Control of organic plant products exported to the European Union

Guidance for control bodies and authorities in non-EU countries

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ABBREVIATIONS

APEDA	Agricultural and Processed Food Products Export Development Authority (India)
CB	control body
COI	certificate of inspection
COLEAD	Committee Linking Entrepreneurship-Agriculture-Development
DEFRA	Department for Environment Food and Rural Affairs (UK)
DG AGRI	Directorate-General for Agriculture and Rural Development (European Commission)
EGTOP	Expert Group for Technical Advice on Organic Production (European Commission)
EU	European Union
FOAG	Federal Office for Agriculture (Switzerland)
ICS	internal control system
ILAC	International Laboratory Accreditation Cooperation
NCA	national competent authority
NPOP	National Programme for Organic Production (India)
OFIS	Organic Farming Information System (of the European Commission)
TRACES	Trade Control and Expert System

ABOUT THIS GUIDE

This guide is for authorities and control bodies in countries outside the European Union (EU). It explains the new EU control system for the import of organic products into the EU, as introduced by the Organic Regulation (EU) 2018/848, which sets new requirements for the inspection and certification of organic products exported to the European market.

The EU Organic Regulation 2018/848 is a legal act of the European Union, embedded in the EU's wider regulatory framework. This guide aims to explain the legal control requirements of the Organic Regulation in a simplified form for authorities in non-EU countries and control bodies (CBs) active in those countries. It refers to legal texts to help users find the relevant regulatory text. Note that it is not an official interpretation by the European Commission. This guide will continue to evolve as the EU, Member States, or EU courts continue to introduce new secondary acts, additional measures, or rulings to Regulation 2018/848.

AGRINFO has also published *Guidance for operators and groups of operators* on the production, preparation, and export of organic plant products into the European Union. That guidance explains the rules that apply for organic plant production, simple preparation/processing, storage, and export of organic products.

For a full overview of the new applicable rules, reading both guidance documents is recommended. This document focuses on the organic control system, which verifies compliance with the applicable production rules of Regulation 2018/848. These production rules are not explained in this document, but are described in detail in the *Guidance for operators and groups of operators*.

1. INTRODUCTION

1.1 Regulation 2018/848 and its application in non-EU countries

The Organic Regulation (EU) 2018/848 is the basic act that lays down the European Union (EU) rules on organic production and labelling of organic products. It was introduced to revise and strengthen the organic controls system, trade regime, and production rules that had been in place since 2009 under Regulation (EC) 834/2007. It has applied in the EU from January 2022, but for countries outside the EU there have been longer transition periods for the application of some of the new rules.

The new organic regime aims to encourage the sustainable development of organic production in the EU, guarantee fair competition for (EU) farmers and operators, prevent fraud and unfair practices, and improve consumer confidence in organic products in Europe.

While the focus is on the EU organic sector, there are also significant implications for non-EU countries that are exporting to the European Union. For these countries the regulatory approach has fundamentally changed. The rules for exporting to the EU under the earlier Regulation (EC) 834/2007 were based on the principle of *equivalence* – organic goods could be produced and certified in ways that were different from the EU, as long as they gave an equivalent outcome and were aligned with organic principles. The new Organic Regulation's import rules are based on the principle of *compliance*, which requires operators in most non-EU countries to conform to the same set of rules as those used in the EU. This is intended to be fair for all producers, as everyone has to meet the same standards.

For background and an overview of the new EU Organic Regulation 2018/848, see AGRINFO: New EU Organic Regulation explained

The new EU Organic Regulation still gives two options for the certification of organic products exported from non-EU countries into the European Union. Products can be either:

- certified in accordance with the national organic rules in a country where the organic legislation is fully or partially recognised by the EU:
    - through equivalency recognition by the EU – the list of these recognised countries is indicated in EU Regulation 2021/2325; this option will be phased out by 31 December 2026[1]
    - via a bilateral trade agreement on organic products, which will be the only remaining system after the end of the equivalency arrangements.

or

- certified in compliance with the EU Organic Regulation itself, through control bodies (CBs) that are recognised by the EU as able to certify organic products in non-EU countries ("third countries"); this is known as the "compliance regime".

1 In December 2025, the European Commission published a proposal to amend the Organic Regulation by extending the equivalency recognition from 31 December 2026 to 31 December 2036. See AGRINFO: Simplification of organic rules and further AGRINFO updates.

These options for export of organic products to the EU are explained in more detail in section 2.2. ““This guide focuses on the compliance regime, as in most non-EU countries it is the sole option for organic certification of organic exports to the EU. Section 3 explains the requirements and procedures for the recognition of control bodies under the “compliance regime”. Section 4 provides details on inspection and certification of operators and groups of operators in compliance with Regulation 2018/848.

1.2 Terms used in this Guide

Several terms used in the EU regulatory texts are not always easily understood outside the EU. For instance, the term “competent authority” in Regulation 2018/848 does not refer to the national organic authority in a country of production outside the EU (e.g. in Peru or Sri Lanka). It always refers to an EU Member State authority; in the case of imports, for example, this may be the EU country where the organic product is customs cleared into the European Union.

Table 1 provides explanations of some key terms used in this guide that are relevant to the organic control system in non-EU countries. The original EU definitions, as stated in the Official Controls Regulation (2017/625) and the Organic Regulation, are provided in Annex 1 of this document.

Table 1: Simplified explanations of key terms used in the context of organic controls in non-EU (third) countries

Term	Simplified explanation
Competent authority	In Regulation 2018/848 this term always refers to the authority for organic production of an EU Member State, e.g. in the EU importing country. The only exception is where the text specifically states "competent authority in the third country" (in Regulation 2021/1698). For more information on the role of national competent authorities (NCAs) in non-EU countries under the new compliance regime, see section 3.3.
Organic controls	The inspection and certification of organic operators and groups of operators, including mass balance checks, issue of certificates of inspection for export consignments, and other physical or documentary checks to verify compliance with the Organic Regulation.
Control body (CB)	A private company authorised to carry out official controls (inspection and certification). To carry out controls of organic operators and groups of operators in countries outside the EU, CBs must be recognised by the European Commission for each country separately.
Control authority	Within the EU, organic control is carried out by (public) control authorities as well as (private) control bodies. The Regulation therefore refers to "control bodies/control authorities" in all legal texts. In non-EU countries, only (private) control bodies are so far recognised for compliance certification.
Group of operators	This is a new concept, defined in the Organic Regulation, Art 36.1.A group of operators has a legal personality and is composed of up to 2,000 members, all of whom are organic/in-conversion farmers (or algae/aquaculture operators), and are under a maximum farm size/organic turnover limit. The group must also have an internal control system (ICS) and a joint marketing system for organic products. Certification is issued for the group as a whole.
Operator	This can be a farm, corporate plantation, processor, exporter, etc., that is certified and responsible for compliance with the Organic Regulation. Operators are certified individually. Each operator (e.g. plantation) is controlled annually.
Organic products	In this guide, this term is used for both "organic" and "in-conversion" products certified according to the Organic Regulation. For more information about organic production rules, conversion to organic, and rules for labelling organic and in-conversion products, see AGRINFO's *Guidance for operators and groups of operators*
Preparation	The operations of preserving or processing of organic or in-conversion products, or any other operation that is carried out on an unprocessed product without altering the initial product, such as slaughtering, cutting, cleaning or milling, as well as packaging, labelling or alterations made to the labelling relating to organic production (Regulation 852/2004). Preparation may also include processing activities.
Processing and processed products	Processing is any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion, or a combination of those processes; this includes the use of substances (allowed ingredients according to Arts. 24 and 25 of Regulation 2018/848) but does not include packaging or labelling operations. Processed products means foodstuffs resulting from the processing of unprocessed products (Regulation 852/2004).
Unprocessed products	Foods that have undergone preparation but not processing. This includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen, or thawed. Examples are pineapple slices, washed sweet potatoes, husked hazelnuts, frozen mango cubes, thawed shrimps – but only if no additives, processing additives, or additional ingredients are used.

