Countries are indicated in the Regulation on Controls in Third Countries 2021/1698.

Plant Production as Operator or Group of Operator

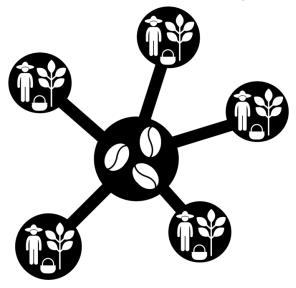
Farm "Operator"

(individually certified plantation or estate)



Group of Operators

(e.g. a smallholder farmers cooperative)





Other than most existing organic regulations and standards, the new regulation is specifically written for both individual "operators" (e.g. a certified plantation/farms or a processing company) and "groups of operators" (\rightarrow see details in Section 1.2 of this Guide). Some rules differ slightly between application as an "operator" under direct control by the CB and when applied to farms as members in a Group of Operators through an Internal Control System. For some production rules, the following summaries therefore indicate additional guidance on how to apply in a Group of Operators with ICS.

What's New (Plant Production)?

The rules for organic plant production are stronger and clearer in parts, but have not changed in many aspects compared to Reg. (EU) 834/2007.

However every farm in Third countries will need to comply with all detailed EU rules for plant production (not with their CB's "equivalent organic standard"). This may in effect mean stricter rules and tighter control for many operations.

Some key changes farm production in Third Countries:

Documented preventive and precautionary measures

Stricter Requirements for separation in case of mixed production (organic / non-organic) and for parallel production

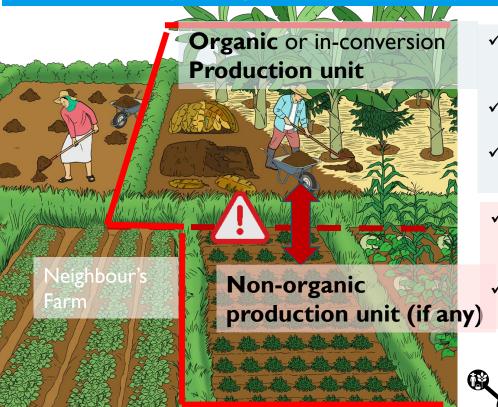
New authorised input list; many new restrictions esp. for plant protection; Stronger rotation / crop diversity requirements

Stricter requirements for authorising exceptions (e.g. recognition of conversion, non-organic planting material,)

Production in living soil (not pots, no hydroponics)

Farm Holding & Production Units

The entire farm (holding) shall be managed organically. Alternatively, the holding may be split in clearly and effectively separate organic, in-conversion and/or non-organic "production units" (Art 9.2 & 9.7):



- √ all crops in this/these unit(s) must be managed in line with the organic production rules!
- ✓ all land for production of organic crops shall be in the "organic unit", including rotation land!
- ✓ New: in-conversion unit must be separate from organic unit
- Non-organic activities only in clearly **separate non-organic unit** = on defined land parcels
- **Strict separation** of activities & prevention of contamination by members

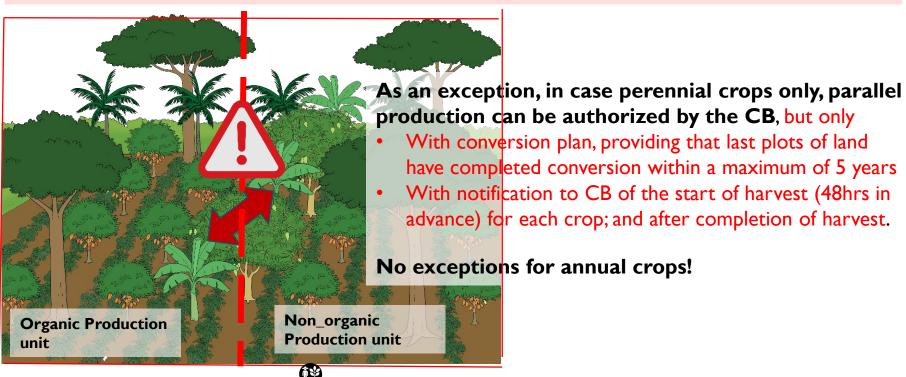


GoO: Details of non-organic unit of each member need to be registered by ICS & included in the GoO List of Members!

2018/848: Art 9.2 & 9.7 Reg 2021/279 Art 5 (GoO list of members)

Same Crop in Organic & Non-Organic Unit

In general, the cultivation of the same crop (or not easily distinguishable variety) in both the organic (or in-conversion) and the non-organic farm unit is not permitted ("no parallel production"), e.g. all plots with cacao trees should be managed in line with organic rules



Reg 2018/848 Art 9.7 & 9.8;

GoO members: Parallel production (of perennial crops) not recommended: HIGH risk, increased control; most ICS unable to meet all conditions and manage the higher risk.

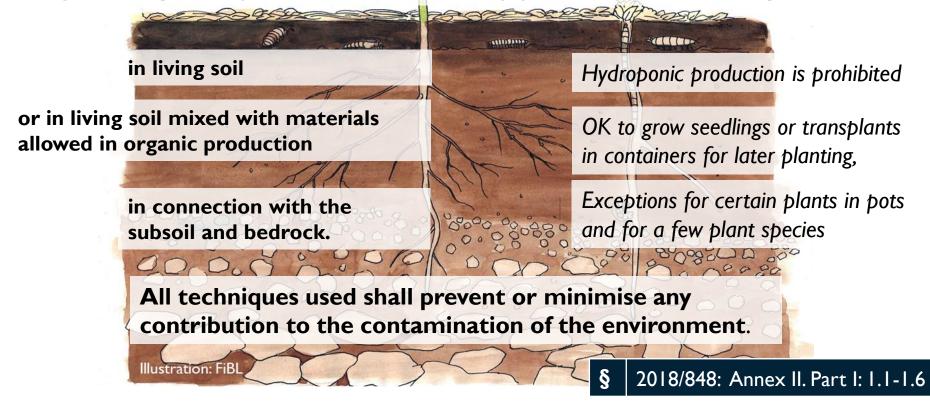
1.3.2 Organic Plant Production Rules



General Requirements Plant Production



Organic crops, except those which are naturally grown in water, shall be produced:



Origin of Plants and Plant Reproductive Materials

For production of organic plants and plant products, only ORGANIC plant reproductive material (PRM) shall be used.

"plant reproductive material" means plants and all parts of plants, including seeds, at any stage of growth that are capable of, and intended for, producing entire plants;

Organic Plant Reproductive Materials (PRM):

- the mother plant is under certified organic production for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.
- **All multiplication practices** shall be carried out under certified organic management
- Specific additional rules apply for producing PRM to be sold as an organic product (art 13, Annex II, 1.8)

Note: The new regulation (Art 13) also permits use and marketing of "plant reproductive material of heterogeneous material" without complying with the EU general seed certification requirements

2018/848: Annex II. Part I: 1.8 & Art. 13

Operators shall give preference to organic PRM suitable for organic agriculture.

llustration: FiBl

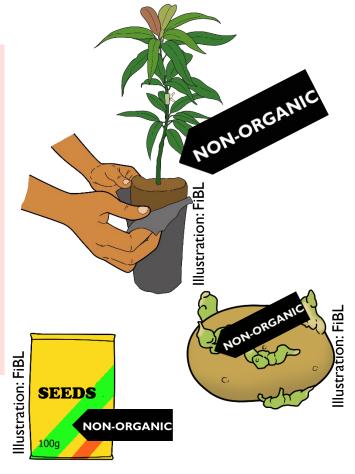
Exceptional Use of Non-Organic Plant Reproductive Material (PRM)

If organic PRM is not available in the country \rightarrow in-conversion PRM* shall

be used (no authorisation needed in third countries)

Use of untreated non-organic PRM in an organic and in-conversion production unit in a third country may be authorised by the CB:

- Only when organic or in-conversion plant reproductive material is not available in sufficient quality or quantity in the third country (of the operator) Note: difference to EU, can be authorized only in case of confirmed un-availability in official databases.
- Must be authorized BEFORE sowing or planting
- Authorisation granted only for one season at a time; CB to keep list of quantities authorised



2018/848: Annex II. Part I: 1.8.5.2 2021/1698 Art 25

S

Conditions for Exceptional Use of Non-Organic PRM



The non-organic PRM (incl. seeds!) may not be treated after harvest with plant protection products other than authorized for organic production If treated seeds are used in the organic unit (even for intercrops that are not sold as organic) \rightarrow land needs to undergo conversion

2018/848: Annex II. Part I: 1.8.5.3.



Non-organically grown SEEDLINGS are not permitted!

= young plants from the germination of seeds and not from cutting. Only species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product. (2018/848 Annex II Part 1 1.8.5.8)

- Seedlings must be grown in line with organic rules
- The seeds used to grow the seedling shall be organic, but use of non-organic untreated seeds may be authorised by CB as "organically usable" seedling

Prohibition of the Use of GMO



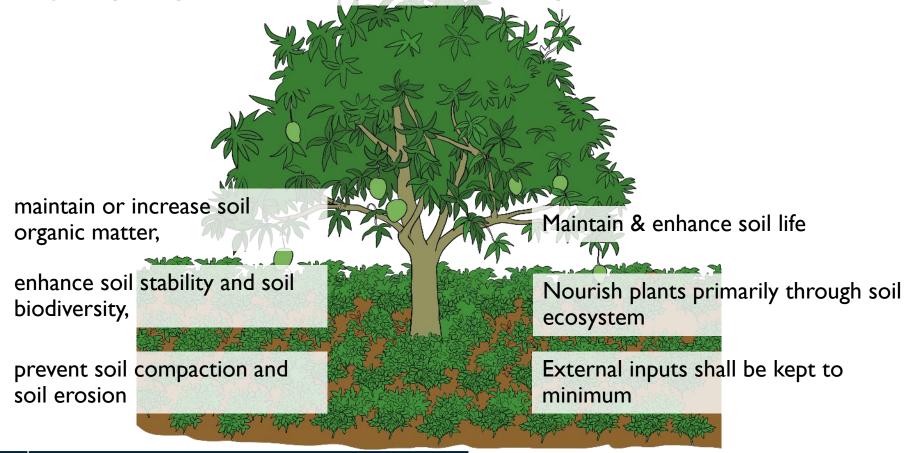
GMOs, products produced from or by GMOs, shall not be used

- in organic food or feed
- or as plant protection products, fertilisers, soil conditioners, plant reproductive material, microorganisms, food, feed, processing aids, or animals in organic production

Operators using non-organic farm inputs purchased from third parties shall require the vendor to confirm that those products are not GMO, neither produced from GMOs nor produced by GMOs.

Organic Soil Management Principles

In organic plant production, tillage and cultivation practices shall be used that:



2018/848: Art. 6 & Annex II, Part I, 1.9

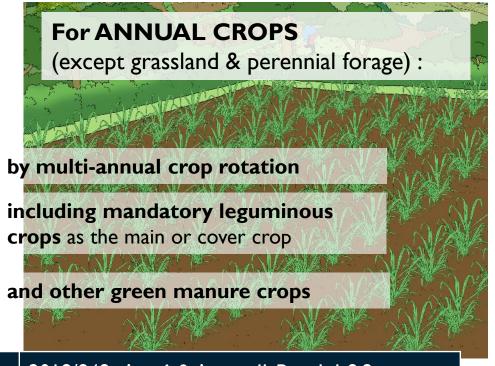
Crop Rotation to Maintain & Increase Soil Fertility

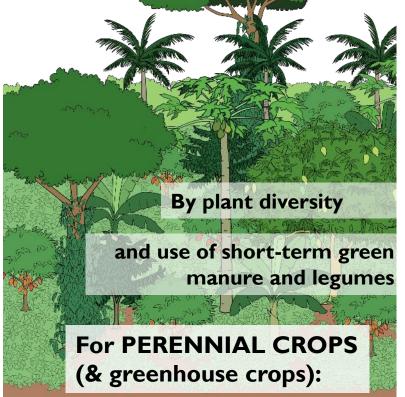
The fertility and biological activity of the soil shall be maintained and increased:

by application of livestock manure or organic matter, preferably composted,

from organic production.

AND





Use of Fertilizers and Soil Conditioners

Total amount of livestock manure: < 170 kg Nitrogen per ha per year

Preparations of micro-organisms & biodynamic preparations may be used



Only if the nutritional needs of plants can not be met by crop rotation & application of livestock manure or compost



For compost activation: plant based preparations & micro-organisms may be used Use of fertilizers and soil conditioners authorized for use in organic production (listed in EU Regulation 2021/1165 Annex II)

2018/848: Art. 6 & Annex II, Part I, 1.9.2

Authorised Organic Fertilizers (Reg. 2021/1165)

Only the products and substances listed in Annex II Regulation 2021/1165 may be used in organic production as fertilisers and soil conditioners for plant nutrition, some according to specific conditions:, e.g.

Composted or Fermented mixture of vegetable matter; vermi-compost

ANIMAL Manures (not from factory farming):

Farmyard manure; dehydrated poultry manure, composted animal excrements

Liquid animal excrements, Guano

Products & by-products of plant origin. e.g. oilseed cake, cocoa husk

EXAMPLES on the list

Products & By-products of animal origin (not applied to edible part of plant; no Chromium detectable) e.g. Blood meal, horn meal, bone meal

Micro-organisms to improve soil conditions or nutrient availability

> Saw dust, wood chips, composted bark, wood ash (wood not chemically treated)

For details and complete list see Regulation 2021/1165 Annex II

Authorized Soil Conditioners (Reg 2021/1165)

Only the products and substances listed in Annex II Regulation 2021/1165 may be used. Various restrictions apply (e.g. minimum content nutrients, max level contamination), please check in Annex II

Soft ground Rock Phosphate Aluminium Calcium Phosphate Basic Slag (Thomas Phosphate)

Calcium carbonate (chalk, ground limestone) **Industrial Lime** from sugar production of vacuum salt production only.

Elemental Sulphur

Inorganic Micronutrient Fertilizers

EXAMPLES on the list



Potassium sulphate, magnesium sulphate, calcium sulphate

Stone meal, clay minerals, organic rich sediments of freshwater bodies

Bio-Char

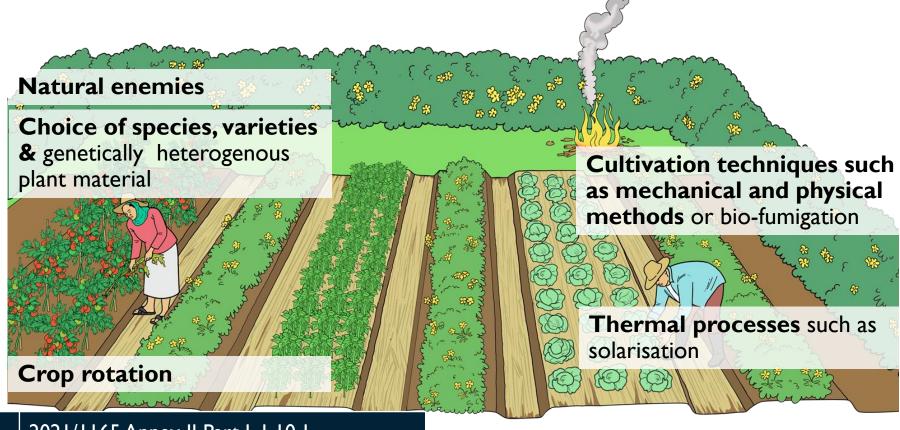
Xylite, Leonardite (mining byproducts)

Humic & fulvic acids

Any off-farm input products will need to be authorized by the CB for use.

Principles Organic Pest & Weed Management

The prevention of damage caused by pests and weeds shall rely primarily on the protection by



Use of Authorized Substances Pest & Weed Management

Only where these measures are not sufficient or in case of an ESTABLISHED threat to the crops, products & substances authorized in Annex I of Reg. 2021/1165 may be used

Only "to the extent necessary"



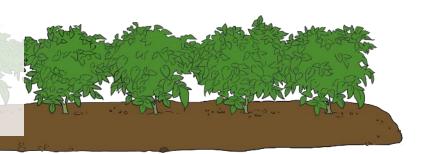
Keeping records for external inputs

- Proving the need for the products used
- Date & name of product, amount applied crops & parcels

Substances in traps & dispensers, other than pheromones: prevent contact with crops & release of substances into the environment

No use of any herbicides!

Not even authorized substances like e.g. vinegar or fatty acids can be used for herbicidal purposes!



2018/848 Annex II Part I, 1.10.2&3

Authorized Substances for Pest Control

Only the products and substances listed in Annex II Regulation 2021/1165 may be used IMPORTANT: many substances have very specific & new conditions. Substances must also be authorized for use in EU agriculture, (EU pesticide data base for active substances; or Reg. 540/2011) All inputs will need to be re-evaluated for compliance by CB before use!

Examples of allowed substances

Specified "Basic substances" from plant and animal origin and based on food e.g. vinegar, whey, sunflower oil, onion oil, sodium, chloride, cow milk, allium extract.

Microorganisms including viruses: not GMO. Only if strain is EU- authorized in Reg. 540/2011).

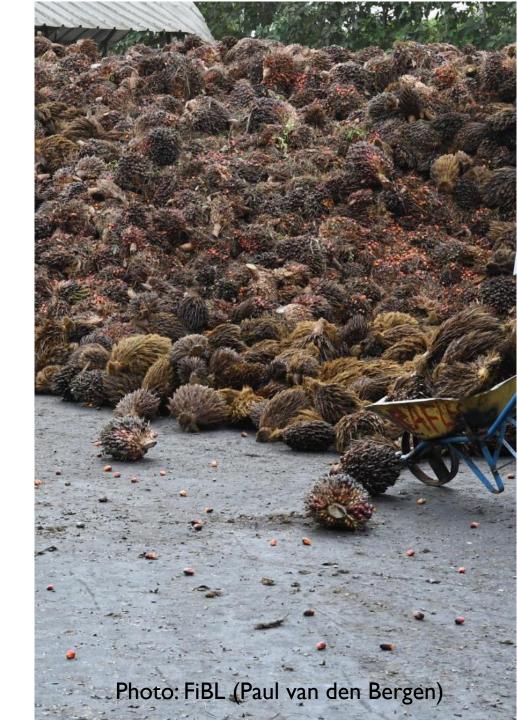
Oils: citronella, clove, rape seed, spearmint, orange, tea tree

Azadirachtin (from neem), **Pyrethrins** from plants **Repellents** by smell of animal or plant origin **Pheromones** in traps/dispensers

Sulphur; lime sulphur Copper oxide, oxychloride, hydroxide; Bordeaux mixture, tribasic copper sulphate Paraffin oils

Kaolin (aluminium silicate), diatomaceous earth **Ethylene** (only bananas potatoes; citrus) **Spinosad**

2021/1165 Annex I Reg (EU) 540/2011 (consolidated version) 1.3.2 Rules for preparation, processing and export



Certified Product Handling Activities

The new certificate model for Third Countries lists the following activities:

- **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
 - Operations carried out on an unprocessed product without altering initial product (e.g. cleaning, milling)
 - Packaging & Labelling
- **Storage**
- **Export**

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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 products
- C- Algae & unprocessed aquaculture products
- E- Feed F- Wine G- other specified products

General Production Rules Product Handling



No ionised radiation (Art 9.4)

Precautionary measures (art 9.6) to prevent commingling (organic / in-conversion / non-organic) and contamination of organic products must be taken & documented

- During harvest & post harvest
- During storage & transport (detailed rules on measures during collection & storage – Annex III)
- During processing (detailed rules in Annex II, Part IV)

Only specified products will be allowed for cleaning & disinfection on-farm production, processing and **storage** from 2024 (will be included in Reg. 2021/1165;

Reg. 2018/848: Art 9; Annex III Reg. 2021/2119, Art. 2

Ş

Records (including stock & financial) records shall be kept to allow check of precautionary measures, traceability checks & mass balance checks. (Reg 2021/2119)

On-Farm Storage and Post Harvest Handling

Farmers must observe organic production rules also during any post harvest preparation, processing and storage



The ICS must be check also post-harvest activities and storage during internal inspections!.

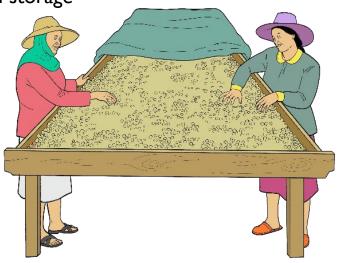
Precautionary measures during harvest post-harvest and storage

- Clean & separately used machinery & tools
- Clean & separate drying, processing and storage areas
- Only permitted ingredients/processing aids
- Storage in closed containers, no contamination.



No input products other than those authorised for use in organic production shall be stored in organic or in-conversion farm production units (Annex III, 7.2)

Reg. 2018/848: Art 9; Annex III Reg. 2021/2119, Art. 2



Collection, Transport and Storage of Organic Products

Annex III provides a detailed list of rules to ensure organic product integrity during collection, transport and storage with a special focus on measures in case of simultaneous handling of organic, in-conversion and non-organic products.