2. THE ORGANIC CONTROL SYSTEM IN THE EUROPEAN UNION

Note: For ease of reading, in this section only, this document uses the term "operator" instead of "operator or group of operators" (although the latter is more correct). For the first time, the Organic Regulation allows EU organic farmers to be certified as a group of operators, but in practice all farms in Europe are certified as individual operators. Food and feed processors, warehouses, and traders of organic products are always certified as individual "operators".

2.1 Overview of the organic control system in the EU

2.1.1 Legislative framework for organic controls in the EU

The EU legal framework applicable to the organic control system in EU Member States is defined by the :

- Official Controls Regulation (EU) 2017/625, which is the regulation for all official controls in the food and feed sector, *and*
- Organic Regulation (EU) 2018/848 and related secondary legislation, which sets additional control rules to verify that – throughout all stages of production, preparation, and distribution – organic and in-conversion products have been produced in compliance with the Regulation.

There is a close relationship between the Official Controls Regulation and the Organic Regulation. Article 37 of the Organic Regulation establishes that the organic control system is not a standalone regime, but is deeply integrated into the Official Controls Regulation. The Organic Regulation defines specific extra requirements (including annual on-site controls), but whenever it does not specify a rule (e.g. regarding sampling methods or laboratory accreditation), the general provisions of the Official Controls Regulation automatically apply.

In addition to the legislation established at EU level for organic production, labelling, and official controls, competent authorities in EU Member States may introduce additional provisions to implement the EU regulations (e.g. how to address non-compliances in the "catalogue of measures"). They may also introduce additional or different (stricter) measures or rules, provided they do not prohibit or restrict the marketing of organic/in-conversion products certified in other Member States as compliant with the Organic Regulation.

2.1.2 Control system in the food and feed sector in the EU

The official control system within the EU is organised as follows: every EU Member State (country) appoints a competent authority that is responsible for the organisation of official controls, and is ultimately responsible for making sure that EU organic rules are followed. Usually this is either a Department of Agriculture or a Department of Public Health. Once a year, Member States report to the European Commission on the results of the controls carried out on organic operators, and on the measures taken in cases of non-compliance.

It is possible for the competent authority to delegate its role to:

- one or more private CBs (e.g. Italy, Germany)
- one or more public control authorities (e.g. Denmark, Finland)
- a mixed system with both private CBs and public control authorities (e.g. Spain, Poland).

Note: for the official definitions of competent authority, control authority, and control body, see Annex 1 of this document.

EU Member States must keep a regularly updated list of:

- names and addresses of the competent authorities, and
- names, addresses, and code numbers of the control authorities and CBs.

EU Member State country profiles, including a description of the official control system: https://ec.europa.eu/food/audits-analysis/country/profile

While the competent authority of the EU Member State is responsible for ensuring that the rules are followed, the role of the European Commission is to supervise Member States to ensure that they fulfil their responsibilities. This helps build consumer trust, as EU consumers know that organic goods will have been rigorously inspected regardless of which EU country they originated in. The European Commission uses the reports submitted by Member States as well as its own regular audits to make sure that adequate controls are being carried out.

2.1.3 Delegation of tasks to control bodies

According to the Organic Regulation (Art. 40), EU Member State competent authorities may delegate certain official control tasks to control bodies (CBs) only if the CBs satisfy certain conditions. Also there is a written delegation giving a precise description of the delegated tasks, including reporting obligations.

To be delegated, a CB must:

- have the expertise, equipment, and infrastructure required to perform the official control tasks that are being delegated to it
- have a sufficient number of suitably qualified and experienced staff
- be impartial and free from any conflict of interest, and not be in a situation that may, directly or indirectly, affect the impartiality of its professional conduct when performing the official control tasks delegated to it
- work and be accredited in accordance with ISO 17065:2012 “Conformity assessment – Requirements for bodies certifying products, processes and services”
- have sufficient powers to perform the official control tasks delegated to it.

Prior to approval, the CB must have submitted to the competent authorities:

- the risk assessment procedure it uses to determine the intensity and frequency of controls applied to operators and groups of operators
- its standard control procedure, including a detailed description of the control measures that the CB undertakes to apply

- a list of measures that are to be applied in cases of suspected or established non-compliance
- arrangements for effective monitoring of the official control tasks carried out by operators.

In addition, it is very important that arrangements are in place to ensure efficient and effective coordination between the delegating competent authorities and the delegated body (see Figure 1).

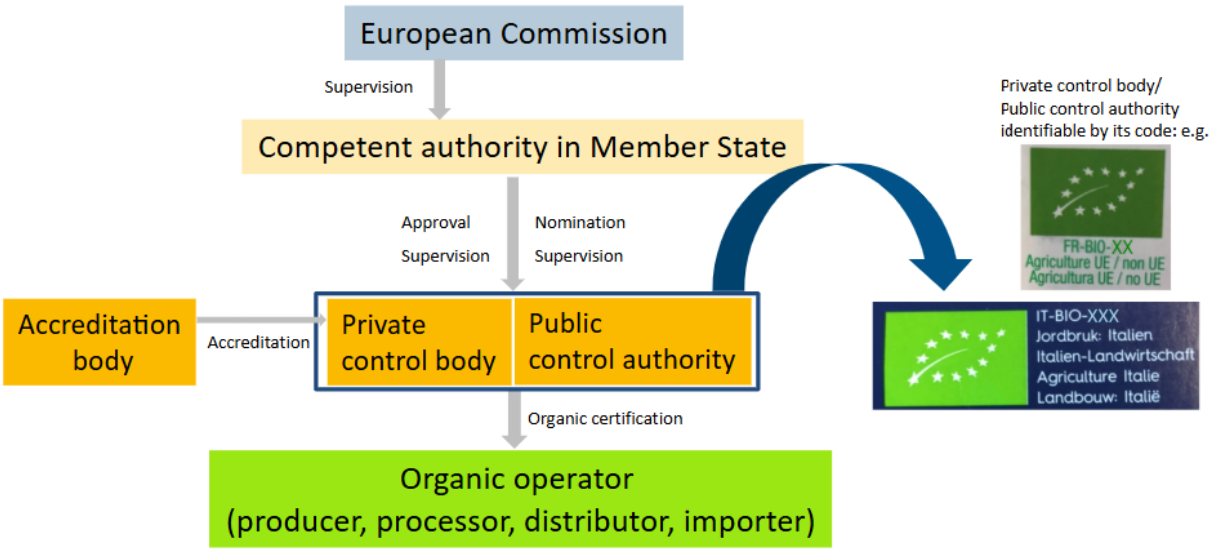


Figure 1: Control system for products produced in the European Union

Source: European Court of Auditors (2019) Special Report 4/2019: Organic food

2.1.4 Tasks not to be delegated

The EU Regulations also list specific activities that competent authorities cannot delegate, for example, the:

- supervision and audit of control authorities or CBs
- power to grant derogations, other than derogations for the use of plant reproductive material not obtained from organic production
- authority to receive notifications of activities by operators
- establishment of the common catalogue of measures.