- Rules on collection & transport
- Closed Packaging and transport to other units, compulsory label indications during transport





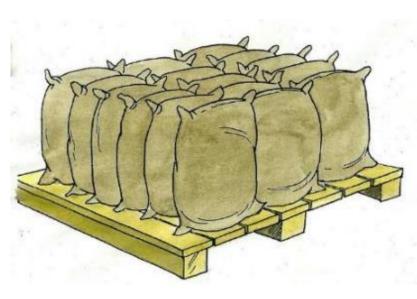
The rules apply to GoOs too - in combination with ICS traceability requirements.

GoO: Farmers deliver to a purchase centre:

- ✓ Receipt to farmer & purchase record
- Documented Reception check: member certification status & yield estimate

In case of farmgate collection system: Detailed measures to be taken by driver, especially in case of simultaneous collecton: Annex III. I

Annex III: 7. Storage of Organic Products



Only authorized substances may be used at any time for pest control in any area where organic products are stored or handled.

Appropriate management to storage areas to allow identification and prevent mixing or contamination

Clear identification of organic and inconversion products at any times

Detailed precautionary measures in case operators handle organic, or in-conversion or non-organic products in any combination and the organic or in-conversion products are stored in storage facilities in which also other agricultural products or foodstuffs are stored: see Annex III, 7.4

Only authorised products for cleaning & disinfection in storage facilities (will be included in 2021/1165 from 2024)

Detailed Rules for the Production of Processed Food



Illustration: FiBL

Processing" = any action that substantially alters the initial product,

e.g. heating, curing, extracting, marinating, drying

Note: CBs to apply this definition case by case to determine if a product is "processed" or "unprocessed"

If an operator is engaged in production of <u>processed</u> food, i.e. if products are being "processed" (e.g. oil extraction, cutting and drying fruits in a solar dryer, curing of vanilla beans, de-hulling of green coffee) \rightarrow the detailed rules of Annex II, Part IV Processed Food Production apply

- Practices shall comply with good manufacturing principles and based on identification of critical processing steps
- Procedures shall ensure that products comply with the regulation at all times, in particular:
 - Take pre-cautionary measures and record them
 - Suitable cleaning measures (recorded) + use of authorised products only
 - non-organic products are never marketed as "organic" (or "in-conversion")
- The preparation of processed organic, in-conversion and non-organic products shall be kept separate from each other in time or space.
- Where organic, in-conversion and non-organic products, are prepared or stored in the unit \rightarrow see detailed list of measures in section 1.5

Additives, Processing Aids and Non-Organic Ingredients

In production of organic processed food, the rules of Annex II, Part IV, section 2 apply:

- Rules on use of preparations of micro-organisms and food enzymes (2.2.2a, flavours (2.2.2b), natural colours (2.2.2, water & salt, minerals)
- Additives, processing aids and non-organic ingredients only authorized in Regulation 2021/1165 (Annex V). The lists will need to be complied with (no longer in an "equivalent" way, permitting use of local alternatives).
 - → But CBs in Third countries can authorize temporary use of non-organic ingredients due to temporary unavailability (Article 25 of regulation 2018/848)

Substances for Cleaning and disinfection of storage facilities and in processing will be restricted from Jan 2024, and records will need to be kept (authorized products will be listed in Annex IV of Regulation 2021/1165)

Reg. 2018/848: Annex II, Part IV, Section 2.2.

Reg. 2021/1165, Annex IV

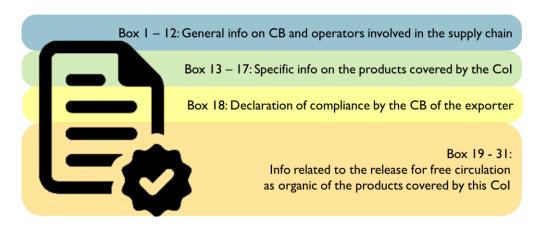
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Reg. 2021/1698 Art 27 (for CBs) and 2018/848 Art 25.4 as regards possibilities to use non-organic ingredients

Certificate of Inspection

Each imported consignment to the EU needs to be accompanied by a Certificate of Inspection (COI)

- Until 30 June 2022 COI may be issued on paper after being completed in TRACES
- New boxes to be filled on traders, registration, estimated time of arrival
- Product category to be included
- TRACES: connection with customs & upload of commercial documents



Reg (EU) 2021/2306



Further information on controls to be carried out in the future compliance scheme, see chapters 2.2

Other new EU import rules relevant for exporters

There are some new rules in secondary acts regarding documents and notifications required for EU import of organic products, which are relevant for exporters to be aware of

- Regulation (EU) 2021/2307: Amended provisions for the COI and rules for prior notification before arrival (via TRACES) min. I working day before arrival. Since June 2022 COIs can no longer be issued on paper. The COI must be issued before the consignment leaves the Third Country.
- The import company in the EU notifies its control body (or control authority) about its imports through TRACES. At the point of entry, the competent authority at the border control performs official control on all consignments for verification of compliance with applicable EU agri-food legislation, including organic labelling rules For organic products, this includes examination of the COI and supporting documents as well as, where required, results of residue tests (see Regulation (EU) 2021/2306).
- Organic produce that requires a phytosanitary certificate have to pass through Border Control Points (as opposed to "Border Control Posts"), with stricter controls and a limited number of EU ports of entry. See Regulation (EU) 2021/2305.
- In case a competent authority in the import country or a CB finds or suspects any non-authorized substances in organic products, the measures or Art 29 of the 2018/848 are triggered, incl temporary blocking of lots & official investigation of the source and the cause of the contamination. Suspected or confirmed non-compliances that affect the organic products integrity are notified in the EU's OFIS (Organic Farming Information System). See Regulation (EU) 2021/279, Art 9.

After customs clearance, the imported lots can be traded freely in all member states of the EU.



















The ITC Guide to the New EU Organic Regulation

Part I: The new EU Organic Production Rules

I.4 Organic Production Rules for Livestock, Beekeeping & Aquaculture

Author: FiBL Research Institute for Organic Agriculture

Final Technical Version for ITC 31.10.2022

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Content Chapter I.4: Organic Production Rules for Livestock, Beekeeping & Aquaculture

- 1.4.1 Overview Organic Livestock Production
- 1.4.2 Overview Organic Bee Keeping Production rules
- 1.4.3 Overview Organic Aquaculture Production rules

Please note that this section focusses on specific production rules for livestock, beekeeping and aquaculture.. Other relevant basic production rules of 2018/8484, e.g no GMO, precautionary measures, separation of production units, collection, storage, preparation and processing rules also apply and the crop production rules apply for the farm's pasture or feed production areas.



The most important organic production rules with focus on crop production and processing are described in Section 1.3 of this Guide.

I.4.1 Organic Livestock Production



Livestock Species, Breeds and Conversion

Scope: land-related livestock production: Bovine (cattle), Ovine (sheep), Caprine (goats), Equine (horses), Cervine (deer), and Porcine animals (pigs), Poultry and Rabbits. Beekeeping: see next section

Conversion from conventional to organic

- When land and animals are converted simultaneously, after 2 years all products and all animals* are organic
- Individual non-organic animals may be introduced but only for breeding purposes (not for fattening)
- Age / weight shall not exceed species specific limits
- Not more than 10% of the adult animals of the herd each year
- In any case, a derogation from the CB is required

Breeds and breeding techniques

- Adapted to local conditions
- Only natural reproduction techniques are allowed

Annex II, Part II, section I

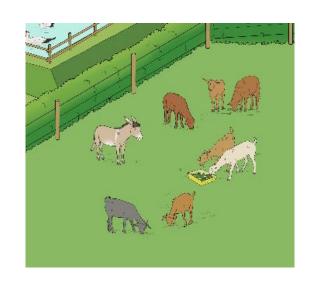
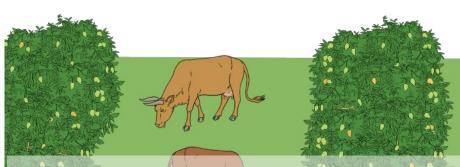


Illustration: FIBL

^{*} Provided that they were present at the beginning of the conversion period or born from such animals on that farm

Nutrition



General

- Feed shall be primarily obtained from own farm or from regional feed suppliers
- Ruminant animals shall have permanent access to pasture or roughage
- Suckling animals need to be fed with maternal milk during first days

Grazing

- Non-organic animals may graze on organic pasture under certain conditions
- Organic animals may graze common land under certain conditions

Illustration: FiBL "In-conversion" feed (= Harvested at least 12 months after the start of the conversion period) 25%per year is allowed if that feed is purchased, 100% if it is from own holding Non-organic "feed" Max 20% per year of annual ration for grazing, perennial forage or protein crops may come from fields in 1st year of conversion

Max 5% non-organic protein feed may be

fed to young pigs (1.9.3) and young

Reg 2018/848 Annex II, Part II; 1.4 Reg. 2020/464

poultry (1.9.4)

Health Care

Disease prevention

Breed and strain selection. high-quality feed, exercise, appropriate stocking density, hygiene

No preventive treatments with chemical products

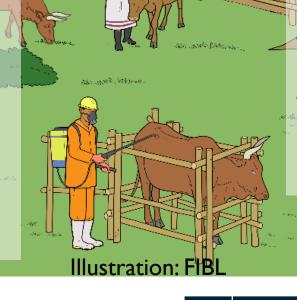
No preventive use of antibiotics

No hormones or similar substances

Cleaning and disinfection of housing and equipment and only with authorized products/substances



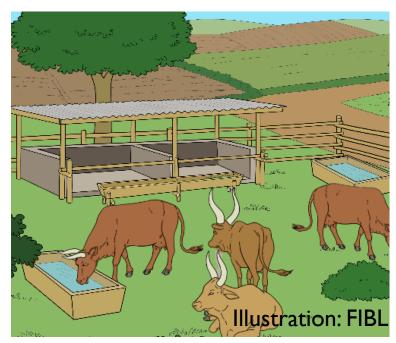
- Sick or injured animals must be treated immediately
 - Veterinary medicinal products, e.g. antibiotics, may be used under the responsibility of a veterinarian
- The withdrawal period shall be doubled and be at least 48 hours
- More than 3 treatments per year (for animals living longer than I year) shall result in new conversion period



Housing and Husbandry Practices

Housing:

- Housing shall ensure well-being of the animals characterised by ventilation, suitable temperature and abundance of natural light
- Maximum stocking density of the organic production units is 170 kg N/y.ha
- Housing shall respect minimum surfaces for indoor and outdoor areas
- Cages, boxes and flat decks to raise livestock shall not be used





Regulation 2021/464 provides additional detailed species requirements on stocking density and housing for poultry species



Reg 2018/848 Annex II, Part II; 1.6 Reg. 2020/464 Art 2-21, Art 26, Annex I

Animal Welfare

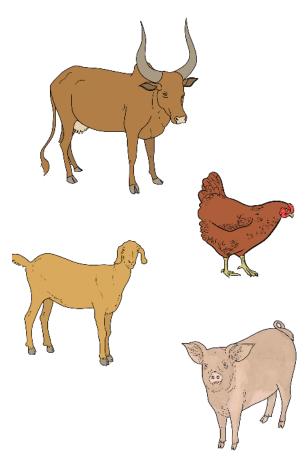
- Persons keeping and handling animals shall have basic knowledge and skills for those activities
- Animals shall have permanent access to open air areas to exercise
- Tethering or isolation of livestock only after derogation granted
- Suffering and pain of animals shall be minimised
- Management of animals by beak trimming, dehorning and other is subject to derogation.
- Physical castration is allowed.



Transport of animals shall be

- without use of electrical or other stimulation during loading/unloading
- Use of tranquilisers and duration shall be minimal.

Other Requirements



Products and substances may only be used when authorised for the following purposes (See Reg. 2021/1165)

- Feed additives and processing aids
- Non-organic feed materials
- Products for cleaning and disinfection

Preparation other than processing of unprocessed products

- Slaughtering and other preparation activities carried out by a subcontractor, are subject to controls, not necessarily to certification
- Requires the identification of critical steps
- Increases the risks for
 - Contamination of organic with not authorised products and substances
 - Mixing and substitution of organic with non-organic products
- Demands for systematic identification of organic products and separation from non-organic products

Record keeping



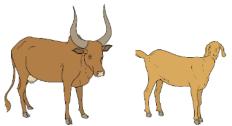
Operators need to keep the following records

- Origin of animals, veterinary records of the animals, date of arrival and conversion period
- Feeding regime (including among another name of feed, daily rations, periods of access to grazing areas)
- Products used for cleaning and disinfection, dates, name of products used, location of use
- · Veterinary treatments applied: identification of treated animals, dates, posology, veterinary prescriptions, withdrawal period, ...
- · Animals leaving the holding: age, identification, weight of slaughter animals, destination
- Period of emptiness of the (poultry) runs (except farms where poultry is not kept in batches)



Reg 2018/848 Annex II, Part II; 1.3.4.5 (origins), 1.4.4 (nutrition), 1.5.1.6 (cleaning/disinfection). 1.5.2.7 (veterinary treatment, 1.7.12 (interventions).

Species specific requirements



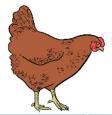


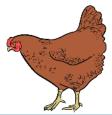
	Povino ovino capvino oquino	Porcine
	Bovine, ovine, caprine, equine	Forcine
Nutrition	 Feed shall come from own farm/region for at least 70% of the annual ration (from 1/1/2024) Animals shall have acces to pasturage for grazing At least 60% of daily ration shall be roughage, fodder or silage 	 Feed shall come from own farm/region for at least 30% of the annual ration Roughage, fodder or silage shall be added to daily ration Max 5% non-organic protein feed on annual basis may be fed to piglets (≤ 35 kg) and only until 31/12/2026
Housing and husbandry practices	 Smooth but no slippery floors Animals shall have permanent access to a comfortable, clean and dry laying or rest area Sick and isolated animals, while isolated, must have access to same housing conditions 	 Smooth but no slippery floors Animals shall have access to a comfortable, clean and dry laying or rest area All pigs must be able to lie down in most space consuming way Sows shall be kept in groups, except in the last stage of pregnancy and during the suckling period Exercise area shall permit dunging and rooting

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Reg 2018/848 Annex II, Part II; 1.9.6.3

Specific requirements Poultry

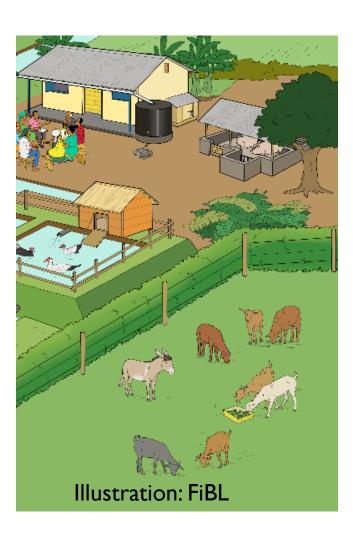




	Poultry
Origin	 Non-organic pullets may be only 3 days old when introduced in the organic production unit Farmers shall use slow growing strains or respect the specific minimum slaughtering age
Nutrition	 Feed from own farm/region shall be at least 30% of the annual ration Roughage, fodder or silage shall be added to daily ration Max 5% non-organic protein feed only for feeding poultry and until 31/12/2026
Housing and husbandry practices	 At least one third of the floor area shall be solid and covered with litter Buildings shall be emptied of livestock between each batch, cleaned and disinfected Runs shall be left empty (duration to be decided by the certification body) Poultry shall have access to outdoor area during at least one third of their life Open air areas shall be covered mainly with vegetation Not more than 3000 laying hens in a single compartment Total usable surface for fattening poultry shall not exceed 1600m²
Animal welfare	• Live plucking of poultry is prohibited

Reg 2018/848 Annex II, Part II; 1.9.6.4

Summary of Changes Compared to Reg. (EU) 889/2008



Change in Scope

- Detailed production rules for Rabbits and Deer
- Possibility to label raw hides, wool and other non-food livestock products with EU organic symbol

Introducing non-organic animals

- Need for derogation based on availability of organic animals in the third country concerned (Database based in the EU)
- Start of the conversion period for individual non-organic animals introduced after the start of the simultaneous conversion is time of arrival in the organic production unit. Duration of the "individual conversion period is species specific.

Nutrition

- Reduction from 30 to 25% of in-conversion feed from second year if this type of feed is purchased
- Possibility to feed young poulty and pigs with non-organic protein feed (up to 5% of dry matter in annual ration and latest until 31/12/2026)
- pastoral organic animals shall be kept separate from other animals

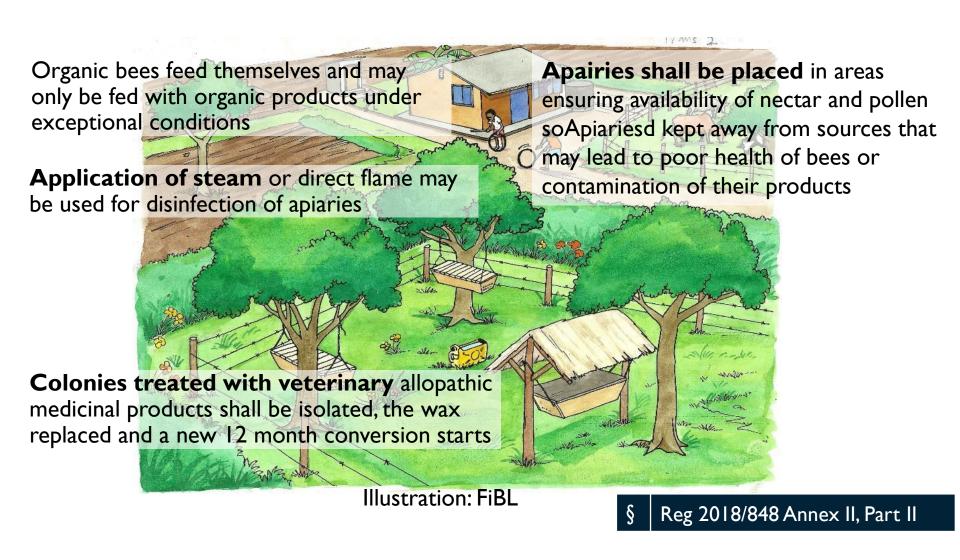
Housing

 Verandas (poultry) are not open air areas; Detailed requirements for poultry housing (popholes, max number of tiers, ...)

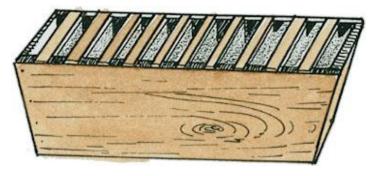
1.4.2 Organic Beekeeping



Bee Keeping Requirements: Annex II, Part II 1.9.6



Beekeeping: Change in Requirements - I



- During the conversion period, the wax shall be replaced with wax from organic beekeeping or with nonorganic beeswax under certain conditions (1.2.2f)
- For the renovation of apiaries, in any case, I swarm or queen bee may be replaced by non-organic swarm or queen bee and under certain conditions this may be up to 20%
- Under certain conditions, bee colonies shall be fed. They may be fed with organic honey, organic pollen, sugar syrups or organic sugar (1.9.6.2b)

Products and substances used for cleaning and disinfection of the hives must also be in authorized substance list in regulation 2021/1165 (lists in Annex IV not published yet)

Bee Keeping requirements continued

The hives shall be made of natural materials



While harvesting beekeeping products, care shall be taken not to destroy bees



Record keeping (specific for beekeeping):

- Zone where the apiary is situated, identification of the hives and period of moving
- All measures applied to the hives (removals of the supers and honey extraction, including amounts harvested and date of harvesting)
- Map allowing the identification of the location of the hives

Beekeeping in a Group of Operators. Changes



Small beekeepers can be certified as a "group of Operators" with an internal control system

- → see guide section 1.2.
- For beekeeping, the relevant farmer limit according to Art 36.1(b) is the maximum turnover of 25'000€/year, not the size of the farm holding.

Note: Beekeeping is the only livestock production that may be "landless".

What's new compared to Reg. (EU) 889/2008:

- For the renovation of apiaries, 20% per year of the queen bees and swarms may be replaced by non-organic queen bees and swarms
- Under certain conditions, organic pollen may also be fed to bees

I.4.3 Organic Aquaculture Production



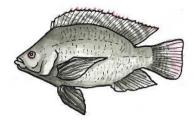
Organic Aquaculture: Algae and Aquatic Animals

'Aquaculture' means the rearing or cultivation of aquatic organisms using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment, where the organisms remain the property of a natural or legal person throughout the rearing and culture stage, up to and including harvesting;

Algae (aquatic plants)

- Wild collection OR cultivation
- In fresh water OR seat water

Aquatic animals



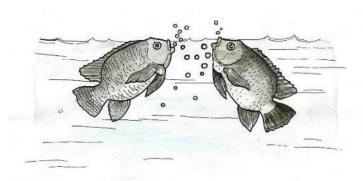
The new regulation allows to certify **aquatic plants** from wild collection or cultivated as well as rearing of aquatic animals (but not wild catch / collection)

Reg 2018/848 Art 3 referring to Reg 1380/2013 Art 4

Applicable production rules

The most important production rules for Aquaculture can be found in the following sections of the regulation

- ✓ 2018/848: Annex ||, Part III: Production rules for algae and aquaculture animals
- ✓ 2020/464: Art 22 \rightarrow Annex II: stocking density, characertisitics of production systems and containment systems for different species
- ✓ Authorized substances 2021/1165: Annex III (substances for use as feed), 2021/1698: Art 26 (derogations juvenile animals aquaculture)



Additionally, the general production rules in Reg. 20187/848 apply also to aquaculture production, e.g. the separation of production units, no GMO, preparation rules (including processing), precautionary measures, etc.

Conversion

The conversion periods for the production of aquaculture products vary from 3 to 24 months.



- There is no possibility for reduction of the conversion period
- And also no possibility for labelling aquaculture products with reference to "inconversion"

Algae:

- harvesting: 6 months
- cultivation: the longest of 6 months and one full production cycle

Aquaculture animals:

- Facilities that cannot be drained, cleaned/disinfected: 24 months
- Facilities that have been drained or fallowed: 12 months
- Facilities that have been drained, cleaned/disinfected: 6 months
- Open water facilities: 3 months

Specific Records to be kept



See Annex II → Part III

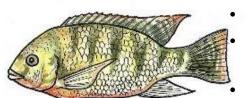
Algae:

- Fertilisers (2.2.2c)
- Nutrients (2.3.2)

Aquaculture animals:

- Use of non-organic juveniles (1.11)
- Origin (3.1.2.4)
- Feeding (3.1.3.5)
- Disease prevention (3.1.4.3)
- Housing and water quality (3.1.5.3 §5)
- Animal welfare (3.1.6.5 §1))
- Escaped and recaptured animals (3.1.5.8)
- Oxygen used (3.1.6.5)
- Wild seed (molluscs) (3.2.1)

Aquaculture Animals: Changes



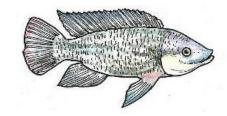
Requirements as regards the origin of aquaculture animals (3.1.2)

- They shall come from organic production units (instead of organic holdings)
- Non-organic aquaculture animals or wild-caught animals may be brought into a holding for breeding purposes only and under certain conditions
- There are NEW rules as regards juvenile production

Nutrition: animals may be fed with organic feed or feed from "sustainable fisheries". (3.1.3)

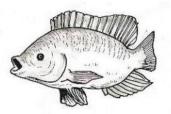
Health care:

- Disease prevention is done by taking into account additionally, species requirements for good water quality, flow and exchange rate (3.1.4.1)
- Veterinary treatments are still allowed but the maximum number of treatments has been more refined by limiting the number of parasite treatments (3.1.4.2e)



Housing and husbandry practices:

- Animals need to be kept in water of good quality with in addition, adequate flow and exchange rate and low level of metabolites (3.1.5.3 §1b)
- Fertilisation may only be done with authorised substances and with a max application of 20 kg N/ha



Reg 2018/848 Ann II, Part III

Algae production rules : Changes

NEW requirements which require additional attention:

- The nutrient levels in effluent water shall be the same or lower than in inflowing water
- During the collection of wild algae, operators need to ensure that bycatches are prevented
- Operators cultivating algae need to ensure that the collection of juvenile algae is based on sustainable practices and shall take place on a regular basis to maintain and increase diversity of indoor culture stock.

Definition of Algae vs seaweeds has been replaced by "Algae" which means that plants growing in fresh water can also be certified in relation to the EU Organic Regulation.



















The ITC Guide to the New EU Organic Regulation

Part 2: The new EU organic legal framework and key changes to the import system

2.1 Overview of the new EU Organic Control System and Options for Trade with the EU

Author: FiBL Research Institute for Organic Agriculture

Final Technical Version for ITC 31.10.2022

This Technical Guide development was funded by the European Union (EU). Its contents are the sole responsibility of Arise Plus Thailand project implemented by the International Trade Centre (ITC) and do not necessarily reflect the views of the EU.

Content Chapter 2.1 Overview EU Control System and **Options for Trade with the EU**

- 2.1.1 The organic control system in a nutshell
- 2.1.2 Current and Future options for third countries exporting organic products to the EU
- 2.1.3 The new EU regulatory framework and Transition **Periods**

Introduction to the EU Organic Control System in Third Countries: From Equivalence to Compliance







Most countries worldwide, including Thailand, currently export organic products to the EU under an "equivalence scheme" for imported products.

- In all "third countries" outside the EU, except the 14 countries whose organic legislation was recognized as "equivalent".
- Organic Control Bodies in these "Third countries" submitted their "equivalent organic standard" and a detailed annual dossier to the EU for being authorized to certify organic products according to the equivalent standard which could then be imported into the EU as organic.
- This equivalence system meant that operators were not controlled directly according to the EU regulatory requirements and CB had some limited flexibility to apply the EU rules to local conditions in an "equivalent way". In particular, the special control system for smallholder producer groups was regulated only in "EU import guidelines", not the EU regulation itself.

With the new regulation, the equivalence system is phased out and "compliance" with the EU regulation will be required.

- The new regulation is explicitly developed for application within the EU and in "third countries".
- Operators and CBs will need to comply directly with all production and control rules of the EU regulation with only some minor adjustments for third countries.

In this introductory overview chapter, the EU control system and options for trade are presented in a simplified way, mainly for operators, control bodies and local authorities in non-EU-recognized third countries.



Section 2.2 of this guide provides more technical details on the compliance control system Section 2.3 of this guide provide more information on country equivalence & trade agreements

2.1.1 The EU Organic Control System in a Nutshell

- as applicable in Third Countries like Thailand (without EU country equivalence recognition) -



Products need to be controlled to be "organic".

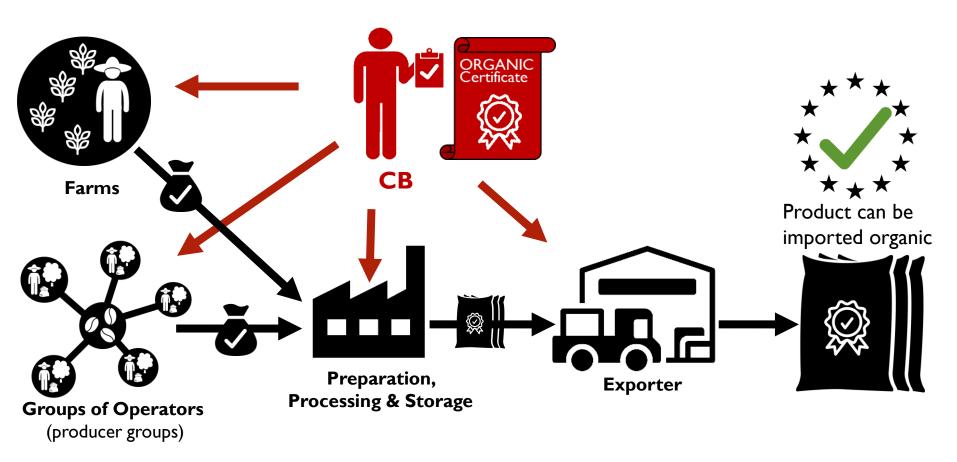
All operators involved in production and handling of products which shall be marketed as organic in the EU need to be controlled according to the EU organic regulation by accredited & approved control bodies (CB) or "control authorities". It is legally NOT allowed to market any product as "organic" or "ecological" in the EU unless they are certified and imported according to the Regulation.



- → Section 2.2 explains the process for recognition and supervision of CBs under the EU's new compliance system.
- → Section 2.4 provides information of role of competent authorities in the EU control system

Control of Operators along the supply chain

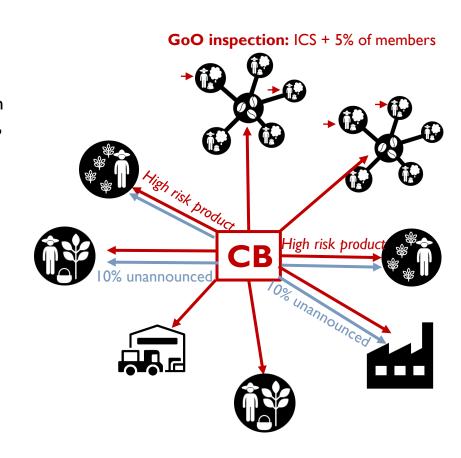
All operators in Third countries involved in the agricultural production, preparation / processing and trade of organic products need to be certified according to the EU organic regulation by an authorized Control Body.



Each operator is inspected at least once a year

Physical on-the-spot inspection of all certified operators and groups at least once a year to verify compliance:

- ✓ For Groups of Operator (GoO) the physical inspection includes: re-inspection of at least 5% of members, (not less than 10)
- Compliance Control shall be performed following a risk based approach Inspections and sampling shall be done at appropriate times
- ✓ At least 10% of all operators & GoOs certified by the CB are subject to additional inspections without prior notice
- For a future EU list of "high risk products" (Art 8 of 2021/1698) in Third Countries: 2 inspections / year will be required, thereof one without prior notice



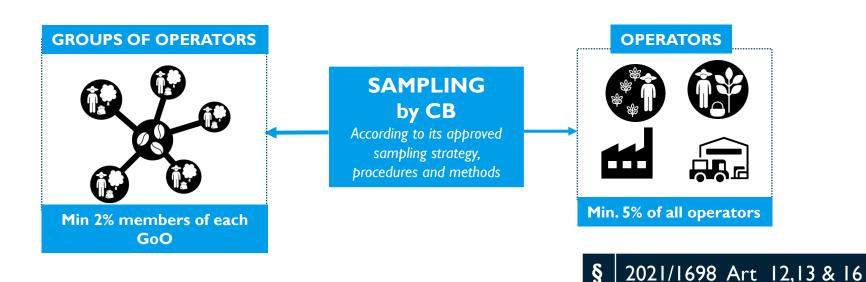
Compulsory Sampling for Analysis



As part of their compulsory control measures, CBs need to take and analyse riskbased samples to check for potential use of non-authorized substances or production techniques or for detecting possible contamination

- **Minimum 5%** of all single operators need to be subject to sampling
- Minimum 2% of members in a GoO are subject to sampling
- Higher sampling requirements for all "high risk products" (at least 1 sample per consignment)

There are also defined minimum quality requirements for analysis methods and laboratories.



New EU databases strengthen control of imports

All Third Country Operators data will be in EU database



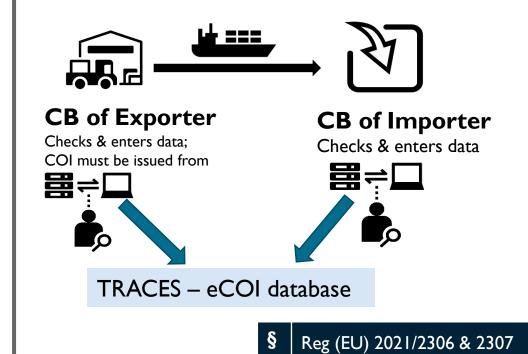
The CB will need to enter all data of certified operator into the EUTRACES database to issue the organic operator certificate



TRACES – CB/CA database

Reg (EU) 2021/1698

When the product is imported, all data must be in TRACES.





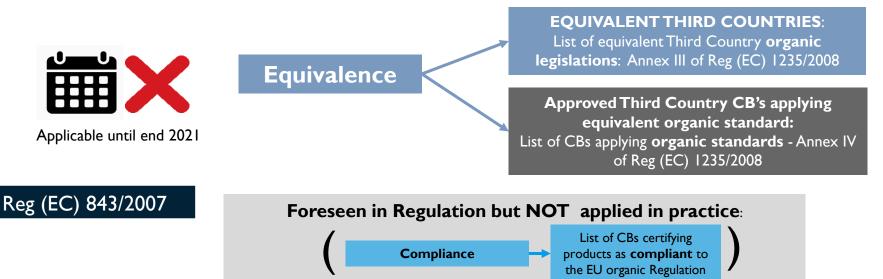
All certified operator data will need to be entered into a new CA/CB database of TRACES, the EU's Trade Control and Export System, in order to issue the organic operator certificate. This allows cross-verification of data for imports. If an organic product is imported into the EU, it has to be accompanied by a Certificate of Inspection (COI) which must be issued in TRACES by the CB of the exporter before the product leaves the Third country.

2.1.2 Current and Future Options for Importing organic products to the EU



The "old" EU Import Regime – Until End of 2021

The Import regime for organic products according to the previous Organic Regulation (EC) 843/2007 was in force until end of 2021





In the past, there were two import schemes in the Regulation. For 14 countries the EU considered their national organic regulation equivalent to the one of the EU. Certain organic products, certified in accordance with these legislations could be exported to the EU without additional EU organic certification. Products originating from other Third countries needed to be certified by CBs approved to have equivalent organic standards and to perform organic certification of specific products/scope in the respective country. The compliance system was not applied in practice in the past.

New EU Import Regime – Conditions for organic imports

For an imported product to be sold as organic:

- it must comply with the same rules as those applying to organic goods produced in the EU.
- Required procedures must be followed for labelling
- Procedures depend on country origin as some countries' organic standards are recognized as equivalent to the EU

States

The Product can be certified as organic according to the EU Organic Regulation

Product complies with EU organic standard **QR** organic Standards recognised by the EU

Operators can provide full traceability

Sales as organic only if all conditions are met

Reg (EU) 2018/848 - Article 45 (1)

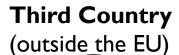
New Import options for of organic products from "Third Countries"

Country recognized by EU as "equivalent"

Argentina, Australia, Canada,, Costa Rica, India, Israel, Japan, the Republic of Korea,, Tunisia, USA, New Zealand (1235/2008) Chile, UK Switzerland by trade agreement (status: July 22)

Country Equivalence System

- Reg. 2021/2325: List of third country organic legislative systems and list of recognized CB's recognized in these countries
- System is gradually replaced by trade agreements between each country and the EU. Countries with trade agreements are no longer listed in 2021/2325!





All other countries worldwide

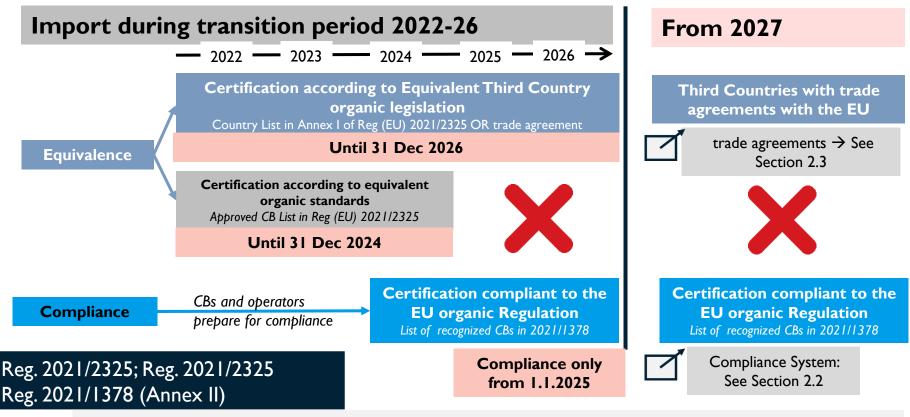
New EU Organic Compliance system

- All organic production and control rules of Regulation 2018/848 must be complied with also outside the EU.
- Only some minor adaptations for Third countries, especially with regard to control procedures
- Third Country CBs need to apply to be recognized by the EU to perform "compliant" certification according to Reg. 2018/848.



Transition periods apply for the change to "compliance" and trade agreements.

Import Regime - Transition to the new System





The organic equivalence import scheme is gradually replaced by the compliance system with defined transition periods for the existing systems. The country equivalence recognition system is being replaced by trade agreements. The EU has concluded 3 agreements and authorized negotiations for trade agreements with 11 countries. In all other countries CBs and operators must change to the compliance system. CBs can set their own timeline for the transition. CBs must submit a dossier to be recognized for certification compliant to the new Regulation. Recognized CBs for compliant certification will be listed in Reg. (EU)2021/2325 (Annex II)

Negotiations with recognized equivalent Third countries for new trade agreements

As of 2022, the EU recognizes 14 countries legislation as equivalent to the EU organic legislation through the equivalence system or already by trade agreement. Certain products, certified organic in accordance with these legislations, could be exported to the EU without additional EU organic certification.

From 1 Jan 2027 this is no longer possible and general trade agreements (covering trade in various products & services, not only organic products) will replace the current system.



Concluded & Planned Trade Agreements

- The EU has already concluded trade agreements with 3 countries: Chile, Switzerland, UK.
- As per Council Decision 2021/1345 the EU has authorized negotiations for agreements with Argentina, Australia, Canada, Costa Rica, India, Israel, Japan, New Zealand, South Korea, Tunisia and the United States with a view to concluding agreements on trade in organic products before 2027.

Once trade agreements are concluded, the country is no longer listed as equivalent in Regulation 2021/2325 and the list of CBs authorized to operate in these countries can be found on the EC website (and not in the Regulation anymore)



Further information on country equivalence and trade agreements in chapter 2.3 of this Guide

2.1.2 Import Regime – conditions for import



3 conditions for import to the EU

Product can be certified

a) the product is a product as referred to in Article $2(1)^*$



One of the following applies **b**)

Compliance

Country Equivalence



Full traceability provided

- Product complies with Reg (EU) 2018/848 and all operators have been subject to controls by recognized control entities (cf. Art 46) and have received a certificate confirming the compliance; OR
- Product originates from recognized Third Country in accordance with Art 47 ii. and complies with conditions laid down in relevant trade agreement; OR
- iii. Product originates from recognized Third Country in accordance with Art 48 and complies with equivalent production and control rules and a Certificate of Inspection was issued;
- TC operators can provide full traceability. Information to be made available to control entities of importer

Reg (EU) 2018/848 - Article 45 (1)

What products can be certified as organic?



Products that can be certified as organic according to 2018/848

Art 2 .1:This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union

- (a) live or unprocessed agricultural products*, including seeds and other plant reproductive material;
- (b) processed agricultural products* for use as food;
- (c) feed

The regulation also applies to a defined list of products closely related to agriculture: natural cork, essential oils, yeast, vine leaves, cotton, wool, raw hides and untreated skin, palm hearts and other edible plant parts, sea salt, beeswax, plant based traditional herbal preparations. (see Annex I of regulation 2018/848 for full details)

Note: agricultural products include products from wild collection

§ Reg (EU) 2018/848 – Article 2 (1)

2.3. Overview of the new EU Organic regulatory Framework

- as relevant for Third Countries like Thailand -



The Regulatory Framework of the New EU regulation

THE REGULATION (EU) N° 2018/848 (Consolidated Version):

The Consolidated Version of Regulation 2018/848 includes all changes by amending "secondary regulations at regular intervals (Version at time of writing: January 2022). EU regulations are available in all EU languages.



SECONDARY ACTS (apply in addition to the consolidated Version of 2018/848) **Most relevant** for Operators & CBs in Third Countries (outside the EU; not recognized as equivalent third countries);

Regulations are easy to find on EURO-LEX by searching in browser by number

2021/1698: Recognition of CBs & control procedure in Third countries

2021/279: Measures ensuring traceability & compliance (incl. groups)

2021/771: Documentary Accounts & Control of Groups of Operators

2021/1695 List of Authorized Substances (in organic production)

2021/2306 Official Control consignments & COI (certificate of inspection)



As already explained in section 1.1, the new EU Organic Regulation (EU) 2018/848 has been amended and complemented by secondary acts (approx. 25 by Aug 2022), and the legislative process continues. You can find more information about the process to develop the EU Regulation in section 2.4. Some of the regulations are being incorporated into **consolidated versions of Reg. 2018/848**, but others remain additional separate legal acts.