In the EU, Member State competent authorities have responsibility for the official control system in their country (or region) and for ensuring that the EU rules are followed.

- Operators who want to start organic production and apply for certification need to notify their organic activity to their competent authority, in addition to applying for organic certification.
- Most derogations (e.g. the retroactive recognition of parts of the conversion period, or temporary approval of parallel production) cannot be granted by the CB, and need the approval of the competent authority.

2.1.5 Reporting by delegated control bodies/control authorities and competent authorities

Each year CBs have to provide to the competent authority a list of the operators that they have inspected, and information on the official controls they have carried out in the previous year (e.g. number and type of controls, number and result of samples, number and type of measures applied). This information is used to support the preparation of their Member State's annual report to the European Commission.

In addition, EU Member States must report to the European Commission other significant data, such as derogations granted for non-organic plant reproductive material, animals, juveniles, protein feed, and cases of contamination with non-authorised products or substances.

2.1.6 Supervision by the competent authority

When tasks are delegated, competent authorities must have in place procedures and arrangements to ensure the supervision of CBs. These must verify that the delegated tasks are carried out effectively, independently, and objectively, particularly regarding the intensity and frequency of controls.

At least once a year, competent authorities must carry out audits of the delegated CBs to verify their performance. These may include head office audits, audits of other branch offices, and review-and-witness audits. If outcomes are not satisfactory, competent authorities may suspend or withdraw the delegation of tasks to a CB.

In addition, competent authorities must exchange information with the national accreditation bodies.

2.2 Organic imports from non-EU countries

§ Regulation 2018/848
Art. 46 Recognition of control authorities and control bodies
Art. 47 Equivalence under a trade agreement
Art. 48 Equivalence under Regulation (EC) No 834/2007

Regulation 2021/2325 [*List of equivalent countries*]
Regulation 2021/1378 [*Third country certificate and list of CBs recognised for compliance*]

As noted in section 1.1, the new EU Organic Regulation still gives two options for the certification of organic products exported from non-EU countries into the European Union. Products can either be:

- certified according to national rules that are recognised by the EU as equivalent, either through unilateral recognition or by trade agreement, *or*
- certified in compliance with the EU Organic Regulation itself through CBs) that are recognised by the EU as able to certify organic products in non-EU countries (the "compliance regime").

2.2.1 Transition periods for the different import options

Table 2 provides an overview of the currently available options for certifying organic products to be imported into the EU, with reference to the respective articles in Regulation 2018/848.

Table 2: Options for certifying organic products to be imported into the European Union

Import regime	Timeframe	Notes
Control bodies – compliance regime (Art. 46)	Compulsory from 1 January 2025	This is the only option for organic certification in most non-EU countries (all except those recognised under third country equivalence or by trade agreement). Non-EU country CBs are recognised by the EU for organic certification for specific non-EU countries and product categories. Recognised CBs are listed in Regulation 2021/1378, Annex II. See sections 3 and 4 of this document.
"Third country equivalence" (Art. 48)	Currently set to expire on 31 December 2026, but a proposed amendment would extend this to 31 December 2036	Under the Organic Regulation(Art. 48), 11 non-EU countries are recognised for the purpose of equivalence with the previous organic Regulation (EC) 834/2007 ("equivalent countries"). These equivalent countries are listed in Regulation 2021/2325, Annex I. As of August 2026, the list includes Argentina, Australia, Canada, Costa Rica, India, Israel, Japan, Korea, Tunisia, USA, and New Zealand. See section 2.2.2 of this document.
"Third country trade agreements" (Art. 47)	Applicable from 1 January 2022	The EU intends to conclude mutual trade agreements on organic products, replacing the country equivalence system. So far agreements have been signed with Chile, Switzerland, and UK. See section 2.2.3 of this document.
Control bodies – equivalence (Art. 57)	Phased out on 31 December 2024	No longer an option.

Three non-EU European countries – Iceland, Lichtenstein, and Norway) are part of the European Economic Area and therefore are part of the EU's single market, where Regulation 2018/848 applies.

For all import options, to be imported into the EU as organic a consignment must be accompanied by an electronic certificate of inspection (e-COI). Certificates of inspection are administered through the EU's Trade Control and Expert System (TRACES), issued by the organic CB of the exporter, and checked by customs when the product enters the EU. Once imported into the EU, an organic product may be sold as organic to operators in any of the EU's 27 Member States. This means, for example, that bananas may be imported by an importer in the Netherlands and then sold to a retailer in Germany.

2.2.2 Equivalent countries

From most non-EU countries, products can only be imported into the EU as organic if they are certified in accordance with the compliance regime. There are currently only 11 countries where the EU recognises their national organic production and control systems as equivalent (in whole or in part) to those of the EU. Recognition of the organic system of a non-EU country as equivalent means that the system has been assessed as meeting the same objectives and principles as those of the EU by applying rules that ensure the same level of "assurance of conformity", even if it is achieved through different means. As of January 2026, the list of equivalent countries in Annex I of Regulation 2021/2325included Argentina, Australia, Canada, Costa Rica, India, Israel, Japan, Korea, New Zealand, Tunisia, and USA.

According to Regulation 2018/848, this system of country equivalence recognition is being replaced by a new system of trade agreements covering organic products. At the time of writing, three previously equivalent

countries (Chile, Switzerland, and UK) have already completed trade agreements on organic products. Negotiations are in progress with the remaining 11 equivalent countries and with two additional countries (Colombia and Mexico).

Originally, the country equivalence option was set to expire on 31 December 2026, after which only the trade agreement option would remain. In December 2025, the EU proposed to extend this deadline by 10 years until 31 December 2036,[2] to allow sufficient time for the technical exchanges needed to conclude trade agreements, and to avoid disruptions in the trade of organic products. Country equivalency recognition may therefore remain a valid option for the current equivalent countries for longer, provided they remain recognised (listed in Regulation 2021/2325).

During this period, if a re-evaluation concludes that a country's system no longer meets the same standard as the EU, recognition of the 11 countries concerned may be removed, withdrawn, or adapted by the EU at any time by updating the list of recognised countries (in Regulation 2021/2325, Annex I). A country is also removed from this list when it successfully concludes a trade agreement on organic products (see section 2.2.3).

Besides the technical challenges of the alignment process, there are strategic and political factors to consider. For example, some countries may face political obstacles to passing a mutual trade agreement.