Regulatory framework New EU regulation: structure



Regulation (EU) N° 2018/848:

Best read as "Consolidated Text Version" (available in multiple languages)

"Delegated" Acts

"Implementing" Acts

Amending

included in consolidated versions of 2018/848

2021/715 : Groups/ICS 2020/1794 Planting material 2020/427 Annex II + more than 10 other amending acts

already included in consolidated 2018/848

Supplementing

2021/279: Measures ensuring traceability & compliance (incl. groups)

2021/771: Documentary Accounts & Control of Groups of Operators

2021/1698: Recognition of CBs & control in Third countries

2021/1165 List of Authorized Substances (in organic production)

2021/1378 Certificates in Third Countries, 2021/2119 Records and Declarations, 2022/474 Nonorganic seedlings and PRM



for

ONDARY ACT

SEC

KEY

The new regulatory framework on organic production is composed of the "basic act", Regulation (EU) 2018/848, and > 25 secondary acts . All "amending delegated" acts are included into the consolidated Versions of Regulation (EU) 2018/848, but "supplementing delegated acts" and "implementing acts" remain separate regulations to complement the main regulation. Some regulatory texts apply only to the EU, others fully or partially to Third Countries. Rregulations are categorized as being on "production", "control" or "trade". This guide focusses on regulatory requirements that are most relevant for certified organic operators (crop production, producer groups, processors, exporters) in Third Countries like Thailand.

Transition to the new EU Organic Regulation

The new regulation 2018/848 applies in the EU since January 2022.



However for imported products there is a transition period to change to compliance with the new system of regulation 2018/848

1) Transition: Third Countries (not listed as EU equivalent) until 31.12.2024



2) Transition period for the countries that are EU recognized as "equivalent" (listed in 2021/2325):

→ until end of 2026

Relevant secondary acts during the transition period: 2021/2325 and 2021/1342



Information on the process for CBs to become EU recognized for compliant certification \rightarrow section 2.2. Information on the changes in the country equivalence system \rightarrow Section 2.3

Secondary Acts: Control (Compliance in Third Countries)



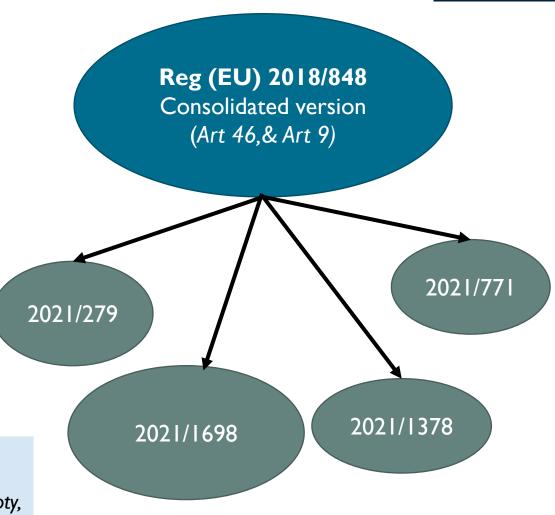
Reg 2021/279 (Art 4-6):

Requirements for operators in the event of presence of prohibited substances and requirements for groups of operators

2021/771 (Art 2): Rules about controls of groups of operators

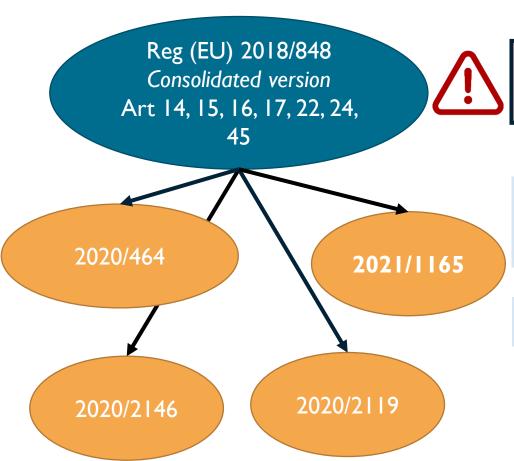
2021/1698: Rules about the controls and certification of operators and groups of operators and on recognition of control bodies in Third Countries that comply with the new regulation

Reg. 2021/1378: Certificate in third Countries & list of recognized control authorities / control bodies (currently empty, but will be where recognized CBs will be listed)



Secondary Acts Production Rules for Operators and Groups of Operators in Third Countries





2021/1165: Lists of authorised products and substances for organic production

2020/464: Production rules for different livestock species & aquaculture, and for processing of food and feed.

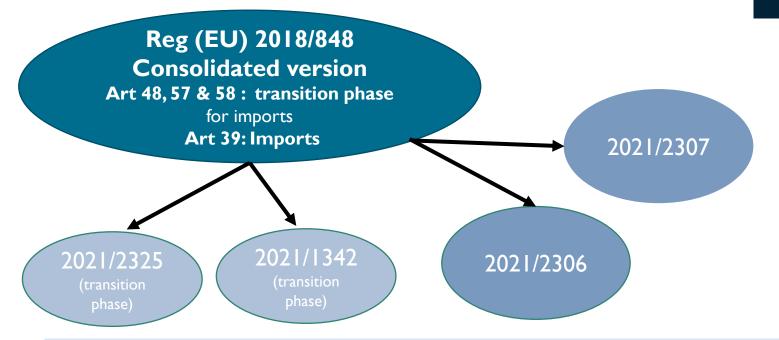
Note. Art 1: applies to EU operators only.

2020/2146: Detailed production rules in the event of catastrophic circumstances

2020/2119: Records to be kept and declarations for official controls

Secondary Acts on Imports into the EU





2021/2325: information about the control authorities/bodies recognised to continue certification based on «equivalence» during the transition to the new import systems

2021/1342: Details about the supervision of the control authorities/bodies during the transition to the new import systems.

2021/2306: Official control import consignments & Certificate of inspection.

2021/2307: Documents and notifications required for import of organic/conversion products



















The ITC Guide to the New EU Organic Regulation

Part 2: The new EU organic legal framework and key changes to the import system

2.2 The new EU "compliant" system for imports from Third countries

Author: FiBL Research Institute for Organic Agriculture

Final Technical Version for ITC 31.10.2022

This Technical Guide development was funded by the European Union (EU). Its contents are the sole responsibility of Arise Plus Thailand project implemented by the International Trade Centre (ITC) and do not necessarily reflect the views of the EU.

Content of this Section 2.2. The new EU Compliant System for Imports from Third Countries

- 2. 2. I Overview and transition from equivalence to compliance
- 2.2.2 The EU Regulation's control system in Third Countries
- 2.2.3 Recognition of Third Country CBs as EU compliant

2.2.1 Overview and Transition from Equivalence to Compliance



The EU Organic Control System in non-recognized Third Countries: From Equivalence to Compliance



Most countries outside the EU currently export organic products to the EU under the equivalence scheme for Third Country CBs.

Organic Control Bodies in all "Third countries", except the 14 "equivalent countries" whose organic legislation is recognized by the EU, certify products for export to the EU according to their own "equivalent organic standard" and to EU-approved equivalent control procedures.

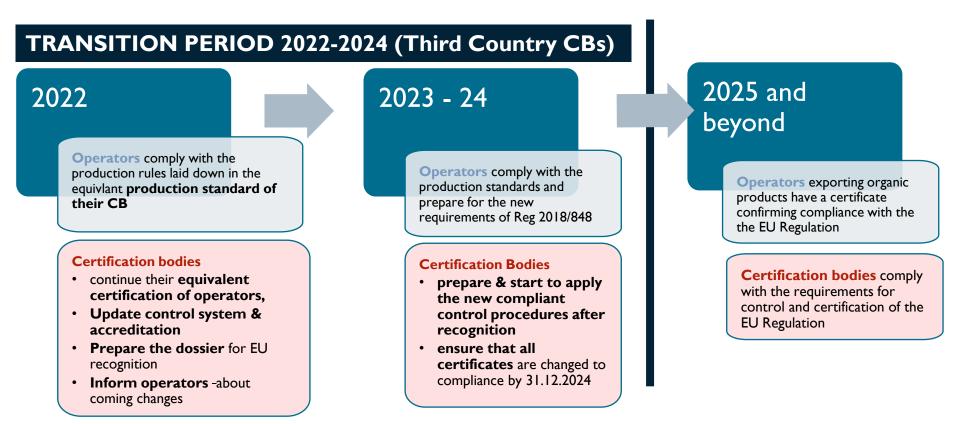
The CB equivalence option for organic exports to the EU is phasing out until the end of 2024 and will be replaced by the "compliance" regime.

- → All Third Country CBs who wish to continue certifying organic products for export to the EU need to apply for recognition as a compliant CB, based on a detailed technical dossier and a standard control system aligned to all requirements of Regulation 2018/848.
- → All certified organic operations will need to be inspected and be certified as compliant with Regulation 2018/848 at the very latest until the 31.12.2024. From 01.01.2025 only compliance based certificates of inspection (COI) are accepted for organic imports.
- → This means a lot of work for CBs to align their control system to the new requirements, inform operators, achieve accreditation, prepare the dossier, train staff and manage the transition to compliance for all operators on time



See Section 2.3 for information on the change from country equivalence to trade contracts for the 14 countries that have an organic legislation recognized by the EU.

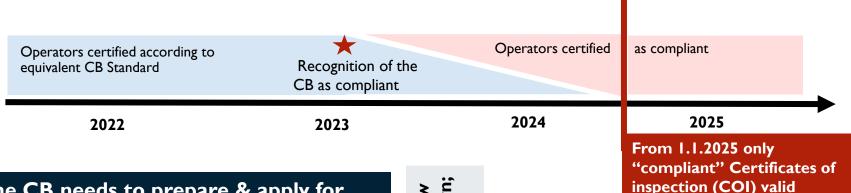
I. Change from the current system of equivalent CB standards to compliance with the EU Regulation





In the EU, the new organic regulation is in force since 1 Jan 2022 but for CBs in Third Countries there is 3 year transition period. During this period, the CBs need to adapt their control system to the new regulation, update their accreditation & apply for recognition with the EU, and — once granted - certify all organic operations as compliant with the EU regulation latest by 31.12.2024.

The 3 years transition from equivalence to compliance in a Third Country CB



The CB needs to prepare & apply for recognition by the EU Commission

Analyse the new regulation and align its control procedures, IT system & QS documents to the new regulation

Apply to accreditation body to update its accreditation to the new regulation (assessment visit; witness audits).

Prepare all data & documents for the dossier to submit in OFIS to the EU Commission (see Art 1 of Reg 2021/1698)

dossier & issue recognition unknown; Time for EU Commission to review 6 months expected

Once the CB is recognized as compliant CB (2021/1378 Ann II)

Most CBs will chose to "jump" to compliance in one go (if compliance & equivalence system in parallel \rightarrow 2 annual reports to the EU).

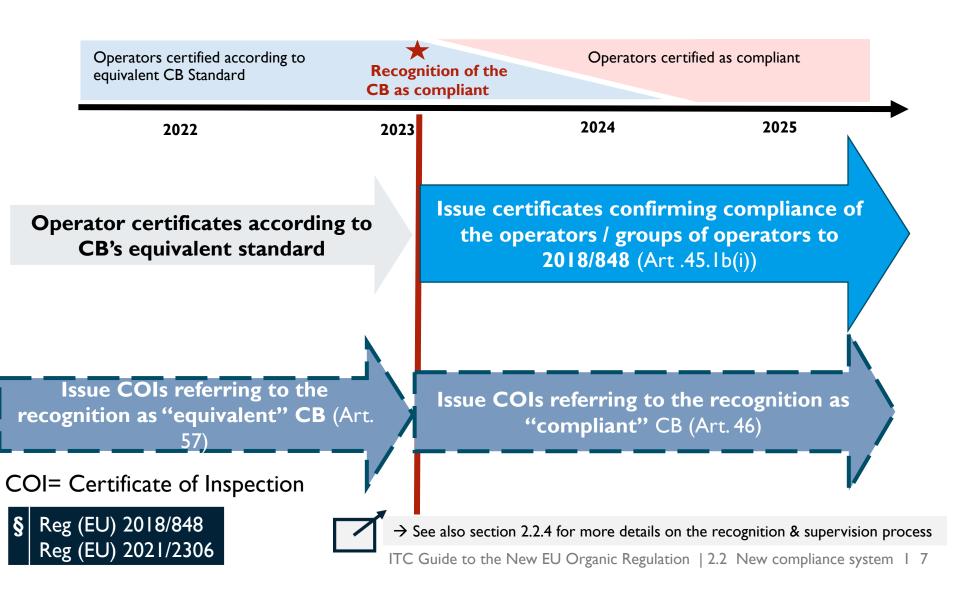
Inspection & certification of all organic operators as compliant to 2018/848;

There will be a period ending not later than 31.12.24 when only new compliant certificates are issued, but exports of some organic products are continued under the equivlance scheme until all "old" certificates are replaced.





Issue of Certificates During the Transition



Overview of parts of the EU regulation applicable to operators in Third countries under compliance

There are requirements and rules in the EU organic regulation that need to be followed by operators in Third Countries if they wish to export organic products to the EU. The following slides give an overview of the concerned topics.



Principles and objectives

Production rules including



General requirements for organic production Holding and production units, preventive and precautionary measures, prohibition of the use of GMO, ionising radiation and limited lists of products and substances authorised to be used in organic production



Specific production standards for organic (plant) products

Soil related plant production, use and production of organic plant reproductive material, soil management and fertilisation, pest and weed management, preparation of unprocessed products, collection of wild plants, preparation of unprocessed products



Conversion rules and requirements (plant production)

Start of the conversion period, simultaneous conversion, conversion of individual fields, labelling restrictions, retroactive recognition of a conversion period, extension of the conversion period, use of in-conversion plant reproductive material (including seedlings), processed in-conversion products





Overview of parts of the EU regulation applicable to operators in Third countries under compliance (2)

4	Positive lists for products and substances authorised for use in organic plant production	 EU lists and additional lists for Third Countries Fertilisers/soil amendments/nutrients, active substances (plant protection) and products for cleaning and disinfection
a== a==	Record keeping	
	Possible derogations and procedures (plant production related)	Use of non-organic plant reproductive material, retro-active recognition of the conversion period
2222	Post-harvest requirements for processed and unprocessed products	Simultaneous collection of organic and non-organic products, transport, storage of products, reception of products from other operators or other units
	Lablelling rules	
→	Exchange of information	Parallel production arrangements, derogations, declaration, presence of non-authorised products or substances, catastrophic circumstances
	Rules specific for groups of operators	→ See Guide section 1.2 Rules for Groups of Operators



Reg (EU) 2028/848, Reg (EU) 2021/2119, Reg (EU) 2021/1698, Reg (EU) 2021/1165, Reg (EU) 2021/771, Reg (EU) 2021/279

2.2.2 The EU Regulation's compliant control system in Third Countries



Competent authority for Certification in Third Countries



For products certified by Control Bodies (CBs) with recognized compliant standards, the European Commission takes over the role of a Competent Authorities, assisted by

- Member States based on assessment reports issued by
- Accreditation bodies

The European Commission is authorised to

recognise and/or



The European Commission organizes risk based supervision based on

- Technical dossier and Annual report
- Monitoring of exchange of information between the Commission and the CB
- On-site visits, traceability checks and other sources of information

Inspections of Operators & Groups of Operators – the basics

lx/yr



A recognised Control Body (CB) shall carry out an inspection:

- At least once per year "on-the-spot"
 - For each operator and each group of operators
 - Of (all) the production units or premises (including purchase and collection) centres) used for non-organic products in the case where operators/GoO run such production units or premises



Minimum requirements

- CBs shall verify requests for certification by checking certain criteria before accepting the request
- Risk based approach during all controls
- **Verification of the implementation of the precautionary** measures to ensure effective separation organic / in-conversion and non-organic production units
- Verification of records to confirm separation and identification of organic products, mass balance and traceability.
 - Special attention in those cases where organic and other products are collected simultaneously.

Additional Controls and Sampling



In addition to the annual inspections of each operator and each group of operators, a CB needs to perform additional inspections of

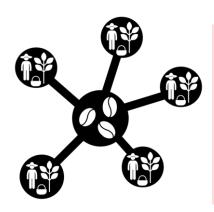
- At least 10% of annual inspections
- At least 10% of all the physical on-the-spot inspections are unannounced



A CB needs to take samples from at least 5% of operators inspected. In a Group of operators the CB shall carry out sampling on at least 2 % of the members of each group

- The CB performs a risk based selection of operators and members of groups of operators where samples will be taken. Mandatory sampling in each case where the use of nonauthorised products and substances or techniques is suspected.
- Conditions for the laboratories: accreditation (ISO 17025) by an accreditation body that has signed the Multi Lateral Agreement of ILAC, have sufficient capacity for analysis and testing and are able to detect pesticides listed in Reg (EU) 2019/533.
- Special attention will be necessary for high-risk products (Art 8 of 2021/1698) once they will be defined

Inspections of Group of Operators



The CB performs a risk based verification of the functioning of the ICS, including re-inspection of members, witness audits of internal inspections and review of ICS Documentation

The specific adapted control process for Groups of Operators is decribed in detail in Regulation 2021/771

- **Verification of the functioning of the ICS and ICS records** (internal controls performed by the ICS inspectors)
- **Re-inspection of at least 5% of members** (but no less than 10, except in groups with less than 10 members)
- Sampling shall be carried out on least 2% of the members of the group



For more introduction on the Group of operators and the Internal Control System, see Guide Section 1.2

Control for consignments of organic products to EU

CBs are to verify consignments of organic products intended for the import to the EU by means of documentary checks and, as appropriate, physical checks

Documentary checks to verify:

- **Traceability**
- Volume included in consignment corresponds to mass balance checks
- Transport and commercial documents
- Processed products: ingredients certified organic

Factors of risk assessment preceding physical checks includes:

- Operations involved with parallel production
- High-risk products: systematic physical checks to be carried out and at least I representative sample per consignment
- Other relevant information

Travel plan for bulk organic products

In case of suspicion: CB to make available list of all operations involved

For further information on controls for high risk products see next slide.

Reg (EU) 2021/1698 Art 16

Higher Control Requirements Apply in Case of High-Risk Products



For a future EU list of high-risk products (see Reg. 2021/1698, Art 8) additional control measures will need need to be followed

Control activity	Organic products in Third countries	High-risk products
Physical on-the spot inspections	I / year Additional 10% of the operators and 10% unannounced Risk based timing	2 / year out of which I unannounced
Sampling rate	5% of all operators under control	100% of operators involved -pre-harvest: risk based timing -post-harvest: raw material, intermediate or processed product sampling
Verification of consignment (TC)	Risk based physical checks	100% physical checks 100% representative sampling (1/consignment)
Checks at EU border:	Documentary Check: Systematic Identity & Physical Check: Risk based	Documentary Check: Systematic Identity check: Systematic Physcial check I sample per consignment

Actions in case of suspicion of non-compliance

In cases of suspicion of non-compliances, both the operators and CB need to take actions

By the operator

- Identify and separate suspected products
- Check suspicious elements
 - Block and not use as organic when suspicion cannot be eliminated
 - Place on the market when suspicion has been eliminated
- Inform control body of blocking and share relevant information
- Cooperate with the control body in verifying the reasons for the suspicion of noncompliance

By Control Body

- Carry out an investigation with a view to verify compliance and prohibit the import as organic into the EU of the products concerned
- Allow the use and labelling of the products as organic if the results of the investigation do not show any non-compliance affecting integrity of organic products
- Apply the catalog of measures if the results of the investigation show non-compliances
- Document the results of the investigation carried out because of the presence of nonauthorised products and substances

Actions in case of suspicion of non-compliance due to non-authorised products and substances

By the operator

- Identify and separate suspected products
- Check suspicious elements
 - For incoming products, operators check label and supplier certificate
 - For all other products, operators examine any possible cause
 - Block and not use as organic when suspicion cannot be eliminated
 - Place on the market when suspicion has been eliminated
- Inform control body of blocking and share relevant information
- Cooperate with the control body in verifying the reasons for the suspicion of non-compliance

By CB

- Carry out an investigation determine the source and cause in order with a view to verify compliance and prohibit the import as organic into the EU of the products concerned
 - The products shall not be marketed as organic in the following cases:
 - Operator has used
 - Operator has not taken precautionary measures
 - Operator has not taken measures in respons to previous requests from the control body
- Allow the use and labelling of the products as organic if the results of the investigation do not show any non-compliance affecting integrity of organic products
- Apply the catalog of measures if the results of the investigation show non-compliances
- Document the results of the investigation carried out because of the presence of non-authorised products and substances
- § Reg (EU) 2018/848 Reg 28.2 + 29; Reg 2021/279 Art 1; Reg 2021/1698 Art 22

Measures in Case of Non-Compliances



CBs have to develop a catalogue of measures to apply in case a noncompliance is identified. There is a pre-determined list of non-compliances and measures listed in the Reg. 2021/1698 Recognition of CBs in Third Countries that needs to be included.

Classification of non-compliances into 3 categories (minor, major, critical)

- Criteria for the classification:
 - √the application of precautionary measures
 - ✓ the impact on the integrity of the organic status of products
 - ✓ the ability of the traceability system to locate the affected product(s) in the supply chain;
 - √the response to previous requests by the control authority or control body



When a CB identifies an established non-compliance with the Regulation, they shall determine the origin and take appropriate measures to ensure the operator concerned remedies the non-compliance and prevents further occurrences. The CB shall consider the nature of the non-compliance and past record of the operator when applying the catalogue of measures. The catalogue needs to be included in the CB's application for recognition and in annual reports.

Reg (EU) 2021/1698, Art 22, 23 & Ann IV

Classification of Non-Compliances

A non-compliance is Minor, when

- Precautionary measures in place and own controls of operator considered as efficient
- Integrity of product NOT effected
- Traceability system functional



A non-compliance is Major, when

- Precautionary measures in place are not appropriate and own controls of operator considered as inefficient.
- Integrity of product effected
- The operator did not correct in a timely manner a minor non-compliance
- Traceability system functional



A non-compliance is Critical, when

- Precautionary measures in place are not appropriate and own controls of operator considered as inefficient
- Integrity of product effected
- The operator fails to correct major non-compliance
- No information on traceability



Depending on the above mentioned different criteria, the CB has to decide in what category the non-compliance is. Based on this assessment, different measures will need to be taken.



Defined classification of certain non-compliances

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There are some cases of non-compliance and the corresponding classification that are mandatory to be included in the catalogue of measures

Non-compliance	Cat
Significant deviation between input and output calculation (mass balance)	Major
Absence of records and financial records showing the compliance	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-authorised substances or products within the scope of the Regulation (EU) 2018/848	Critical
Intentional use of GMOs	Critical
Operator refuses CB/CtrlA 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

Catalogue of measures



CBs shall apply one or more of the following measures in a proportionate manner in cases of non-compliance

Cat of NC	Measure(s)
Minor	 Submission by the operator of an action plan within time limit set on the correction of non-compliance(s)
Major	 No reference to organic production in the labelling and advertising of the entire lot or production run concerned (crop(s) or animal(s) affected New conversion period required Limitation of certificate's scope Improvement of the implementation of the precautionary measures and the controls that the operator has put in place to ensure compliance Prohibition of import from a TC for a given period
Critical	 No reference to organic production in the labelling and advertising of the entire lot or production run concerned crop(s) or animal(s) affected Prohibition of import from a TC for a given period New conversion period required Limitation of the certificate's scope Suspension of the certificate Withdrawal of the certificate

Certification



- Harmonised certificates (defined in Reg. 2021/1378) confirming compliance to be issued in TRACES from 1/1/2023
 - Mandatory part
 - Optional part
- Electronic certificates of inspection (COI) for each consignment destined to enter the EU issued in TRACES with access to
 - Exporters
 - Control body of the exporter
 - Importer
 - Competent Authority in the member state where the consignment is presented for free release
- COI to be issued <u>before</u> the consigment leaves the Third Country

Certification process



Operator / Group of Operators

Sign a declaration and submit it to the CB containing

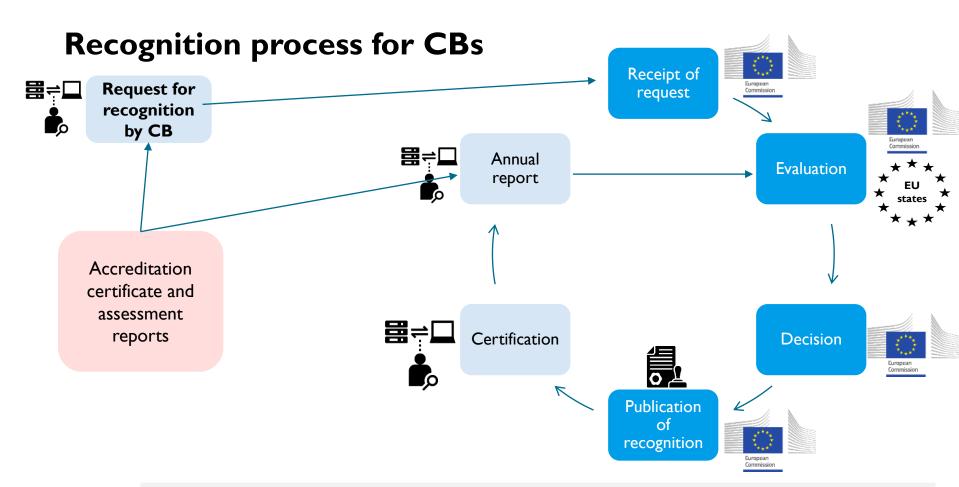
- A description of the production unit, relevant measures to comply and to avoid contamination and mixing of organic with other products
- **Confirm** that they, and for groups also their members, have not been certified by another CB
- **Sign to commit** themselves to their fullfil the obligations towards CB

CB

- **Verify that operators and GoO**, and where relevant their subcontractors, **comply with the requirements**
- Verify the certification history and act appropriately where necessary
- Certify operators and groups of operators
- Special checks for operators that were previously certified by another operator

2.2.3 Recognition of Third Country CBs as EU compliant

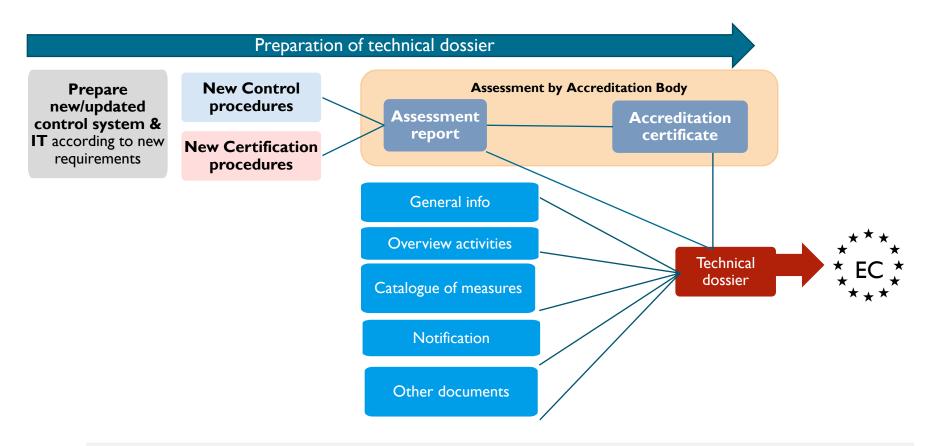






The accredited CBs submit their request for recognition in accordance with Art 46 (1) of Reg 2018/848 (= compliance) to the European Commission. The EC evaluates the request together with EU member states and decides whether the recognition is granted. If the evaluation is positive, the EC publishes the recognized CB in Annex II of Reg (EU) 2021/1378 and the CB can certify organic products compliant. Recognized CBs are obliged to submit annual reports to the EC for the purpose of supervision (by 28 Feb each year). Additionally, the CB's accreditation bodies assess implementation of the new Regulation and issue an accreditation certificate and assessment reports, which feed into the application and annual report.

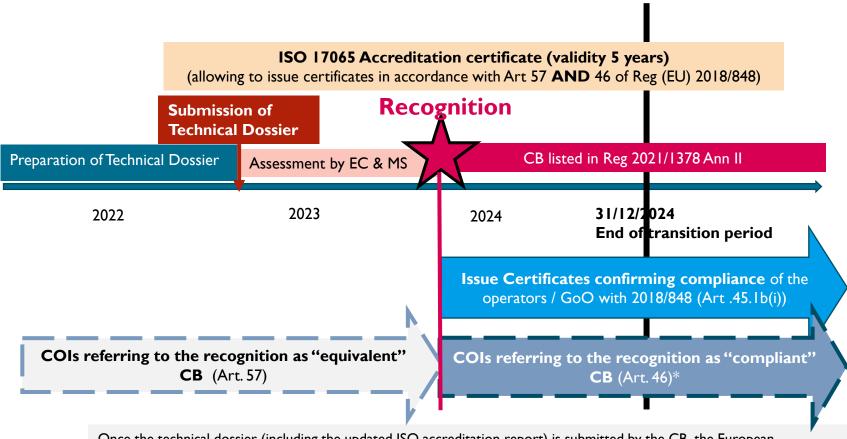
Preparation of the Technical Dossier





In order to be recognized for compliance, a CB will have to adapt it existing control and certification procedures as well as create additional procedures. It will need to get accreditation by its accreditation body for the scope of the new Regulation. The CB has to include all required information as listed in Regulation 2021/1698 Art 1 including the accreditation assessment report in the technical dossier. The European Commission might request additional information from the CB after the submission of the technical dossier.

Accreditation, Technical dossier and Certificate





Once the technical dossier (including the updated ISO accreditation report) is submitted by the CB, the European Commission (EC) and Member States (MS) assess it. Once the assessment is finalized and with a positive outcome, the CB is recognized and included in the list of recognized CBs in Reg 2021/1378 Ann II.

From then on the CB can issue new Certificates (model 2021/1378 Ann I) and COI's referring to Art 46 (or possibly during a short time to Art 46 & Art 57 in parallel).

It is expected that there will be a period ending no later than 31.12.2024, when, although only new compliant certificates are issued, the old "equivalent" certificates are also still valid, until replaced by compliant certificates after the first "compliant" inspection.

Product Categories for CB Recognition

Product categories for which CBs can be recognized

	Category	Product
	A	unprocessed plants and plant products, including seeds and other plant reproductive material
2	В	livestock and unprocessed livestock products
*	С	algae and unprocessed aquaculture products
	D	processed agricultural products, including aquaculture products, for use as food
5	E	Feed
	F	Wine
	G	other products listed in Annex I to Regulation (EU) 2018/848 or not covered by the previous categories



CBs can be recognized for one or more product categories. They are only entitled to certify products for which they are authorised. Compared to the past, there are more products now that can be certifies organic.

§ Reg (EU) 2021/1378 Annex II

Technical Dossier





CBs in Third countries need to submit a request for recognition of compliance to the European Commission (EC) by submitting a technical dossier in a specific new OFIS module, providing all information required by the EU Regulation

With the technical dossier the CB has to provide the following information in one of the official EU languages.

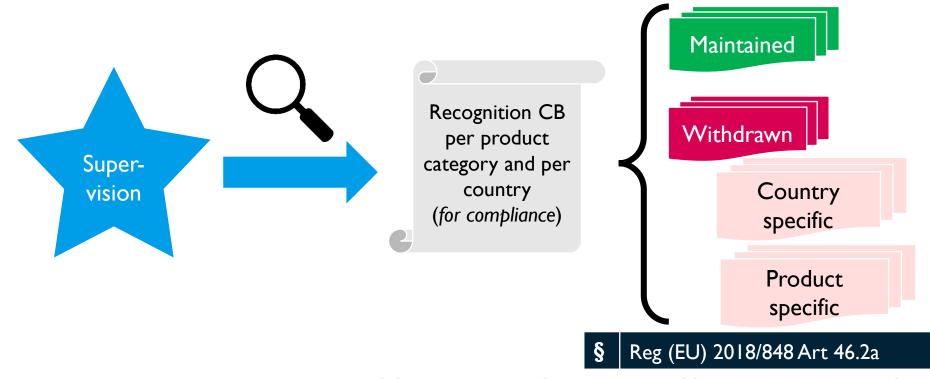
- General information about the CB (incl. name, contact details, name of accreditation body, website)
- Overview of intended activities (incl. indication of organic products intended for import)
- Description of the CB (incl. size, IT management system branch offices, type of activities, organisational chart, quality management system)
- Certification procedures
- Translation of production rules and control measures in languages that are understandable for the contracted operators in the Third Countries the CB is active
- Documents proving that conditions for recognition are fulfilled (incl. accreditation certificate)
- Procedures describing in detail the functioning and implementation of the control measures
- Catalogue of measures to be taken in cases of established non-compliances
- Copy of the most recent assessment report by accreditation body (incl. witness audit report & guarantees that CB has the ability to ensure imported products meet conditions for import to EU and that it has the capacity to effectively implement control requirements)
- Proof that the CB has notified its activities to the relevant competent authority & its undertaking to respect national legal requirements
- Undertaking to give access to its offices & facilities
- Statement of not having been subject to withdrawal or suspension in past 24 months
- Other relevant information

Review of recognition of CBs



The EU Commission may change the recognition of recognized compliant Third Country CBs based on its supervision activities e.g.

- ✓ If the CB does not make available requested additional information, its recognition may be suspended;
- If the CB fails to take appropriate action to remedy non-compliant situation, its recognition will be suspended;
- If the annual report is not sent in time, its recognition may be withdrawn



Useful Institutions and Sources for Information



European Organic Certifiers Council

Membership organisation of Organic CBs. Founded by European CBs, but many Third Country CBs joined EOCC to receive information and participate in CB exhcange on relavant topics around the new EU regulation.





IFOAM Organics International & IFOAM Organic Europe are membership-based organization promoting organic agriculture and supporting the organic sector globally and specifically in Europe. IFOAM is working on guidance to the new EU regulation



FiBL, the Research Institute for Organic Agriculture provides studies and training materials on various topics around organic farming and the new EU Regulation.



















The ITC Guide to the New EU Organic Regulation

Part 2: The new EU organic legal framework and key changes to the import system

2.3 Third Country Recognition and Future System of "Trade Agreements"

Author: FiBL Research Institute for Organic Agriculture

Final Technical Version for ITC 31.10.2022

This Technical Guide development was funded by the European Union (EU). Its contents are the sole responsibility of Arise Plus Thailand project implemented by the International Trade Centre (ITC) and do not necessarily reflect the views of the EU.

Content of this chapter 2.3 Third Country Recognition and **Future System of Trade Contracts**

- 2.3. I The current system of Third Country equivalence recognition
- 2.3.2 The new system of trade agreements
- 2.3.3 Conclusions for other Third Countries

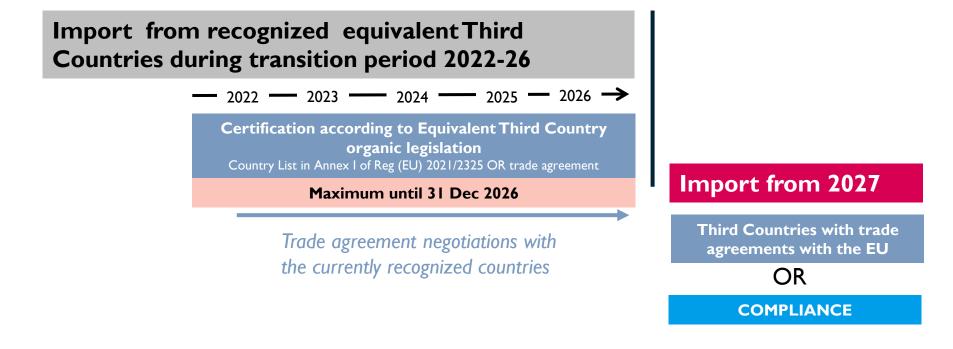
2.3.1 The current system of Third Country equivalent organic legislation recognition



Third Country Equivalence is being phased out



As of 2022, the EU recognizes the organic legislation of 14 countries as equivalent to the EU organic legislation through the equivalence system or by a trade agreement. Defined products, certified organic in accordance with these legislations, can be exported to the EU without additional EU organic certification. The country equivalence system is being phased out and replaced by trade agreements latest by the end of 2026. As of Jan 2027 import of organic products is possible only under a trade agreement or under the compliance system (see section 2.2)



Recognized Third Countries

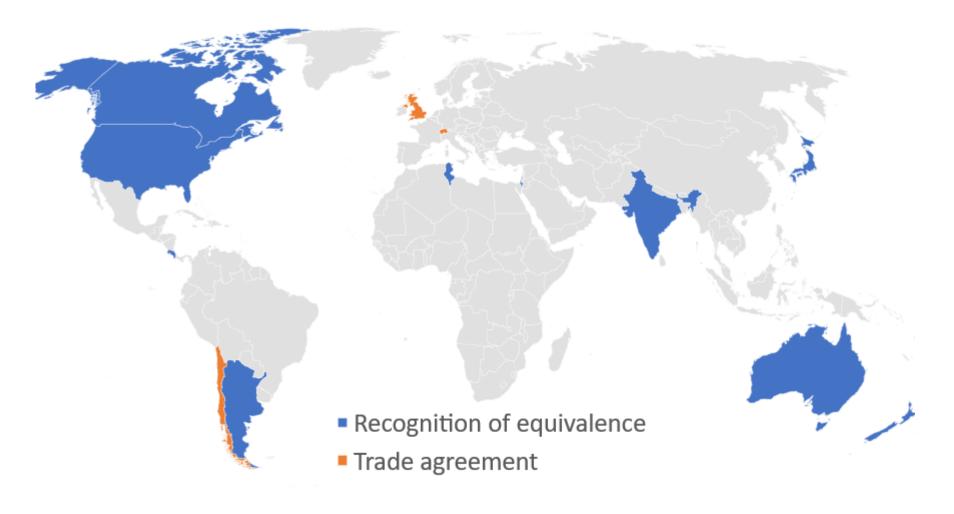
- The previous EU regulation which listed recognized equivalent countries (Regulation (EC) 1235/2008)) is no longer valid since January 2022.
- Since January 2022 the list of <u>equivalent</u> third countries is indicated in Annex I of Reg (EU) 2021/2325 which applies during the transition period until 31.12.2026.
- I I countries are recognized as equivalent to the EU organic legislation (08/2022):



Chile, Switzerland and UK have already signed trade agreements on organic products with EU and are no longer listed in transition regulation list of equivalent countries (Regulation 2021/2325) Specific agreements

Note: The list of approved CBs in each recognized country can also change, due to suspensions or other sanctions issued by the EU.

Third Countries with an organic legislation equivalent to the European Organic Regulation (Status Aug 2022)



Supervision of recognized Third Countries

The European Commission (EC) is responsible to supervise the organic control system in the TC

- Annual report according to requirements to be sent to EC each year by 31 March.
- Notification of any changes made to the measures in force and implementation of the control system.
- EC may request additional information
- Possible on-the-spot visits organized by EC based on risk assessment or in case of suspicions.
- EC notifies competent authority of third country in case of a substantiated suspicion of an irregularity or infringement.



Reg (EU) 2021/1342 Art 1



For the purpose of supervision there is a constant exchange of information between the competent authority of a recognized Third Country and the European Commission. The competent authority is obliged to provide certain information in a timely manner to the EC. Based on the information obtained, the EC may change the recognition. If e.g. the TC competent authority does not send the annual report in time, its recognition may be withdrawn.

2.3.3 The new system of trade agreements for organic products



ITC Guide to the New EU Organic Regulation

Introduction to trade agreements for organic products

Trade agreements grant access to the EU market for organic products coming from Third Countries that have been recognized as having a system of production meeting the same objectives and principles. This means they apply rules which ensure the same level of assurance of conformity as those of the Union. Each trade agreement is unique.



→ Agreements on trade in organic products are listed on the European Commission Website:

https://agriculture.ec.europa.eu/farming/organic-farming/trade/agreements-trade-organic-products en



Trade agreements grant mutually-beneficial access to the markets of both the EU and the countries concerned. Each Agreement is different. Once the Commission completes the negotiations, it publishes the agreement and presents the deal to the Council and the European Parliament. The Council and the European Parliament examine the final agreement and decide whether or not to approve it. If they both approve it, the EU can sign the agreement. The partner can then ratify this signed agreement, after which the Council can declare the agreement concluded.

A trade agreement is the result of a political process aiming at fostering trade. Trade agreements tend to cover various topics, products and services, not only organic products...

For more information about EU trade agreements (not specifically for organic products), see <u>EUTrade</u> agreements (europa.eu)

Organic products imported under a trade agreement



The recognition for the purposes of equivalence of TC on the basis of Reg (EC) No 834/2007 will expire on 31 December 2026.

Trade agreements will replace the recognition of equivalence .

Organic products imported into the EU under a trade agreement:



- Comply with the organic legislation of a third country
 - Inspection and certification of organic products must be carried out by the control bodies which have been recognized by the competent national authorities
 - arrangements for the imports of organic products are in place with these countries as their standards and control measures have been assessed as equivalent to those in place in the EU
- Comply with the **EU labelling** rules



Each consignment of organic products for import into the EU must be accompanied by the Certificate of Inspection (COI) issued by a control body recognized by the national authorities, but using a code number assigned to them by the EU Commission.

Negotiations with TC for new trade agreements



In order to replace the former equivalence scheme, the European Union enters in negotiations for trade agreements in organic products with the following countries:

Argentina, Australia, Canada, Costa Rica, India, Israel, Japan, New Zealand, South Korea, Tunisia and the United States

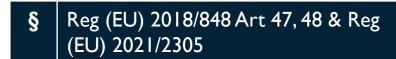
(Council Decision 2021/1345)

EU member states will be involved in the negotiations together with the European Commission.

Currently (status Aug 22,) there are three countries that have concluded trade agreements with the EU for organic products: UK, Switzerland and Chile



Once a trade agreement is concluded, the list of CBs operating in the respective country can be found on **EC** website (and not in the Regulation anymore)



Example trade agreement with UK



The Trade and Cooperation Agreement (TCA) between the European Union and the United Kingdom (UK) establishes a reciprocal recognition of equivalence of the current organic legislation and control system of both parties. The TCA also regulates various other cooperation and trade aspects

The EU and the UK have concluded a trade agreement covering the following product categories. A detailed list is included in the Annex of the agreement. Only for these products the two parties recognized the equivalence of their respective standards.