While the equivalent country system remains in place, it is important to understand its limitations and restrictions. Recognition of countries as having an equivalent organic production and control system is usually according to three aspects:

- product categories (see Table 3)
- agricultural origin and, where relevant, country of processing
- recognised CBs.

The product categories for the recognition of *equivalent* countries are slightly different from those used for recognition of CBs under the new *compliance* regime (see section 2.2.1).

*Table 3: EU product categories for recognition of non-EU countries with **equivalent** organic control systems according to Regulation 2021/2325, Annex I*

Category	Products
A	Unprocessed plants and plant products
B	Livestock and unprocessed livestock products
C	Unprocessed aquaculture products and algae
D	Processed agricultural products for use as food
E	Processed agricultural products for use as feed
F	Vegetative propagation material and seeds for cultivation

2 The targeted amendment of Regulation 2018/848 is still being debated at the time of writing. See European Parliament (2026) Organic production: Targeted updates and simplification. Briefing – EU Legislation in Progress; and Council of the European Union (2026) Organic farming: Council negotiating position on simpler and clearer organic farming rules agreed, Press release, 11 May. The amended Regulation is planned to be finalised before the end of 2026.

As a general rule, the EU does not recognise CBs for controls under the compliance regime in countries and for product categories that are fully recognised as equivalent. For example, if plant production (product category A) under the national legislation is recognised as equivalent, no CBs will be recognised in that country for certification of plant production under the compliance regime. However, some producers and operators, even in recognised countries, may still need to be controlled by a recognised CB under the compliance regime for some categories. This is the case where there is only partial recognition of the national organic production and control system of the respective country (see examples below).

The CB control number format on the product label is different depending on whether an organic product is exported to the EU under equivalence recognition or under compliance certification:

- for products certified under country equivalence, the CB code starts with a "0" (e.g. TN-BIO-**0**XX) as per the CB code for the respective country in Regulation 2021/2325
- for products controlled under the compliance regime, the CB code starts with a "1" (e.g. IN-BIO-**1**XX) as per the CB code for the respective country in Regulation 2021/1378.

Example

Tunisia: Partial recognition of the Tunisian organic legislation

According to Regulation 2021/2325, Annex I, Tunisia's organic control system and its production standards, as defined in the Tunisian "Loi 99-30", are recognised as equivalent, but only in part. The EU's equivalence recognition covers only:

- unprocessed plant products and processed products (containing only ingredients of plant origin) for use as food as well as vegetative propagating material and seeds for cultivation
- products grown in Tunisia and processed in Tunisia using ingredients organically grown in Tunisia
- CBs that are recognised in Tunisia and listed in Regulation 2021/2325.

The following are covered by the current equivalence recognition for Tunisia and may be imported into the EU with a Tunisian organic certificate and the certificate of inspection (COI). For example:

- ✓ olives produced in Tunisia and certified by a recognised CB (unprocessed Tunisian plant product)
- ✓ olive oil made from Tunisian olives, processed in Tunisia, and certified by one or more recognised CBs (processed Tunisian product for use as food).

The following combinations are not covered by the EU's current equivalency recognition for Tunisia:

- × products that belong to other product categories, such as animal products (e.g. honey, milk, and cheese)
- × composite products that contain ingredients of both plant and livestock origin (e.g. yoghurt with a fruit base)
- × unprocessed products not produced in Tunisia but packaged in Tunisia and exported by a company based in Tunisia (e.g. Algerian fresh dates or figs packaged in Tunisia)
- × processed products produced in Tunisia but processed in and exported from Algeria.

To be imported into the EU as organic, these products must be certified according to the EU Organic Regulation under the compliance regime, thus the CB must be recognised by the EU for Tunisia for the respective product category (listed in Annex II of Regulation 2021/1378).

Example

India: Partial recognition of the Indian organic legislation

According to Regulation 2021/2325, Annex I, India's National Programme for Organic Production (NPOP) is recognised as equivalent, but only partially.

The EU equivalence recognition covers:

- unprocessed plant products, vegetative propagating material, and seeds for cultivation as food
- products grown in India
- CBs that are listed in Annex I of Regulation 2021/2325 (which does *not* include all CBs recognised under the NPOP by the national competent authority, the Agricultural and Processed Food Products Export Development Authority, APEDA).

This means that only unprocessed plant products (e.g. fresh mangoes) produced in India and certified by a CB listed in Annex I of Regulation 2021/2325 in accordance with the NPOP can be imported into the EU under the equivalence recognition.

Products not covered by the equivalence recognition (including all processed products) must be certified under compliance. The limitations of the equivalence recognition in India pose some unique practical challenges for organic exports to the EU.

- Organic crop production in India can only be certified according to the NPOP, and cannot be certified in compliance with Regulation 2018/848.
- Processed products can only be certified under the compliance regime by CBs recognised for compliance by the EU for India (product category D). As of December 2025, only one out of the 15 CBs recognised by the EU for compliance (Annex II of Regulation 2021/1378) is also recognised for EU-equivalent NPOP certification (Annex I of Regulation 2021/2325).

This means that for exports to the EU, many organic operators and groups of operators producing processed products need to be certified by two different CBs (one for plant production under the NPOP, and one for processing under Regulation 2018/848).

2.2.3 Trade agreements on organic products

When the current import regime of country equivalence recognition expires (see section 2.2.2), trade agreements on organic production will be the only option for recognition of a country's own organic legislation for exports to the EU. The difference between a trade agreement and a recognition of equivalence of organic legislation is that a trade agreement is a bilateral agreement, while the recognition of equivalence is mostly unilateral.

At the time of writing, a non-EU country may be in one of the following situations.

- Has not signed a trade agreement at all.
- Has signed a trade agreement, but not covering organic products; this includes countries:
    - where the EU did not recognise the organic legislation (if any), so the compliance regime is the only option for organic exports to the EU, *or*
    - where the EU recognised the country's organic legislation as equivalent (e.g. Tunisia), and the European Parliament may start negotiations on a trade agreement.

- Has signed a trade agreement on organic products; this includes Chile and Switzerland (previously equivalent countries), and the UK (previously an EU Member State).

The EU provides an up-to-date list of Agreements on trade in organic products. Please note that countries that are recognised under a trade agreement are no longer listed as equivalent countries in Annex I of Regulation 2021/2325.

Process to negotiate a trade agreement

A trade agreement between the EU and a non-EU country is a four-step process.

- Step 1. The Council of the European Union and the European Parliament must reach a (political) agreement giving a mandate to the European Commission to start negotiations with the partner country. Together with the mandate, the Council may give the Commission direction regarding the objectives and scope of the agreement to be discussed.
- Step 2. The Commission negotiates with the partner country and, while doing so, stays in close contact with the Council and the Parliament. As part of the process, there is a review and evaluation of the country's organic standard and control system.
- Step 3. After the negotiations, the Commission presents the outcome of the agreement to the Council, which has the responsibility to approve the result for adoption.
- Step 4. When the Council has approved the text of the agreement, it is submitted to the Parliament for approval. Following this, the text must be ratified by the EU and the partner country concerned. The Council then adopts the final agreement, and it enters into force.