Category of products or products	Designation of category	Limitations (origin)
Unprocessed plant products	Α	
Live animals or unprocessed animal products, including honey	В	Produced in the UK
Aquaculture products and seaweeds	С	
Processed plant products for use as food	D	Processed in the UK with
Processed agricultural products for use as feed	Е	ingredients that have been grown in the UK or have been imported in the UK in accordance with UK laws and regulations
Vegetative propagating material and seeds for cultivation	F	Produced in the UK

Example trade agreement with Chile



A trade agreement is the result of a political process aiming at contributing to the development and expansion of the organic sectors in both the EU and the Chile by creating new export opportunities. This will be achieved in full respect for the principles of organic production, of guarantee of the control systems and of integrity of organic products.

The EU and Chile have concluded a trade agreement covering the following product categories. A detailed list is included in the Annex of the agreement. Only for these products the two parties recognized the equivalence of their respective standards. The list of products recognized by the EU is different to the list recognized by Chile.

Category of products or products	Designation of cat as in Ann IV	Limitations (origin and conditions)
Unprocessed plant products	Α	Only products listed in the Agreement
Honey	-	Only products listed in the Agreement
Processed plant products for use as food	D	Only products listed in the Agreement
Vegetative propagating material and seeds for cultivation	F	Only products listed in the Agreement

Recognition of product categories



There are different product categories defined for organic products. Depending on the country of origin, both the recognition of equivalence as well as future trade agreements cover different product categories.

The product categories are based on the EU classification system of Ann III of Reg 1235/2008 until 31/12/2026 (A, B, C, D, E, F)

Cat	Description
Α	Unprocessed plant products
В	Live animals or unprocessed animal products
С	Unprocessed aquaculture products and algae
D	Processed agricultural products for use as food
E	Processed agricultural products for use as feed
F	Vegetative propagating material and seeds for cultivation

Limitations may apply for specific countries e.g.

For Australia: "D" means Only processed plant products; Wine and yeast are excluded For Chile "D" means = only those Nace codes listed in the agreement

Origin of products from category D



Depending on the recognized Third Country, ingredients for processed products, may only come from domestic production or may be imported.

Possibilities which apply: no import, import from EU, import from countries recognised by the EU and/or import recognised by the third country concerned

Country	Domestic	Import from country with "own recognition"	Import from EU	Import from countries recognised by EU
Argentina	×			
Australia	×			
Canada	×	x		
Costa Rica	×			
Israel	×		x	×
Japan	×	x	x	
Korea	x	x	x	
New Zealand	x	x (ingredient up to max 5%)	x	x
Tunisia	×			
USA	×	×		

Hierarchy between Trade agreement and recognition for compliance - Example of Tunisia - I



EU - TC "arrangements"

The trade agreements are expected to cover the same product categories so far recognized for equivalence.

Product categories not covered by recognition or trade agreement can be certified according to private standards by CBs



	Product Categories					
Example: Tunisia	А	В	С	D	Е	F
Recognition as equivalent national legislation? (Reg 1235/2008 Ann III and Reg 2021/2325 Ann I)	YES	No	No	YES	No	YES
Expected to be covered by the scope of the future trade agreement?	YES	No	No	YES	No	YES
Examples:	Grapes, fresh dates, fresh olives	Honey	Fish	Olive oil, date puree	Feed	Seeds

Hierarchy between Trade agreement and recognition for compliance - Example of Tunisia - 2



During the transition phase (2022 - 2026), products which are covered by a trade agreement or recognition of equivalence of an organic third country legislation cannot be certified by a CB applying its own "equivalent" standard.

Whether a product is certified in accordance with a CB standard or with an equivalent organic legislation of a Third Country can be deducted from the code number of the CB on the labelling of the product: code number starting with

"0": EU - Third Country "recognition / agreement"

" I ": EU – private CB arrangement

For example:

- Product Category A (unprocessed plant products) is recognized as equivalent
 - → Code number on product would be TN-BIO-0xx
- Product category B (live animals or unprocessed animal products) is not recognized
 - → Code Number on product would be TN-BIO-IXX

§ Reg (EU) 2021/2325 Ann 1

2.3.3 Conclusions for other Third Countries



Third Countries: Prospects to sign Trade Agreements

For any not yet recognized Third country with an active organic sector exporting to the EU, becoming an "equivalent Third country" has long been an aspiration, as this status holds various obvious advantages:

- ✓ A locally adapted organic regulation and legal framework
- ✓ Easier trade in those products covered by the agreement
- ✓ Lower certification costs

However, it is not clear when and whether a trade agreement with the **EU can be achieved**, even if a country's organic legislation & control system would be very well aligned to the EU's system.

- > Trade agreements take many years to conclude
- > Beyond the negotiations with currently equivalent countries or possibly those where negotiations have already started, no new trade agreement negotiations on organic products can be expected to start until 2027.
- > Trade agreements are a highly political process, which seems to be mainly based on trade volumes and trade interests.

Compliance is the only option for the next years



For all countries worldwide, which are currently not recognized as equivalent by the EU:

- import of organic products via a trade agreement is, at best, a mid-term perspective and won't be achieved for many years to come.
- The current equivalence system ends in December 2024, and from 1.1.2025 only new compliance certificates will be accepted for import of organic products



- → Operators and certification bodies in Third Countries need to prepare for COMPLIANCE with the EU regulation.
- → National authorities and supporting organisations should aim to support their organic operations and control bodies in achieving compliance in order to continue export to the EU



For details on the Compliance system, see Guide Section 2.2



















The ITC Guide to the New EU Organic Regulation

Part 2: The new EU organic legal framework and key changes to the import system

2.4 The Role and Responsibilities of Competent Authorities in the EU System

Author: FiBL Research Institute for Organic Agriculture

Final Technical Version for ITC 31.10.2022

This Technical Guide development was funded by the European Union (EU). Its contents are the sole responsibility of Arise Plus Thailand project implemented by the International Trade Centre (ITC) and do not necessarily reflect the views of the EU.

Content of this section 2.4 The role and responsibilities of competent authorities in the EU system

- 2.4.1. Competent authorities and their role in setting rules and additional guidance
- 2.4.2. Role of competent authorities in the control process
- 2.4.3 Supervision of control bodies to ensure consistent application

2.4.1 Competent Authorities and their role in setting the rules



The Organic Control System within the EU

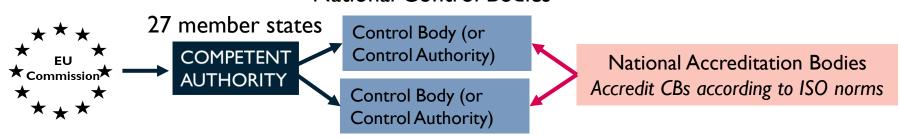


- Every country in the European Union appoints a 'competent authority' who is ultimately responsible for making sure that EU organics rules and procedures are followed as described in the EU organic regulation
- Usually a competent authority is either a department of agriculture or a department of public health.
- Competent authority may delegate certain tasks to private Control Bodies or public Control Authorities (see section 2.4.3) or both.



The European Commission supervises EU countries to ensure that they fulfil their responsibilities. The Commission uses both the reports submitted by EU countries and regular audits to make sure that adequate controls are being carried out

National Control Bodies



Member States and competent authorities for organic production in the EU

In the EU, the 27 Member States have designated 106 competent authorities for Organic production.

Some countries have

- A central Competent Authority, e.g. Greece or Poland
- Regional Competent Authorities, e.g. Span has 19 competent authorities; Italy has 22.
- A central Competent Authority as well as regional Competent Authorities.



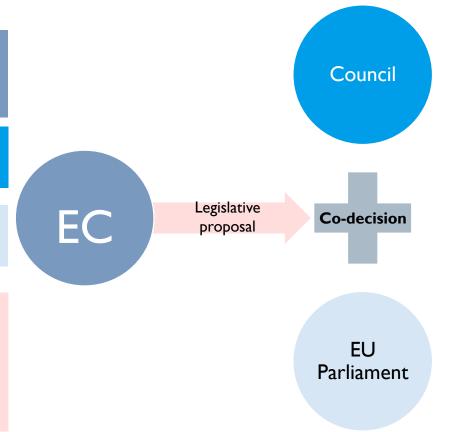
EU legislative process – **EU** institutions & legislative proposals

The European Commission (EC) is the executive of the EU with the right to make legislative proposals.

The Council is a group of Ministers of the member states.

The EU Parliament is elected by the people of the member states.

The EU Organic Regulation 2018/848 is the result of a discussion between the Council and the EU Parliament in view of adopting EU legislation following a proposal of the European Commission.





In the EU the three European Institutions have different roles and responsibilities. Based on a legislative proposal by the European Commission the European Council and the European Parliament co-deicide and adopt laws.

EU legislative process - Legislation and Committees

Regulation and Secondary Acts



Regulation: the term is used for a binding legislative act. It must be applied in its entirety across the EU, by all the Member States.



Delegated and Implementing Acts are so called "secondary legislation". The EU Commission can only adopt such legislative acts after consultation of all the member states (Implementing Acts) or after consulting expert groups of each member state (Delegated Acts). During a period of 4 weeks before the vote for adoption, citizens of member states have the possibility to comment on proposals of Implementing Acts.

Expert groups



COP: The Committee on organic production represents the views of the Member States on current and upcoming organic legislation. It serves as a key link between the EU Commission and the Member States.



The Expert Group for Technical advice on Organic Production (EGTOP) provides advice to the European Institutions. EGTOP produces reports on organic production and assesses requests from Member States to amend technical annexes.

Additional Guidance at Country Level

Countries may give additional guidance on organic production.

Examples include:

- **List of inputs** approved for use in organic farming in the country
- Organic Seeds Database, e.g. Ireland commissions FiBL to run the organicXseeds database, through which seed requests are proved by the BC
- Guidance on the new EU **Regulation per topic**, e.g. guidance on organic poultry, pigs, crops, preparation by SKAL, the public control authority in the Netherlands
- Additional requirements for CBs, e.g. strategy for analysis in France

Example France: The French National Institute of Origin and Quality (INAO) offers useful materials and information for organic operators.

- Readers guides, e.g. on Plant reproductive material; Use of plant protection products, Measures in case of doubt /suspicion about organic integrity
- List of approved inputs in France
- Additional requirements on controls and certification:: List of tasks delegated to CB, Strategy for analysis by certification bodies



INAO: https://www.inao.gouv.fr/

2.4.2. Role in the control process



Role of Competent Authorities in Organic Control

In the EU the national Competent Authorities have various responsibilities in the control process and information they need to provide to the European Commission, other EU countries, Accreditation Bodies, CBs and Operators as necessary for the implementation and monitoring of the application of the Regulation.

In a nutshell, important responsibilities of authorities include



Overseeing due implementation by CBs: e.g. Approval and supervision (including audits) of organic CBs (see also section 4.3.3), Procedures to approve and publish derogations



Measures to ensure Organic Product Integrity: Measures to prevent fraudulent claims, Measures and investigations to prevent and/or follow-up on unauthorised substances in organic products or suspected /confirmed cases of non-compliance.



Information & Databases: providing list of CBs, providing database on availability of organic planting materials, list of contaminated products, data on certified operators in the country.



Active role in the control process of organic operators in the EU: organic operators must "notify" their organic activity to the competent authority; Only authorities (not CBs) can grant retroactive recognition of conversion period, and approve the conversion plan in case of parallel production.

Database on organic operations

Currently no universal list of organic operations available but different initiatives where operators in various countries can be looked up.

From I January 2023 on, all organic operators certificates will be available via TRACES



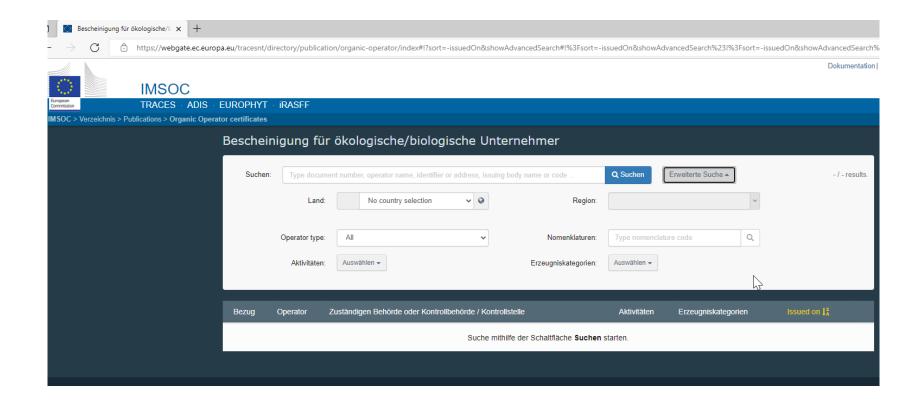
Public domain of the list of organic operators and their certificates in TRACES:

https://webgate.ec.europa.eu/tracesnt/directory/publication/organicoperator/index#!?sort=-issuedOn



There is a test environment for TRACES and access can be requested from the European Commission.

TRACES



In the organic regulation there is a new model for the organic operators certificate.

Reg (EU) 2018/848 Annex VI

EU Official Control Regulation (OCR) and Relation to Organic Regulation







In the EU a set of regulations defines the rules and requirements for organic production, labelling and controls.

- The Official Control Regulation OCR sets out the overall rules for official controls including on organic
- The Organic regulation determines further rules for controls on organic that have to be followed in addition to the rules of the OCR

Competent Authority responsibilities towards EU Commission and other EU countries (1)



	Activity & Information to be provided	Ref in 2018/848
← →	Exchange of information (investigation, mass balance or traceability checks)	Art 43.4
Q	Transmission of the information necessary for the implementation and monitoring of the application of the Regulation	Art 51.I
	List of competent authorities and certification bodies	Art 52.I
+ 🖺 👸	Provide technical dossier where a MS considers that a product or substance should be added to one of the technical annexes, or be withdrawn from it, or specifications for its use be amended	Art 24.7
	Documentation of the results of the investigations carried out in relation to the detection of non-authorised products/substances in organic products	Art 29.6
<u>L</u>	Measures taken on MS territory to avoid the unintended presence of products/substances not authorised for use in organic production	Art 29.7
×	Information on any decision to except operators that sell unpacked organic products from being in possession of a certificate (retailers only)	Art 35.8
	Any measures taken, including provision for the necessary sanctions to prevent fraudulent use of any reference to organic	Artl.3

Competent Authority responsibilities towards EU Commission and other EU countries (2)



	Activity & Information to be provided	Legal Ref
A	Notification of suspicion or established of non-compliance during verification of consignment via OFIS	2021/2307.Art.7
ψ	Information on any suspected or established non-compliance affecting the integrity of organic products	2018/848 Art 43.1 and 2021/279, Art 9
	By 31st of March, every year, transmission of relevant information involving contamination with non-authorised products/substances in the previous year	2018/848,Art 29.9
* <u>L</u>	Compulsory measures related to treatment with a product not authorised for use in organic production	2018/848, Annex II.I. 1.7.4. I
	Listing of any organic heterogeneous material	2018/848 Art 13.2
	Information provided in the database referred to in Art 26 (listing of the organic and in-conversion PRM,	2018/848,Art 53 + 2020/464.25.1+4-5
	link to the internet website where the updated lists referred to in 848.II.I.8.5.6 and 848.II.I.1.8.5.7 are made available	
	information on the derogations granted in accordance with 848.II.I.1.8.6	
₩ •••• ••••• •••••••••••••••••••••••••	Derogations granted under catastrophic circumstances	2020/2146.4

Competent Authority responsibilities towards other actors



Information exchange with Accreditation bodies and inter-governmental

Activity & Information to be provided	Legal Ref
Exchange information on the supervision of control bodies with the national accreditation bodies	2018/848.Art 43.5
Establish procedures in order to ensure that results of the controls are communicated to the agency paying organic farming subsidies.	2018/848.Art 43.6

Responsibilities towards control bodies

	Activity & Information to be provided	Legal Ref
×	System to except operators that sell unpacked organic products other than fee from being in possession of a certificate (retailers only)	848.35.8
Å	Detailed description of the delegated official control tasks and tasks related to other official activities	848.40.1a
	Carry out, at least once per year, an audit	848.40.1b
8 = = = = = = = = = = = = = = = = = = =	Provide the national catalogue of measures for cases of suspected and established non-compliance	848.41.4 and 2021/279.8
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	The recognition of catastrophic circumstances	2020/2146.1

Competent Authority responsibilities towards operators (I)



	Activity & Information to be provided	Legal Ref
&= &= &=	List of certification bodies	848.52.1
@	Provide contact point to send the notification of organic activity	848.34.4
@= @= @=	Updated lists of operators and groups of operators that have notified their organic activity	848.34.6
	Inform the operators of the validity of the certificates issued in the event of suspension or withdrawal of the delegation of a certification body	848.40.7 and 40.8
②	Confirmation of the conversion plan in case of parallel production	848.9.8c
>	Answer as regards retroactive recognition of conversion	2020/464.1
X	Granting derogation under catastrophic circumstances	848.22 + 2021/2146.1

Competent authority responsibilities towards operators (2)



	Activity & Information to be provided	Legal Ref
(<u>)</u>	New conversion period in the event of treatment of land with prohibited products/substances (including the use of non-organic treated seeds)	848.II.I.1.7.3 and 848.II.I.1.8.5.3 §2
	Database for organic and in-conversion PRM, organic animals or organic aquaculture juveniles	848.26.1
×	List of species, subspecies or varieties for which no derogation for use of non-organic PRM may be used shall be kept up to date and made publicly available	848.II.I.1.8.5.6 §2
la	List of species, subspecies or varieties for which an annual derogation has been granted as regards the use of non-organic PRM	848.II.I.1.8.5.7
~	List of species, subspecies or varieties for which a general derogation has been issued on annual basis	848.II.I.1.8.5.7 §3

Delegation of official control task to CBs



Competent Authorities may delegate official control tasks and other official activities to CBs

- Official controls of operators to verify compliance
 - Annual verification of compliance
 - Additional controls and sampling (may set higher% than the minimum required by Reg 2018/848)
- Other official activities
 - Official investigations
 - Publishing the list of certified operators and certified groups of operators
 - Issuance of official certificates
 - Actions to be taken and measures in case of non-compliance
 - Checks for the purpose of the retroactive recognition of the conversion period
 - Granting derogations for the use of non-organic plant reproductive material

There are some activities a CA may NOT delegate

- Supervision and audit of control bodies
- The power to grant derogations other than for the use of plant reproductive material not obtained from organic production
- The authority to receive notifications of activities
- The assessment of the likelihood of non-compliance at borders of the EU

2.4.3 Supervision of control bodies to ensure consistent application



Supervision by Competent Authorities



Competent Authorities are responsible for the approval and supervision of the activities of the CBs in their country

This includes:

- **Annual supervision audits**
 - On-site (office of the certification body)
 - Witness audit (accompanying the certification body's inspector during an official control)
 - Own inspection of the selected operators in absence of the certification body's representative
- Own procedure for follow-up of findings of shortcomings at CB level
- Clarification as regards the obligation of the CB to inform the operators involved in case of suspension/withdrawal of certification

Supervision by Accreditation Bodies



Organic Certification Bodies are closely supervised by National Accreditation Bodies according to International Norms for Inspection and Certification, e.g. ISO 17065

Annual surveillance audits

- On-site (office of the certification body), one auditor for ISO norm, plus additional technical expert in the Organic Regulation for which the CB shall be accredited.
- Multiannual organisation of
 - Witness audits (accompanying the certification body's inspector during an official control): usually a complete set of witness audits in accordance with EA 3/12 - 22 over a period of 4 years
- **Standarized procedure for follow-up** of findings of shortcomings at CB level



















The ITC Guide to the New EU Organic Regulation

Part 3: Preliminary Study of Expected Implications of the New EU Organic Regulation for Thailand

Author: FiBL Research Institute for Organic Agriculture

Final Technical Version for ITC 31.10.2022

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Content of this Chapter 3 Implications of the new EU Organic Regulation for Thailand

- 3.1 Overview Thai Organic Sector
- 3.2 Analysis of potential challenges of applying the new EU regulation in Thailand
- 3.3 Selected Findings from Case Studies
- 3.4 Summary and Recommendations

Introduction to this section

This part of the ITC Guide is a preliminary study of expected implications and challenges arising from the implementation of the new EU Organic regulation for operators in Thailand and the likely impact to the Thai Organic sector.

The study was compiled by regional experts in organic farming, based on document review, internet search, interviews and email surveys and sample case studies. FiBL reached out to known key private sector and government actors of the Thai organic sector and EU approved Certification Bodies operating in Thailand for input.