So far, the European Parliament has mandated the European Commission to start negotiations with the remaining 11 currently recognised equivalent countries, as well as two new countries, Colombia and Mexico.

Historically, many more non-EU countries hoped to have their systems recognised by the EU. Under either equivalence or trade agreements, it is important to note that countries will need not only an organic regulation, but also a strong and effective official control system, equivalent to the EU's own organic control system (see section 2.1).

The decision to negotiate a mutual trade agreement is primarily an economic and political one. In the coming years, the EU's main focus is expected to be on finalising negotiations with the currently recognised countries (and the two new candidates), most of which are in the pipeline. For other countries, aiming for country recognition is a long-term ambition, and in the meantime adapting to the new compliance regime for imports is the only option.

Example

The EU–UK trade agreement

Following the UK's departure from the European Union, an EU–UK Agreement on trade in organic products was signed on 30 December 2020 and has provisionally applied since 1 January 2021. In the face of the new EU rules for organic products, the EU and UK confirmed equivalence on 6 December 2023. In the context of the EU–UK trade agreement, Northern Ireland is not included.

Regarding organic production, the agreement covers all product categories. In terms of origin, organic products include unprocessed agricultural or aquaculture products produced in the UK, and processed agricultural products for use as food or feed that have been processed in the UK with ingredients that have been grown in the UK, or that have been imported into the UK in accordance with UK laws and regulations.

The legal basis for organic production and labelling in the UK (excluding Northern Ireland) is the "retained" Regulation (EC) 834/2007 (which is no longer in force in the EU). Imports of organic products into the EU must be in line with Art. 33 of Regulation 834/2007. This lays down the possibility for the recognition of countries and CBs applying their own production standard and control measures in other countries which are considered equivalent. For both systems the competent authority, the Department for Environment Food and Rural Affairs (DEFRA), establishes Organic registers: lists of non-UK countries, territories, control bodies and control authorities.

The UK list of recognised equivalent countries is currently the same as the EU's list. Additionally, Sri Lanka is in the process of signing a trade agreement with the UK (excluding Northern Ireland) that includes organic products.

For imports from all other non-EU countries, a valid organic compliance certification according to Regulation 2018/848 is not directly valid for exporting organic products to the UK. However, the UK list of recognised CBs seems to be in line with the EU's list of CBs recognised for compliance so, in practical terms, there should not be any additional obstacles for exports to the UK.

Regarding organic exports to the UK with a final destination in the EU, the trade agreement between the EU and the UK imposes strict conditions. For products not produced in the UK, the trade agreement only covers products *processed* in the UK using imported ingredients. "Processing" is defined very specifically in the EU (see section 1.2). Simple repackaging, or changing of packaging or re-labelling of imported products, does not qualify as "processing", so is not covered by the agreement, and a UK CB could not issue the required COI for such exports to the EU.

Examples

The EU–Chile trade agreement

The EU and Chile concluded an Agreement on trade in organic products in 2017, which entered into force in January 2018.

The agreement covers unprocessed plant products (category A), honey, processed products for use as food (category D), and vegetative propagating material (category F) that are certified according to Chile's Law 20.089 of 17 January 2006, which regulates the national certification system for agricultural organic products. For recognition under the trade agreement, the products must be produced in Chile; the use of imported ingredients is only possible for products that are processed in Chile. The agreement also contains a list of CBs recognised by the competent authority of Chile.

The EU–Switzerland trade agreement

The Agreement on trade in organic products with Switzerland covers all product categories except category C. Regarding origin, the agreement specifies that products of categories A and F must have been grown in Switzerland. Products of categories D and E must have been processed in Switzerland with organic ingredients that have been grown in Switzerland, or that have been imported into Switzerland from the EU or a non-EU country according to the Swiss organic regulation.

The Organic Farming Ordinance of the Swiss Federal Office for Agriculture (FOAG) (SR 910.18) sets out the principles for the production, preparation, storage, marketing, import, and export of organic products in Switzerland. Products can be imported into Switzerland as organic if they meet an equivalent standard and are controlled in a manner equivalent to the Swiss Ordinance.

Annex 1 of the Organic Farming Ordinance sets out the list of countries whose production and inspection regulations are recognised as being equivalent to those in Switzerland – the list includes the EU and the countries that are recognised by the EU. All EU-recognised CBs (listed in Regulation 2021/1378) for certification in compliance with Regulation 2018/848 are automatically accepted as equivalent CBs for import into Switzerland.

2.2.4 Compliance regime for imports of organic products from all other non-EU (third) countries

In all other non-EU countries without equivalence recognition or a trade agreement in place, organic certification for the EU market must be conducted by CBs recognised by the European Commission as competent to carry out inspections and issue organic certificates in compliance with Regulation 2018/848.

The list of recognised CBs is indicated in Annex II of Regulation 2021/1378 (the most up-to-date consolidated version). The list specifies for each CB the countries and respective product categories (see categories section in 2.2.1), for which the CB or control authority has been recognised.

Example

Information provided for a recognised control body in a non-EU countrys (compliance regime)

Code number	Non-EU country	Product category						
		A	B	C	D	E	F	G
GH-BIO-1XX*	Ghana	X			X			X
MA-BIO-1XX*	Morocco	X		X	X		X	
TR-BIO-1XX*	Turkey	X			X	X		x

*1XX represents the unique number provided to each CB (CB codes under compliance always start with a "1").

- In Ghana this CB is recognised to certify category A – unprocessed plants and plant products (including plant production = farming) and category D – processed food products, and category G "other products" (e.g. cotton, essential oils).
- In Turkey this CB is recognised to certify category A – unprocessed plants and plant products (plant production), category D – processed food products, and categories E – feed (e.g. soyabean cake for livestock) and G.

Regulation 2021/1378, Annex II.

Compliance regime: scope of recognition of control bodies and product categories

For the purposes of carrying out controls of organic operators and groups of operators outside the EU, CBs must be recognised by the European Commission for each country separately. And for each country, the recognition is restricted to specified product categories.

Table 4: EU product categories according to Regulation 2018/848, Art. 35[3]

Category	Products
A	Unprocessed plants and plant products, including seeds and other plant reproductive material
B	Livestock and unprocessed livestock products
C	Algae and unprocessed aquaculture products
D	Processed agricultural products,[4] including aquaculture products, for use as food
E	Feed
F	Wine
G	Other products listed in Regulation 2018/848, Annex I, or not covered by the previous categories (e.g. cotton, wool, essential oils, plant-based traditional herbal preparations)

3 The product categories used in the recognition of equivalent countries are based on earlier legislation and differ slightly – see section 2.2.2.

4 The term "processing" is defined very specifically in EU legislation. See section 1.2 for explanation and examples of "processing" and "processed products".

Operators and groups of operators can be certified for the following activities (see model of the certificate in Regulation 2021/1378, Annex I):

- production (agricultural production, or aquaculture or algae production)
- preparation (of "processed" or "unprocessed" products)
- distribution, storing, import, and export in non-EU countries.

Examples

Certified activities and product categories

1. A cocoa producer group in Côte d'Ivoire selling organic fermented cocoa beans (a processed product) from its own production needs to be certified as a group of operators for both:

Product: category A, Activity: agricultural production, *and*

Product: category D, Activity: preparation.

2. A trading company involved in purchasing, storing, and packing fermented cocoa beans (without its own processing activity) would be certified for:

Product: category D, Activity: preparation.

3. A company purchasing coconuts and extracting, packing, and labelling coconut water is doing a preparation activity that includes a processing activity, and also would be certified for:

Product: category D, Activity: preparation.

For more information about the compliance regime, see section 3 for details on the recognition and supervision of CBs, and section 4 for details on the organic inspection and certification process.

3. COMPLIANCE REGIME FOR IMPORTS: RECOGNITION AND SURVEILLANCE OF CONTROL BODIES

3.1 Process and requirements for control bodies to be recognised for the compliance regime

§

Regulation 2018/848

Art. 45 Import of organic and in-conversion products

Art. 46 Recognition of control authorities and control bodies

Regulation 2021/1698

Art. 1 Requirements referred to in point (n) of Art. 46(2) of Regulation 2018/848

Art. 2 Extension of the scope of the recognition

Annex I Content of the assessment report

From January 1 2025, organic and in-conversion products can no longer be imported into the EU based on certification from CBs recognised under the previous EU organic (equivalence) regime (Regulation 2018/848, Art. 57). They can now only be imported into the EU if certified by a CB recognised as compliant with the EU rules in accordance with Regulation 2018/848, Art. 46 (compliance regime).

Note: EU Regulations refer to "control bodies" (private companies) and "control authorities" (public bodies), both of which exist in the EU. Currently, only private control bodies (CBs) are recognised in non-EU countries so this document only addresses the requirements for CBs. If a control authority is seeking recognition, it is advised to consult the legal references provided here for more information, as some requirements differ (e.g. control authorities are not required to have ISO accreditation).

3.1.1 Recognition requirements for control bodies

Control bodies are recognised by the European Commission as competent to carry out inspections (controls) and to issue organic certificates in third (non-EU) countries, provided that all relevant criteria are fulfilled (Regulation 2018/848, Art. 46.2; Regulation 2021/1698, Art. 1). For example, they must:

- have the capacity to conduct controls to ensure that the products comply with the EU Regulation and that the operators hold a certificate confirming compliance
- offer adequate guarantees of objectivity and impartiality, be free from conflicts of interest in the exercise of their control tasks, and have relevant procedures in place
- have the expertise, equipment, and infrastructure required to carry out control tasks, and have a sufficient number of suitable qualified and experienced staff
- have the capacity and competency to carry out their certification and inspection activities for each type of operator (single operator or group of operators) in each non-EU country, and for each category of products for which they seek recognition

- have internal skills, training, and procedures suitable to perform effective controls, including inspections, on operators as well as on the internal control system of a group of operators.

It is important to note that CBs cannot delegate control tasks, except for sampling activities.

Control bodies must be accredited ISO 17065/2012 "Conformity assessment – Requirements for bodies certifying products, processes and services"[5] for the relevant scope of certification. This must be conducted by a national accreditation body in the EU, or by an accreditation body outside the EU that is a signatory to a multilateral recognition arrangement under the International Accreditation Forum.

ISO 17065:2012 accreditation is a rigorous, time-consuming process for CBs. It requires significant resources and technical expertise, and can take some years for CBs undertaking accreditation for the first time.

Assessment reports prepared by the accreditation bodies must be presented to the European Commission as part of the technical dossier submitted by CBs under the recognition application process. Regulation 2021/1698, Annex 1 lists in detail the content of the assessment dossier, including reports on the document and record review, an on-site assessment, and a witness audit.

The assessment by the accreditation body must guarantee that the CB:

- has been satisfactorily assessed on its ability to ensure that products imported into the EU from non-EU countries meet the requirements of the Organic Regulation 2018/848
- has the capacity and competencies to implement the control requirements and fulfil the criteria of Regulation 2018/848 in each non-EU country for which it requests recognition.

3.1.2 Steps towards obtaining recognition

Control bodies wishing to submit a request for recognition first need to register on the European Commission's AGRI Portal (https://webgate.ec.europa.eu/agriportal/). The relevant forms then become available via the Organic Farming Information System 2 (OFIS 2).

The request consists of a technical dossier with all the relevant information needed to ensure that the recognition criteria are met (Regulation 2021/1698, Art 1), including the following.

- An overview of the intended activities in the non-EU countries concerned, including a list of the organic products that are intended to be imported into the EU under the CB's certification during the first year following recognition.
- A description of the structure and size of the CB: its IT management system, branch offices, type of activities and delegated activities, organisational chart, and quality management system.
- Procedures for the implementation of control measures and certification procedures, and a catalogue of measures.

5 The international standard ISO/IEC 17065:2012 specifies requirements for CBs that conduct product certification to ensure they carry out their activities competently, consistently, and impartially. Key requirements include establishing a management system, ensuring the competence of personnel, maintaining impartiality by preventing conflicts of interest, and applying documented procedures for the certification process. The standard is available at https://www.iso.org/standard/46568.html.

- Translation of the production rules and control measures (from Regulation 2018/848 and secondary legislation) into languages understandable to operators in the countries concerned. If the CB decides to use only one language (e.g. English), this must be clearly stated in its procedure and agreement with operators, and it must ensure that the operators can understand the language.
- A copy of the CB's accreditation certificate covering all product categories for which recognition is requested, together with its most recent assessment report by the accreditation body.
- Proof that the CB has notified its activities to the appropriate authorities in the non-EU country concerned, and its undertaking to respect the relevant national legal requirements.
- A website with content available in at least one of the official languages of the EU and understandable by the organic operators in the country, and the CB's list of certified operations.
- A statement by the CB that it has not been subject to withdrawal by the European Commission, or withdrawn or suspended by any accreditation body, in the 24 months preceding their request.

In the case of an extension of the scope of recognition (an additional country or product category), the CB must submit a request for extension and update the relevant parts of the technical dossier.

The European Commission (Directorate-General for Agriculture and Rural Development, DG AGRI) and representatives from two EU countries (Member States) review the technical dossier. If all criteria are met, the CB will obtain recognition and will be listed in Annex II of Regulation 2021/1378.

3.2 Reporting, exchange of information, and supervision of control bodies by the EU

§	Regulation 2018/848 Art. 46 Recognition of control authorities and control bodies Regulation 2021/1698 Art. 3 General requirements for the supervision of control authorities and control bodies Art. 4 Annual report Art. 5 On-the-spot examinations and audits Art. 6 Traceability checks Art. 7 *Ad hoc* request by the European Commission Art. 13 Documented control procedures Art. 17 List of operators and other relevant information to be publicly available Art. 19 Information requirements Art. 20 Systems and procedures for the exchange of information Art. 21 Exchange of information between the Commission, control authorities, control bodies, and competent authorities Art. 24 Checks to be carried out for the purpose of the retroactive recognition of a previous period Art. 25 Authorisations for the use of non-organic plant reproductive material Art. 26 Derogations as regards the use of non-organic animals and aquaculture juveniles Art. 27 Reporting on provisional authorisation for the use of non-organic agricultural ingredients for processed organic food Art. 29 Conditions for derogations Regulation 2021/2306 Art. 10 Information to be provided by a competent authority, control authority, or control body in a third country on suspected or established non-compliances on consignments

Once recognised, the CB must demonstrate:

- that it has effectively implemented activities according to the recognition conditions and criteria described in section 3.1
- compliance with its operating procedures, and the effectiveness of their control measures.yes, the sentence starts above: “the CB mui

Information exchange is a key element of the EU Organic Regulation, so it is important for CBs to manage this aspect very carefully. Failure to meet reporting or information deadlines may result in the withdrawal of recognition.