It should be noted that at the time of contacting operators, CBs and other organisations in Thailand for these study, most stakeholders were not yet fully briefed of the detail requirements of the new Regulation, nor the likely implications. The study should be seen as a preliminary analysis of likely or potential implications and challenges that are likely to arise with application of the new regulation in 2023/2024. The actual impact of the regulation will need to be analysed after full application in the coming years.

3.1 Overview Thai Organic Sector: Operators, CBs and other actors, Standards



Thai Organic Sector Statistics (2020): Operators



99,949

Organic Farmers



4,837 Organic Grower groups

Average size: ~20 farmers/group

92,406 organic farmers

certified in grower groups: 92.45% of all organic farmers



265 Organic processors/handlers

Source: World of Organic Agriculture contributor

Updated Data on National Organic Certification (09/22)

Rice Dept: 94,000 farmers

<u>in 4,600 groups</u>

DoA: 3,603 farmers

- 2,856 single

- 747 in 15 groups

Note: Figures do not include Participatory Guarantee Systems (PGS) production.

Thai Organic Sector Statistics (2020): Land & Crops



179'650 ha

organic land for crop production

Organic land: 277,107.20 ha

Crop production 179,648.68 ha

Wild collection 90,715.84 ha

Livestock 1,142.48 ha

Aquaculture 461.66 ha

Unknown 5,138.55 ha

Organic Crop acreage

-	rice	149,628 ha
-	fruit	7,001 ha
-	sugar cane	4,741 ha
-	mix cultivation	4,200 ha
-	vegetables	1,458 ha
-	coffee	1,279 ha
-	tea	927 ha
-	unknown	10,413 ha

Source: World of Organic Agriculture contributor

Key Actors in the Thai Organic Sector: Private

Some Key Private Sector Actors:

Association/Network: Thai Organic Trade Association (TOTA), founded 2005,

currently 63 members

Thai Organic PGS Federation, established 2017

Farmer organisation: Green Net Cooperative, registered 1993,

social enterprise with 14 grower groups

Lead exporters: Merit Food company (coconut based products & others)

Tops Organic & Supplies company (rice based products)

Local International CB: ACT Organic, established by Alternative Agriculture

Network (AAN) in 1995, registered as foundation in 2001,

set up as a company in 2017. IFOAM Accredited since

2001; Canada Organic Regime (COR) approved since 2009;

EU approved since 2011.

*Blue: Organisations who participated in the survey or interviews for this study









Key Actors in the Thai Organic Sector: Public

Public Sector:

Government agencies under the Ministry of Agriculture and Cooperatives (MoAC)

- National Bureau of Agricultural Commodity and Food Standards (ACFS)
- Department of Agriculture*
- Department of Rice*
- Department of Livestock
- Department of Fisheries
- Department of Land Development
- Agricultural Land Reform Office

^{*} Organisations who participated in the survey or interviews for this study

Organic Claim Management in Thailand

Use of term "organic" in Thai and English is regulated by the FDA in its "Criteria for Food Advertisement B.E. 2551" from 12 Sep 2008. Applicable to both imports and domestic production. Unofficial translation as follows:

Use of terms, "Organic agricultural product", "Organic product" or "Organic" for agricultural products by producer, distributers or importers of such products shall be certified by IFOAM (International Federation of Organic Agriculture Movements) or recommendation of Codex or foreign standards of organic agriculture (in case regulation for organic agricultural products have been issued in those countries) by certification bodies accredited by IFOAM or to ISO/IEC Guide 65 or have been registered by agencies in countries having organic agriculture regulations."

Importers need to submit valid organic certificate for imported product to FDA to make organic claim for Thai market, similarly for domestic producer, manufacturer and distributors.

Note: Enforcement is not rigorous, especially for domestic production. In 2014, a proposal to introduce compulsory accreditation and certification for labelling of organic products was strongly opposed by Thai private sector and the initiative was dropped.

Certification by Governmental Agencies

5 government agencies under the Ministry of Agriculture & Cooperatives (MoAC) provide organic certification within their respective scopes.

- **Department of Agriculture** (from 2002) for multi crop production including rice
- **Department of Rice** (from 2007) for only rice production
- **Department of Livestock**
- **Department of Fisheries**
- The Queen Sirikit Department of Sericulture



Certification is provided FOC. All dropped their respective department's organic seals and use one common "Organic Thailand" seal since 2012.

These "control authorities" do not provide certification to the EU organic scheme.

Note: within the EU, some member states also have governmental "control authorities" in addition to private "control bodies"

Thai Organic Standard

The Thai Organic Standard (TAS) is published by ACFS (National Bureau of Agricultural Commodity and Food Standards)

TAS 9000 : The Production, Processing, Labelling and Marketing of Produce and Products from Organic Agriculture	first issue: July 2003 current version: Feb 2022 transition 2 yrs
TAS 9000 Part 2: Organic Livestock	first issue: May 2005, current version: Nov 2011
TAS 9000 Part 3: Organic Aquatic Animal Feed	first issue: Dec 2009
TAS 9000 Part 4: Organic Rice	first issue: Dec 2010
TAS 9000 Part 5: Organic Snakeskin Gourami	first issue: Dec 2010
TAS 9000 Part 6: Organic Honey Bee	first issue: Nov 2013
TAS 7413: Organic Marine Shrimp Farming	first issue: Jun 2007
TAS 8203 Part I: Organic Silk Cocoon, Silk Filament Sheet and Silk Yarn	first issue: Nov 2017

Organic Certification Criteria (published by ACFS)

CSSA-R-SD-24: Criteria/Condition for Accreditation of	latest version: Dec 2017
Agricultural Commodity and Food CB with Organic Scope	

National Certification & Accreditation

National Accreditation (based on ISO170965) is available through ACFS. ACFS is signatory Accreditation Body to Pacific Accreditation Cooperation (PAC) Multilateral Recognition Arrangement (PAC/MLA) – for Product Certification since 2010.

To-date, 8 local Certification Bodies are accredited by ACFS to offer organic certification.

- Institute of Certified Agricultural Production System, Maejo University (crops)
- Thai GAP 09 Co. Ltd. (crops)
- Central Laboratory (Thailand) Co. Ltd. (crops)
- Thailand Institute of Scientific & Technological Research Office of Certification Body (crops)
- Asia Medical and Agricultural Laboratory and Research Center Co. Ltd (crops)
- A I Future Co. Ltd. (crops)
- Bureau Veritas Certification (Thailand) Ltd (crops)
- Cotecna Inspection (Thailand) Co. Ltd. (crops)

Organic Thailand is regulated and managed by ACFS since 2020. Government is opening option to private CBs to provide service for fee. Two of above CBs are already registered. One is still in registration process to provide the service.

Note: None of the above provide certification to the EU organic scheme. Majority CBs offering organic certification in Thailand are not accredited by ACFS (other slide).

Organic Control Bodies for Export to EU



18 CBs approved by the EU for certification of products in Thailand.

7 appear to be actually active in Thailand.

3 CBs have an office in Thailand.

Only I CB is Thai

3 CBs participated in the survey done for the development of this guide

ACT, Thailand: 155 (136 incl. 55 groups)

Ceres, Germany (Thai office): 90 (incl 16 groups)

Ecocert, France: 14 (incl 5 groups) **Number of operators**

black: from website

blue: from survey

Other EU approved CBs (Operator numbers from Website only):

Control Union, Holland (Thai office): 49

One Cert International, India: 25

Bioagricert, Italy: 10

ACO, Australia: 4

Organic Control Bodies for Export to EU – not active

Other CBs are authorized by the EU with Thailand listed as their geography scope of operation, but do not appear to be active in Thailand.

Not Active: 6

(no Thai operators listed)

- A-Cert. Greece
- Biocert International, India
- CCPB, Italy
- NASAA, Australia
- IMO Control private, India
- Tse Xin, Taiwan

No Info Available: 5

(No accessible info on website)

- Agreco, Germany
- BioInspecta, Switzerland
- Kiwa BCS, Germany
- Soil Association, England
- SRS, Germany

Estimated scale of EU certification in Thailand

- No official statistics or data base by the EU listing all certified operations
- CBs publish their own list of certified operations, with varying degree of details.

Note: Survey done showed operator data indicated on website and collected in direct communication with CBs may differ.

Survey (3 CBs):

- 240 **Total EU certified Operations:**
- Number of Grower Groups: 76 (31.6%)

Based on information from online data and survey interviews, total number of EU certified operations in Thailand is estimated as follows:

Projected total Number of EU certified operators: 328 (>50% processors) **Projected total Number of grower groups in EU scheme: 98** (30% of total)

CB's EU numbers in proportion to national numbers: <5% of organic producers > 55% of processing operations

Organic Exports & Agri-Food Trade Thailand - EU

Major organic export items to the EU (as per survey respond)

- Rice & Rice processed products (e.g. noodles, crackers)
- Coconut milk
- Fresh produce (vegetables, bamboo shoot)
- Condiments (chilly sauce, curries, soy sauce)

Rough estimate of export value of organic products to EU: **EURIOO Millions** (*TOTA guesstimate*)

Import value of agri-food from Thailand to the EU (2021):

Export value of agri-food from EU to Thailand (2021): **EUR 1,222 Mil**

Source: EU commission

From EU side, Thailand is not a top organic supplier country in any product category but very important in rice*

Thailand ranks 30th most important origin country for organic agri-food imports (per volume)*: Total agro-food products 20'077 tons (2021)*

EUR 1,670 Mil

EU Organic Imports RICE	2020 Imports (thousand tons)	2021 Imports (thousand tons)	Change (%)	Share (%, 2021)
Pakistan	38.0	37.0	-5.1	42.8
India	23.2	26.4	13.8	30.5
Thailand	12.2	8.3	-31.9	9.6
Argentina	7.5	7.5	0	8.7
Cambodgia	9.5	6.7	-28.8	7.8
TOTAL	92.9	86.6	-6.8	100
Share of selected countries in total %	98	99		

* EU Agricultural Market briefs: EU Imports of organic agri-food products. Sep 2022

Source: Table 17 in European Commission: EU imports of organic agri-food products Sep 2022

3.3 Analysis of potential challenges of applying the new EU Organic Regulation in Thailand



The New EU Regulation

The new EU regulation and overall implications for Third Countries like Thailand were presented in Detail in Part 1 of this Guide. It is expected that the following fundamental changes are particularly relevant for Thailand:

√ Compliance instead of Equivalence

Previously, organic operators and Groups in Third (non-EU) countries are certified according to their approved CBs' EU equivalent organic standards.

Now operators in Third Countries need to comply to the same very detailed rules as EU operators





✓ Groups of Operators requirements

Previously the EU issued only import guidelines for certification of grower groups, applicable only for Third Countries.

Detailed new requirements for 'Groups of Operators' are included in the regulation and are applicable worldwide

Current Status of Implementation

The new regulation applies since from 1st Jan 2022 for operations in the EU. However, there is a transition period until 31 Dec 2024 for operators in Third Countries (see Guide sections 2.1 and 2.2)

- CBs need to apply to the EU for recognition (see Guide chapter 2.2)
- Expect start of inspections according to new Regulation from 2023
- Only compliant certificates are accepted for import of organic products into the EU from 1st Jan 2025

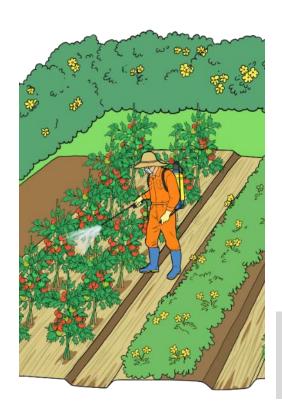
Expected Key Challenges from New EU rules

- Changes for Group of Operators projected to be most significant.
- Some challenges in Crop Production and Processing

Note: A survey with interview was conducted to analyse expected implementation challenges. At the time of interviews ,operators have not yet received notification from their CBs about change of compliance requirements arising from new regulation. Respondents were informed of implications based on information available from IFOAM's guidance for product groups and feedback noted accordingly.

Expected Challenges with regard to Crop Production

General farm management rules are tightened but no substantial changes compared to Reg. (EU) 834/2007.



Narrower allowance for use of agricultural inputs

Previously CBs are permitted to establish their respective approved equivalent input lists that include natural material and formulations of common use in regions. Substances were approved based on a screening criteria and non-inclusion of prohibited materials.

Now only substances listed in Reg 2021/1165 may be used, with various restriction and this will restrict which inputs can be used, especially for plant protection.

Stricter procedures for authorising exceptions e.g.

- non-organic seeds & planting materials
- retroactive recognition of conversion.

Crop Rotation & Diversity with legumes

- **Annual crops:** Multi-annual crop rotation including leguminous crops
- **Perennial crops:** Plant diversity & short-term legumes/green manure

Analysis Expected Challenge: Farm Inputs

Key Challenge: Only substances listed in Reg 2021/1165 may be used, especially challenging: Annex 1: Substances for Plant Protection

- Many substances have very specific use conditions or restrictions.
- All plant protection substances (plant extracts, bacteria, etc.) must also be authorized for general use in agriculture in the EU (in EU pesticide data base).
 Note: for fertilisation or plant strengthening purposes, there is no restriction for plants and micro-organisms (no need for registration)
- New list for substances permitted for cleaning & disinfection (from 2024)

→ Considerably less flexibility than present "equivalency approach"

Respondent CBs noted operators using plant protection inputs that are not approved for use in the EU will face challenge to adjust to only EU listed substances. Other issues (planting material and crop rotation) were not raised.

TOTA members (producers) are awaiting more detail information from their CB to know whether they need to switch substances used. This situation may remain unclear for a while.

- CBs will need to review their present allowed inputs and inform operators accordingly
- Operators will need to adjust to only revised approved substances accordingly.
- Availability and replacement cost may impact productivity and profitability.

Expected Challenge: Processing



General processing & handling rules are tightened but no substantial changes compared to Reg. (EU) 834/2007.

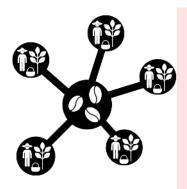
Potential Challenge: Narrower allowance for use of non-organic ingredients, also additives & processing aids

Multi ingredient products must meet a 95% organic ingredient requirement to label product as certified Organic. Previously CBs are permitted to allow use of non-organic ingredients, also additives & processing aids within the 5% non-organic ingredient allowance based on need and availability in the regions where they operate. Approval is based on a screening criteria and exclusion of prohibited materials.



In the future only substances listed in Reg 2021/1165 may be used. However, Art 25 or Reg. 2018/848 permits recognized Third Country CBs to grant a temporary exception for non-organic ingredients in case the organic ingredient is unavailable in sufficient quantity \rightarrow thus, this aspect may not be a major problem; and it only affects few multi-ingredient manufacturers in Thailand

MAJOR Expected Challenge: Groups of Operators



Potential issues identified for groups of operators (GoO) include GoO Composition & Size

- No allowance for Company organised GoO
- Legal Personality; potentially only organic or in-conversion members
- Producer limited to only one GoO membership per product type
- Maximum number of members of 2,000 for a GoO
- Membership criteria (<5 ha land or <Eur25,000 organic turnover)
- Separate certification of processing operation from GoO
- Only one GoO per legal personality

Detailed Rules for the Internal Control System (ICS)

GoO Control Measures

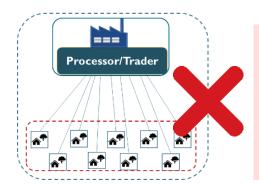
- Re-inspection rate: 5% of total number of members
- Residue sampling rate: 2% of total number of members

Difference between new EU requirements and other organic certification schemes for operations with multiple certifications.



For details on the new requirements for groups of operators,, see Guide Section 1.2

Challenge: No Company Organized GoO



GoO is composed of members who farmers and with legal personality,

i.e. certificate can not be held not held any more by a processing company. Only a separate group composed of organic and inconversion farmers and with legal personality can be certified as GoO.

TOTA estimates that 1/4 to 1/3 of grower groups are organised by processing or trading companies with contract farming arrangement with producers.

- These types of supply chains will need to be re-organised, whereby the organic or inconversion producers organise themselves as a producer based legal personality to apply for a GoO certification.
- The company to apply separately for processing/handling certification as applicable.
- It will affect structural relationship, cost sharing and pricing arrangements.



Based on the estimated number of EU certified grower groups in Thailand \rightarrow this could could mean that there are roughly 20-30 organic supply chains organized by processors/traders that need restructuring.

Challenge No Company Organized GoO -2

TOTA leadership interviewed cite this to be a major **challenge** for producer groups who are not self-organised as an organic business unit, as they have no experience to run an Internal Control System (ICS).

The new rules can be particularly challenging for existing set ups where number of contracted producers is small (10 to 20) or farmers are not familiar with each other.







TOTA expects companies will assist their respective producer suppliers to set themselves up accordingly. New producer groups will face challenge to manage self manage an ICS and manage business operations.

Note: the company can operate the ICS if the ICS manager and the ICS inspectors are "assigned" by the group



Registering a producer based legal personality seems not difficult in Thailand.

Restructuring costs with higher operation and certification costs are anticipated. Cost for certification will escalate for groups holding multiple organic certification schemes, e.g. Canadian Organic or US NOP certification.

Challenge: Member only in I GoO for the same product



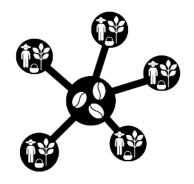
Challenge: Farmer may register with only one GoO for a the same product

- Presently producers may register with different groups supplying to different buyers. In scenarios where crop specific grower groups are organised by companies (buyer) on contract farming basis, A producer (rice) may join more than one rice grower group in the area to ensure market access for all his/her rice harvest.
- This scenario is reportedly open to abuse, whereby producer sells similar projected harvest in separate groups, certified by different CBs without knowledge of double or triple membership. Practice is not encouraged but not prohibited.
- Under new EU rules, producers can only to be a member of one GoO per product. Producers of two commodity crops could still join two separate product specific GoOs.



- According to respondents, multiple group registration is not encouraged and not wide spread in Thailand.
- **No problem** for producers and groups to re-constitute themselves accordingly. Groups/Producers with double membership have time to settle membership accordingly during transition time.

Potential GoO Challenge: max 2000 members



Max. 2000 members per GoO

According to TOTA and 3 CB respondents, there are no grower groups with more than 2,000 members in Thailand.



No impact expected for certified groups in Thailand.

Challenges: only "small farmers" in GoO



Only "small" organic or in-conversion producers can be included as member of a GoO: total land < 5ha OR Organic turnover < 25'000€/year. (see details in guide section 1.2)

- Presently organic grower groups can include small as well as some bigger producers. Bigger producers are always included for external re-inspection in addition to risk based square root re-inspection rate for the rest of the group.
- New rules require big producers to be certified separately as single farm operator units.



TOTA & CB respondents think this is not a major challenge, but can increase costs for some groups (see next slide). They do not expect many cases where members of existing groups no longer qualify for the new GoO certification.

An issue awaiting clarification is, 'How will annual turnover be calculated given variation with yields, foreign exchange rates and market pricing?" . So far operators are awaiting CB's notification. At the time of interview, CB respondents have not concluded development of more detailed guidelines to use.

GoO Challenges: only "small farmers": Effects





Where group member farm size/turnover disqualification applies, the likely implications are

- **Higher certification cost** for individual big producers and hence the group as a whole.
- Whether additional certification cost will be covered as a group (as previously) or by the big producers remains to be settled by the affected groups.
- Higher cost of certification may affect decision of low profit margin big producers and/or group to switch certification scheme if not exporting to EU.
- ❖ If the group is very small (<30-50 members), individual certification of farmers may be better option than GoO with costs for operating various GoO all restrictions plus 10 members external inspection each year.

Note: Not all operators certified to the EU Organic scheme export to the EU. Some use the EU certification to export to non-EU markets or just market domestically. Certification to IFOAM Accredited and external organic schemes were in place earlier than the Thai government scheme and seen as having better market 'brand' recognition.

Potential Challenge: Central Processing by the GoO



Central processing (but not necessarily simple low risk "preparation" like sorting, grading, packaging of organic or inconversion GoO members' products only) even by a cooperative might need to be certified separately as only processing by the group members is described in Art 36.1.

Note: The certification body needs to decide how the new rules apply to the respective business set-up and activities to be certified

Presently group certification can include all activities performed as part of the group. A Cooperative with big and small producers, processing capacity and exporting can include processing and handling units as part of its certification. Processing units are inspected separately.



New rules may require separate "operator" certification for processing units.

If a cooperative also handles products from farms who are non- GoO members, e.g. non-organic farmers in its collective marketing system, It may even be require to separate the groups central preparation unit legally from a future "GoO unit" with only "small" organic of in-conversion members who met all new GoO member criteria which can qualify for GoO certification.