Documented procedures need to be in place for cooperation and communication with other control authorities, CBs, and the European Commission to ensure a timely exchange of information through the OFIS system. When the Regulation uses the term “immediately”, it literally means “without any delay”.

Annual report

Every year, by 28 February, the CB must submit its annual report to the European Commission via OFIS 2, providing the data listed in Annex II of Regulation 2021/1698. This includes an update of the technical dossier; information about any cases of non-compliances and the measures taken; transfer of operators from other CBs; high-risk products; authorisations for the use of non-organic plant reproductive material, livestock, and aquaculture juveniles; and any other information deemed relevant. All information must be provided in one of the official EU languages and in English (if the official language chosen is not English).

The update of the technical dossier must include the annual assessment report from the accreditation body for all offices where certification decisions are taken. This confirms that the CB or control authority still has the capacity and competencies in each non-EU country for which it is recognised.

Update of the technical dossier in the event of changes

Control bodies must notify the European Commission within 30 calendar days of any changes made to the content of their technical dossier, including new witness audit reports.

Exchange of information with the EU, CBs, and competent authorities

- Suspicion of non-compliance: in the event of any suspicion of non-compliance that affects the integrity of organic or in-conversion products, the CB must immediately share information with the European Commission, other CBs, competent authorities of EU Member States, and the competent authority of the non-EU country concerned.
- Subcontracting activities: where operators and/or their subcontractors are subject to controls by more than one CB, they must exchange information on the operations covered by their respective control activities.
- Change of CB: when an operator or group of operators changes its CB, the new CB must request the control file from the previous CB. Within 30 days, the previous CB must provide the control file and written records, the status of the certification, the list of non-compliances, and the corresponding measures taken. The new CB must ensure that non-compliances have been addressed.

- Traceability and mass balance checks: where operators or groups of operators are subject to these checks (requested by the European Commission or competent authorities of EU Member States), CBs must exchange the relevant information to allow their finalisation.

Notification on retroactive recognition of conversion and other derogations

If CBs have granted retroactive recognition of the conversion period (Regulation 2021/1698, Art. 24), they must immediately notify the European Commission, EU Member States, and their accreditation body.

Where provisional authorisation is granted for the use of non-organic agricultural ingredients in processed organic food (Regulation 2018/848, Art. 25.4), CBs must immediately notify the Commission, EU Member States, accreditation bodies, and other recognised CBs via OFIS 2.

Where derogations are granted due to catastrophic circumstances, this must be communicated immediately to the Commission, EU Member States, and the accreditation body via OFIS 2 (Regulation 2021/1698, Arts. 28 and 29).

Where the use of non-organic plant reproductive materials, livestock, or aquaculture juveniles has been authorised, the relevant information must be included in the annual report.

Public information available

Control bodies must make the following information available on their website in at least one official language of the EU: a list of certified operators and groups of operators with names and addresses; and information on certificates (number, category of products certified, status, validity – including suspension reduction, and withdrawal). In the case of groups of operators, it should indicate the name and address of the group, and the number of members.

The list must be updated immediately following any change to the status of the certification. In the event of withdrawal, information must be kept on the list for 5 years after withdrawal.

Updated information on the CB's accreditation must also be available on their website, including a link to the latest accreditation certificate.

Additional supervision and traceability checks

A variety of information is used by the European Commission (DG AGRI) for the supervision of CBs. This includes the organisation of risk-based, on-the-spot examinations and audits in non-EU countries to evaluate the quality and effectiveness of the controls carried out and their operational performance. These activities may include office assessment, review, and witness audits.

In addition, the Commission may conduct traceability checks on products or consignments – these can be organised at random, or based on an annual risk assessment or on complaints received.

Withdrawal of recognition

The European Commission may withdraw the recognition of a CB for a specific non-EU country and/or a category of products. The reasons are often related to failures to meet deadlines, or incomplete information, for example where:

- the Commission has not received the annual report by the deadline, or the information included in the annual report is incomplete, inaccurate, or does not comply with the requirements

- the CB does not provide information requested by the Commission or EU Member State within the deadlines set, or the information is incomplete, inaccurate, or does not comply with the requirements
- the CB does not notify the Commission within 30 calendar days of changes to its technical dossier, or does not make available or communicate all the information related to the technical dossier
- the CB fails to take adequate corrective measures in response to non-compliances and infringements within the deadline set by the Commission
- an operator changes its CB, but the previous CB does not communicate the relevant parts of the control file to the new CB within the time limit of 30 calendar days after receiving the request
- the CB has not certified an operator for 48 consecutive months in a country for which it is recognised.

For the complete list of cases that can lead to withdrawal, refer to Regulation 2018/848, Art. 46.2a.

3.3 Role of third (non-EU) country competent authorities in the new compliance regime

No oversight role for national authorities under the EU compliance regime

In most non-EU countries (referred to as "third countries" in the EU Regulations) , the EU's organic control system now relies primarily on EU-recognised CBs for organic certification.

The new EU organic regulatory framework does not set any responsibilities for national competent authorities (NCAs) in non-EU countries for the supervision or recognition of CBs, or the correct application of the EU Organic Regulation in the country.

The primary responsibility for verifying compliance with the EU organic rules rests solely with the recognised CBs operating in the country, who are overseen directly by the European Commission's Directorate-General for Agriculture and Rural Development (DG AGRI).

National competent authorities in non-EU countries are not officially mandated by the EU to perform the oversight role typically carried out by EU Member State competent authorities. They also do not have an active role in the control process (e.g. for notifications of organic activities), which is also delegated to the recognised CBs. National competent authorities do not have access to OFIS, the EU's electronic Organic Farming Information System.

However, there are two specific instances where Regulation 2021/1698 foresees an information exchange between CBs and the non-EU country NCA:

- when a CB applies to be recognised for a specific country, in the application dossier it must provide proof that it has notified its control activities to the NCA
- if a CB has any suspicion of non-compliance that affects the integrity of organic/in-conversion products, it must immediately inform not only all relevant EU authorities and CBs via the OFIS system, but also the NCA in the country concerned (by letter or a national alert system).

Despite the absence of a direct EU-mandated oversight or control function, NCAs maintain an important and indispensable role in fostering a stable and compliant organic sector capable of meeting EU and other organic

markets' requirements. Note that not all countries have a dedicated NCA for organic production and labelling of organic products.

Support for adaptation and compliance

An important function of the NCA is to support operators and groups of operators who wish to export organic products to Europe – in particular their adaptation to, and ongoing compliance with, the stringent and evolving requirements of the EU legislation.