Potential Challenge: Central Processing by the GoO - 2



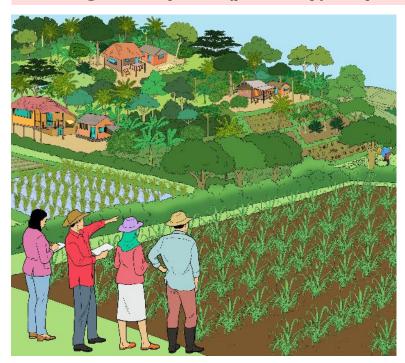
This may affect many group certified to the EU scheme, as many Thai products are categorized as "processed products" (e.g. coconut products). But due to the new GoO rules, new separate GoO units for just the organic/conversion farmers may be needed anyway and the central unit (processor, larger coop) would be certified as preparation and/or processing operator. This has most implication for business set-up and costs.



This restriction combined with the other GoO rules has implication for business setup and costs Higher cost of certification may affect decision of groups to switch certification scheme if not exporting to EU.

Potential Challenge: one GoO per legal entity

One legal entity can (probably) only be certified as one GoO



Presently grower group norms in Thailand require coops with several different crop production sub-groups in different regions of the country to apply for separate grower group certification for each of their sub-groups.

New rules imply such operators could congregate organic groups into one GoO, if total number of members is < 2,000 and if one ICS is able to manage this.

On the other hand, if subgroups have some form of legal personality (e.g. community enterprise), it could be a better solution to continue with current set-up based on risk considerations and as a crop & local situation adapted ICS tends to be more efficient and functional



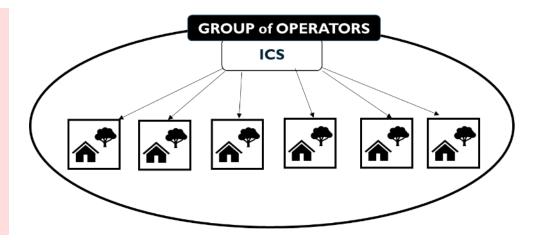


Respondents note there are probably only a few such operators. There could be cost savings in congregating subgroups. However, the local set-up is well established and weakness in any one subgroup can compromise certification of other sub-groups.

A Coop respondent prefers and believes present arrangement can continue and is better solution. Respondent is awaiting further clarification from CB before restructuring.

Potential Challenge: more detailed ICS Rules

- **Documented Procedures**
- **ICS Documents & Records**
- **ICS Manager & Inspectors**
- **Internal Inspections**
- **Managing Non-Compliances**
- **Managing Traceability**
- **Providing Training**



New rules are in line with well established ICS norms, e.g. by IFOAM Norms, in practice.

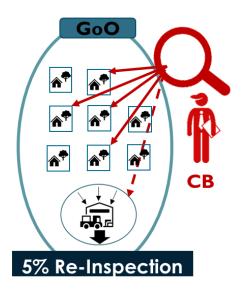


No additional challenge for existing groups which will be eligible also for future GoO certification. Major challenge for company organised groups required to organise themselves.



There is scope for emergence of 3rd party ICS service providers to assist producer groups in implementing an ICS.

Potential Challenge: GoO – New Re-inspection rates



New Rule for Control of GoOs at least 5% of group members must be re-inspected by the CB each year (minimum 10 members)

- Presently group re-inspection rate is Sq Root of total group members (excluding big producers, handling & processing units) plus a Risk factor of 1.2 to 1.4 for medium and high risk assessment.
- New 5% fixed rate means lower re-inspection numbers for groups with less than 400 members and higher rates for groups with > 400 members



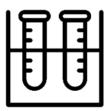
Respondents feedback is that few, if any, groups in Thailand have more than 400 members. All 3 CB respondents do not have groups with more than 400 members.



As many groups in Thailand are rather small, there is scope for some reinspection cost savings due to lower re-inspection numbers, but only in case the group does not also have NOP certification (square root rules applies, may even be increased to 1.4 x square root). However, any cost savings due to fewer re-inspections are likely off set by more sampling testing.

Challenge: New GoO Control Rules on Sampling

New GoO control requirements: at least 2% of members shall be subject to sampling each year.



- Presently residue sampling is risk based from field observation. Cost per sample is relatively expensive. It is not usually imposed unless there are suspected use of prohibited substances.
- New 2% residue sampling requirement will very likely represent a significant additional cost. Thai operators face cost of up to 8 samples annually (2% of 400) to be analysed in accredited laboratories at considerable cost per sample.
- Even if some of sample could possibly be composite samples (as per EU approved sampling policy of the CB), the collection, handling of samples will need significant additional time on top of analysis costs by the laboratory. Also, if a composite sample is positive, more analysis would be needed.



The new GoO sampling rules are likely to increase certification costs, although due to the small size of groups in Thailand and lower re-inspection rates, the cost increase may be less severe than in other countries.

Challenge: Higher Control requirements in general



- ✓ additional unannounced control: 10% of the CB's operators & GoOs
- If any Thai products would be **classified as "high risk":** Physical Inspection twice a year.
- ✓ Residue Sampling for analysis: all "high risk products" annually.
- ✓ **Sampling at least 5%** of single operators, , 2% of members in a GoO



Thai organic products are rather unlikely to be categorized as "high risk", apart from the already mentioned higher sampling requirements, the new rules seem to have no major implications.

Challenge: New GoO rules are different from all other standard systems

> EU Rules for Group Certification is now different to other Organic and Sustainability certification schemes. This has implications for joint certification of groups according to different schemes

Since a wide harmonisation process in the early 2000s, all organic certification bodies and various voluntary sustainability standards (e.g Rainforest Alliance, Utz, Global GAP, FSC) apply the same basis for group certification, with respect to composition, size and control measures.

Previously in line, the new EU regulation is now different. Operators certified to multiple schemes, e.g. USDA NOP and EU now face the scenario of being subject to the 'higher' requirement of each scheme, e.g.

- re-organising / new legal group entities (EU)
- separate certification for processing and big crop production units (EU)
- separate groups if more than 2,000 members (EU) Not applicable in Thailand
- maintain risk based sq root re-inspection (below 400 members) (NOP); revert to 5% re-inspection rate (above 400 members) (EU) Not applicable in Thailand
- plus 2% residue testing (EU)







Challenge: New GoO rules are different from all other standard systems

EU Rules for Group Certification is now different to other Organic and Sustainability certification schemes.





- External Control rate proposed: Square root (members) 1.4x
- USDA is considering maximum number of members/ group; but not proposed yet.





Higher cost & complexity challenge for operators to maintain multiple certifications required for market access, esp if the certifiable legal units are different due to new EU rules

In combination, the stricter rules on each topic will need to be applied, e.g. group with 200 farmers.

- EU requires only 5% = 10 re-inspections
- NOP would require in the future e.g. $1.4 \times \text{square root} = 19 \text{ re-}$ inspection
- → CB would need to do 19 re-inspection in a combined inspection

3.3 Case Study findings



Overview Case Studies analysed for this guide

Case study examples were targeted to represent the cross section of GoO operations in Thailand affected by new EU rules, i.e.

- company organised and self organised groups of small and large numbers
- group with big producers
- group with sub groups

A call for case study respondents was issued with TOTA's assistance to its mailing list. TOTA leadership stepped up and approached operators to augment poor respond to open call. The three case studies conducted include the following:

- **Exporter (processed products) with 4 contract producers**
- Cooperative sub-group of 91 coconut producers
- Coffee processor with 359 producers

Operators were requested to share their last inspection report (2021) as well as invoice to verify certification cost calculations.

Case study was conducted on condition that information presented will focus on impact of new rules to operation without disclosing operator identity and unrelated operational details.

Case A. Exporter (processed products) with 4 contract producers - Overview



Operator is a company exporting organic processed products (e.g. rice wrapping, spices, herbs).

- Has marketing intentions for the EU but presently only exporting to Australia and Middle East.
- Contracts producers for raw material and OEM processors for products.

Company presently holds certificate for export handling and a Group of 4 producers (earlier 10 producers). Total acreage: 117 rai (18.72 ha) Producers use bought-in seeds for some crops.

CB conducts inspection of all group members. Common practice in cases where group numbers are around 10 and/or operator choose 100% inspection option instead of operating an ICS.

Initial certification: 2012

EU & COR (2021) Certification(s) held:

Handling facility and 4 contract farms (without ICS) Certified operation:

Certified products: farm produce: Rice, Rosella, Turmeric, Shallot, Garlic, Sesame,

Chili, Chrysanthemum

Total Farmgate sales: THB 215,523 / THB 55,000 (certification cost) 2021

Market(s): Company exports finished products to Australia and Middle East.

Case A. Exporter (processed products) with 4 contract producers - Implication & Analysis



Projected potential implications of new EU regulation

- Disqualification of company organised group / Validity of small group without ICS status
- Possibly change in permitted input use.

Preliminary Analysis of options to maintain future certification to EU scheme

- ✓ Separate certification for company handling operation. (No Change)
- ✓ Apply for single farm certification for each producer. CB may possibly consider a group discount rate?) Possibly check option with CB whether a legal personality (community enterprise) for group of 4 producers, with 100% inspection would be an option, but this is probably not possible according to the new EU rules
- ✓ Producers may need to adjustment practices with regard to use of seeds (

Case A. Exporter (processed products) with 4 contract producers - COSTS



Re-organisation and cost impact projection

Certification cost (2021)

External inspection Group of 4 farms

Num of inspectors:

Num of onsite inspection days:

Num of residue testing: none

Certification cost: **THB 55,000** for EU & COR

Cost under new EU rules (projection)

4 single farms

2

On average 1 every 5 years*

est. THB 94,800 (THB 23,700 each



Certification of Export handling unit invoiced separately

Export Handling unit: THB (no change)

Cost will nearly double for separate individual farm certificates unless CB offer a group discount

Operator will consider dropping EU certification and continue with present arrangement under COR, if buyers (Australia & Middle East) are agreeable to COR certification.

^{* 5%} of all operators to be sampled by CB \rightarrow each operator once / 20 years. For 4 operators on average every 5 years ITC Guide to the New EU Organic Regulation | Part 3: Preliminary Analysis of Implications for Thailand slide 43

Case B. Coop sub-group with 91 coconut producers - Overview

Group (91 members) is a sub-group of a nationwide Coop. It is presently certified separately as a sub-group of the Coop. The ICS is conducted by the Coop. Group raise own coconut seedlings and use few commercial input. Group supplies coconut fruit to Coop contract processor. Coop exports coconut milk and desiccated coconut to the EU and other markets.

Group comprise of 8 zone sub-groups spread over 3 neighbouring districts. No member was identified as a big producer in 2021 audit. Group raise own coconut seedlings and use few commercial input. Parasitic wasps are cultured for pest control. No serious pest problems identified during 2021 audit.

Initial certification: 2004

Certification(s) held: EU & IFOAM Accredited (2021)

Certified operation: 91 farms (with ICS). Sub-group of a nation wide Coop

Certified products: Coconut fruit.

Sold to Coop for export as coconut milk and desiccated coconut.

THB 2.9 mil / THB 101,500 (certification cost) 2021 Group sales to Coop:

EU: Amt: 116,400 lit. (coconut milk), Value: THB 6.84 Mil (2021) Market(s):

B. Coop sub-group with 91 coconut producers - Implications

Projected potential implications

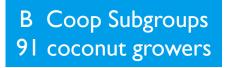
- **Disqualification of big producers from group:** Group will need to exclude 5-7 producers, whose turnover value (2021) is near or over EUR25k (about THB 908,642 at 7th Sep 2022 exchange rate) pending confirmation of CB's turnover formulation calculation.
- Legal Personality of each GoO / One GoO per legal entity In current legal set-up the coop cannot and does not need to aim for separate GoO certifications for different subgroups. (which don't have own legal personality)

Preliminary analysis of options to maintain certification to EU scheme

- ✓ Exclude producers whose annual turnover value exceed EUR25k based on CB's formulation.
- ✓ Excluded big producers to apply for single farm certification., can still sell to coop
- ✓ Register separate legal personality for group to maintain separate GoO certification
- ✓ OR: merge with other subgroups as one nationwide Coop GoO,, however this could be difficult as the central coop is likely to also buy products from Non-GoO members (larger organic farms) and then may need to be legal operator separate unit from the GoO units

Operator is awaiting notification and clarification of new EU GoO composition rules from CB before making decision. Production rules. Changes not expected to create problems

B. Coop sub-group with 91 coconut producers - Costs



Re-organisation and cost impact projection

Certification cost (2021)

(1.2x Sq Root+3) I 5 farmsExternal inspection:

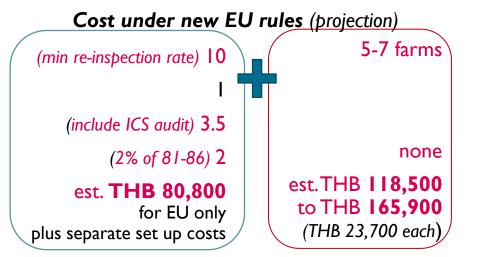
Num of inspectors:

Num of onsite days:

Num of residue testing: none

Certification cost: THB 101,500

for EU & IFOAM Accredited



Total certification cost under new rules may increase more than 2 fold, because of single certification of bigger farms

Present structure is working well. Operator may register separate legal personality of sub-groups to maintain arrangement. Additional 5-7 single farm certifications can more than double total certification costs. Single farm certifications will be partially, if not fully compensated by Coop. Operator will consider dropping IFOAM Accredited certification to save cost.

Case C. Coffee processor with group of 359 producers – Overview

C: Coffee processors + 359 growers

Company started with objective to organise producer groups to export coffee beans to the EU. As prices did not meet expectation, company took on processing coffee for domestic sales. Scenario continued to-date. Presently company sells coffee as well as beans in domestic market only..

Producers are located in 7 separate communities in same province and organised as 7 sub-groups by company. Some sub-groups have registered themselves as community enterprises. Presently each producer signs an agreement with company to form a Group and company implements an ICS.

Sub-groups raise their own coffee seedlings and use few commercial input.

Initial certification: 2011

Certification(s) held: EU, COR & IFOAM Accredited (2021)

Certified operation: Processing unit and 359 producers (7 sub-groups with ICS).

Certified Products: Coffee and coffee beans.

Market(s): Domestic sales only (coffee and coffee beans)

Case C. Coffee processor with group of 359 producers - Implications

C: Coffee processors + 359 growers

Preliminary Projected implications:

- Disqualification of company organised group
- Need to re-structure farmers as GoO composed of organic farmers

Preliminary Analysis of options to maintain certification to EU scheme

- ✓ Apply separate certification for processing operation.
- ✓ Register legal personality (community enterprise) for each community subgroup. (Some have already registered themselves.), or Register a 'federation of community enterprises' to host all 7 sub-groups as one legal GoO entity. Note: if the federation is to be certified as GoO, each farmer would need to sign GoO member agreement directly with the federation and be under the organic federation's ICS & collective system.

A simple single legal personality option for all producers is considered not suitable. Operator is deliberating establishing a federation of community enterprise structure. It will be a novel set up for the country. Will await notification and clarification of new EU GoO composition rules from CB before making decision.

Operator does not expect any impact from production rules. Sub-groups raise their own coffee seedlings and use few commercial input.

Case C. Coffee processor with group of 359 producers – Costs

C: Coffee processors + 359 growers

Re-organisation and cost impact projection

Certification cost (2021)

Processing unit & 26 farms External inspection:

Num of inspectors:

Num of onsite inspection days:

None Num of residue testing:

THB 237,600 Certification cost:

for EU: IFOAM Accredited & COR

Cost under new EU rules (projection)

Processing unit none est. THB 61,000

EU; IFOAM & COR,

19 / 26 farms Federation of 359 members 7 / 5 7/7 THB 167,300 / 228,900 **EU + IFOAM & COR** plus set up costs

Savings from reduced re-inspection if organised as one GoO for just EU. No reduction if maintaining EU +IFOAM & COR.

Will incur residue testing cost (up to THB45,000 for 7 samples. Reduced if some samples are combined for testing

Registering separate groups will increase re-inspection (min. 10 each). Can more than double total certification costs.

Operator may consider just EU certification or drop EU certification as not exporting to the EU.

OR 7 Groups with 50-51 members

(min re-inspection) 10

residue testing (2% of 51)

est.THB 597.100 (THB 85,300 each) **EU + IFOAM & COR**

I.4. Summary of Findings and Analysis

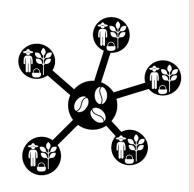


Summary of Key Challenges for Thai Organic **Operators based on Expert Analysis**



Crop Production: Restrictions for inputs, especially for plant protection products due to the new rules

Operators will face challenge to adjust use to only listed substances and substances formally registered in the EU.



Grower group projects face multiple challenges and increased cost arising from

- re-organising group structure (contract farming arrangement merging separate sub-groups into one group, legal entity for just the farmers under organic certification) and ICS management
- separate certification for processing and big production units
- subject to 5% re-inspection or maintain risk based sq root reinspection if also certified to USDA NOP or other schemes
- Costs due to to 2% of member sampling for residue testing

Summary Private Sector Feedback: Opportunities

At the time of survey and interviews, CBs have not completed their review of final implications. Operators were not fully informed of details. TOTA leadership is aware of coming change and briefed through IFOAM's seminar on the matter, but understanding or complex new rules rules keeps evolving. DoA and Rice Dept are aware that EU has changed its organic regulation but not informed of details.

Private sector's feedback from survey, interviews & case studies may be summarised as follows:



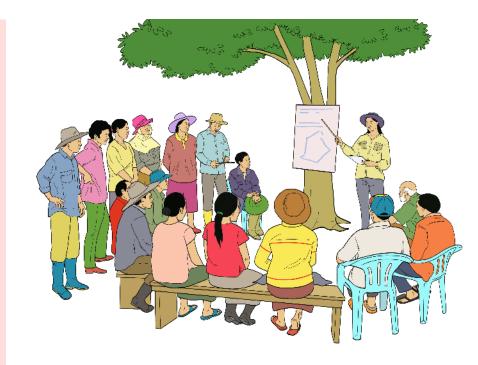
Opportunities

- New requirements do not pose insurmountable problems in the Thai scenario.
- Ease of registering a Community Enterprise as legal unit for producer groups in Thailand is noted. Legal personality registration is noted to be not as easy in neighbouring countries.
- Re-organised producer groups will face challenge to manage an ICS. There is scope for emergence of 3rd party ICS service providers.

Summary Private Sector Feedback: Challenges

Challenges identified in Interviews

- New GoO rules will be disruptive. At one quarter of groups face re-organising from contract farming arrangement with a processor/exporting company to form a new legal unit such as as an association, coop or community enterprise and manage an ICS
- Reduced flexibility in use of input substances for crop protection may impact productivity and profitability. Same for reduced access to non-organic ingredients for processing.



Summary Private Sector Feedback: Costs



Expected Cost implications

- Restructuring costs with higher operation and certification costs seems certain in most scenarios. However, operators with multiple subgroup certifications, totalling up to around 400 members can have savings if merging sub-groups is suitable.
- Based on sample case studies, certification costs can double or more for operations that need to exclude and apply for separate certification for processing units and big producers from group. CBs can mitigate with group discount offer.
- Certification cost will escalate for groups holding other organic certification schemes, e.g. COR, NOP or IFOAM Accredited certification.
- Higher costs could affect viability of EU certification for small group operations. SME operators will need to re-evaluate their Cost and Benefit (profit margin) calculations compared to benefits of EU Certifiction
- Operators, certified to the EU scheme, who are not exporting to the EU are likely to consult buyers, review their marketing objectives and certification option. They can switch to a other credible certification scheme to continue their present set up.

Summary from Public Sector Survey & Interviews

Interface between government Organic Thailand and EU certification

- Some Organic Thailand operators have additional export certifications, e.g. NOP or EU, mainly for organic rice, which is the main export crop.
- Govt supports development of more local private CBs. Not priority for government agency to prepare for external recognition (e.g. EU) to offer export certification. Govt agencies will continue to provide development support to producer groups, for private CBs to follow up with certification.
- Organic Thailand can be stepping stone to export certification. Rice Dept supports large groups, with acreage of 1,600 ha (10,000 rai) or more, that can qualify to apply for export certification.
- Rice Dept provides support and knowledge to set up ICS, also contracts CB (through E-Bidding) and pay for initial certification for EU organic and USDA NOP schemes.
- Group is expected to self manage with support from Company (buyer) or provincial authorities. Rice Dept may continue with annual assessment.

Rice Dept noted there will be challenges for producer groups to organise themselves and implement an ICS. Majority of rice groups are not registered 'legal personalities'. No government plan yet to respond to new EU rules. Too early.

Rice Dept indicate it would be interesting to explore scenario where Organic Thailand is deployed as a group's ICS for export certification.