This supportive role may include, for example:

- taking steps to ensure that any local or national organic standards do not introduce additional complications or requirements that contradict or hinder compliance with EU rules by exporters
- organising and coordinating support and training, for example on EU production rules or internal control systems (ICS) for groups of operators
- working with other governmental ministries, departments, and regional bodies to facilitate the registration of new legal entities (for groups of operators), manage land use documentation, and ensure that farm inputs are registered and available under local law
- promoting and facilitating the exchange of information and best practices between the CBs operating in the country and local authorities, in order to harmonise control standards and improve operational quality
- gathering national statistics on organic farming, including quality data on smallholder production and land under organic management
- providing guidance and best practice recommendations.

General support for development of the national organic sector

Beyond providing support for compliance, NCAs play an essential, long-term role in strengthening the foundation of the national organic sector by:

- actively promoting organic farming for the domestic market and facilitating access to international markets
- providing or facilitating subsidies and financial support schemes for organic farming and conversion, which can be critical for smallholder participation.

4. INSPECTION AND CERTIFICATION OF OPERATORS AND GROUPS OF OPERATORS

Regulation 2018/848 and its secondary legislation (e.g. Regulations 2021/771 and 2021/279) outline the control system that must be followed by control bodies (CBs) and control authorities within the EU under the compliance regime.

For non-EU countries ("third countries"), the primary regulation governing the control system is Regulation 2021/1698. This mirrors the EU's control requirements for inspection and certification, and defines the control procedures to be applied by recognised CBs.

For more information about the production rules to be met by organic operators and groups of operators, which the CB will control to assess compliance, see:
AGRINFO: *Production, preparation, and export of organic plant products into the European Union: Guidance for operators and groups of operators*

The inspection and certification of operators and groups of operators by a CB, including risk assessment and sampling, follow documented standard procedures (see Regulation 2021/1698, Art. 13).

4.1 Basic control requirements for exporting organic products to the EU

§ Regulation 2021/1698
Art. 9 General provisions

Regulation 2021/2306 ruling on the official controls in respect of consignments of organic products and in-conversion products intended for import into the EU and on the certificate of inspection

Farmers, processors, traders, and exporters (referred to as "operators") and groups of operators (farmer organisations that meet all criteria of Art. 36.1 of the Organic Regulation) must be certified by an EU-recognised CB before they can sell their products as organic/in conversion. Once they have been checked and found to be compliant, they receive a certificate confirming compliance with the EU requirements. All operators and groups of operators in non-EU countries involved in the supply chain, up to the point of exporting the product into the EU, must have a conformity certificate, commonly referred to in non-EU countries as an "operator certificate".

All product consignments intended to be imported into the EU as organic/in conversion must be accompanied by a certificate of inspection (COI), which is checked by customs when the products arrive in the EU. The COI confirms that the products have been verified as compliant with the EU Organic Regulation at all stages.

The COI is issued electronically in the EU TRACES platform by the CB that has inspected and certified the exporter (which may or may not also be the producer and/or processor). This is based on verification of the documents for each consignment, including information on the producers and other actors involved in

handling the organic products. Control bodies may require additional documentation (e.g. a domestic organic transaction certificate) if any operators in the supply chain are certified by other CBs.

4.2 Applying for certification

§ Regulation 2021/1698
Art. 9 General provisions
Art. 10 Checks for the certification of operators or group of operators

The control body is recognised to certify the specific product categories

The list of non-EU-country CBs that are recognised to conduct certification in compliance with the Organic Regulation is published in Annex II of Regulation 2021/1378.[6] This indicates which countries and product categories each CB is recognised for (see more information on product categories in sections 2.2.1 and 2.2.4).

Examples

Morocco: a single company

Growing tomatoes and producing dried tomatoes to be exported as organic into the EU.

The company needs to be certified by a CB recognised in Morocco for category A (unprocessed plants and plant products = fresh tomatoes) and category D (processed agricultural products, for use as food = dried tomatoes).

Drying is considered as a processing activity, even sun-drying, as it substantially alters the initial product (see section 2.3).

Burkina Faso: multiple entities

Involved in production, preparation/processing, and export of dried fruit

The processor who exports organic dried fruits to the EU is certified as an operator for the preparation, storage, distribution, and export of processed (category D) products (dried mango and banana). The producers or groups of operators supplying organic fruit to the processor are certified for category A products (unprocessed plant products such as mango and banana).

Certification by only one control body

An operator or group of operators cannot be certified by more than one CB for the same product category (e.g. unprocessed plant products), but they can be certified by different CBs for different product categories, although this unusual. However, different legal entities in the supply chain may be certified by different CBs. This can complicate the export process as the exporter's CB may require national transaction certificates for the organic products received in order to issue the COI for an export consignment.

Application as an operator, or as a group of operators?

The standard certification process in the EU and elsewhere is that each operator (farm, processor, warehouse, importer/exporter) is certified individually as an "operator" (one legal entity = one operator certificate).

6 Please ensure to always follow links to the most up-to-date consolidated version as the list is updated regularly.

However, many smallholder farmers in low- and middle-income countries have long been certified as a group. Under the previous EU organic regime, various forms of producer group could be certified. The new EU Organic Regulation 2018/848 introduced a very specific definition of a "Group of Operators" (in Art. 36.1), and only a group that meets all elements of this definition can be certified as a "Group of Operators". Put simply, a group of operators must: be composed of members that are all organic and/or in-conversion farmers (all under a maximum farm size or turnover limit); have less than 2,000 members; have legal personality; and operate an internal control system (ICS) and a collective marketing system.

For all applications by farmers or farmer groups, the CB must review whether the applicant wishes and is able to be certified as an operator or as a group of operators. Please see the AGRINFO Guidance for operators and groups of operators for detailed information on the new requirements. It is proposed to revise Art. 36.1 of the Organic Regulation in 2026, see the AGRINFO website for updates.

Application process

Control bodies must provide information on their procedures explaining the certification process, along with the application documents (e.g., application, management plan, questionnaire). The CB must also provide a cost estimate for the annual inspection and certification, to be confirmed with the entity concerned (the operator or group of operators).

Before accepting the certification of a given entity, CBs must make sure they have received all the necessary information, including a signed declaration with a description of:

- the production units and activities for organic production
- measures implemented to ensure compliance with the EU Organic Regulation, including the precautionary measures throughout all stages (production, preparation, distribution).

In addition, a signed certification agreement is needed between the operator and the CB, including all details required by Art. 10d of Regulation 2021/1698, and in line with ISO 17065:2012.

Example

Certification budgets

Certification costs, and the way in which budgets are presented to operators or groups of operators, can vary widely across CBs and countries. The following charges for organic certification in non-EU countries are to be expected.

- on-site inspection time and expenses (travel, per-diem, etc.)
- cost of certification (+ additional costs if other organic standards are included in the audit)
- cost of sampling and residue analysis
- cost of issuing COIs for all consignments to the EU
- (if relevant) charges for additional inspections or measures in the event of suspected non-compliance.

The annual certification costs are either inclusive of these, or charged as additional items.

When receiving an application for certification, the CB reviews it and, if all the required information is available and adequate, and the certification budget has been confirmed, the first on-site inspection will be planned – usually as soon as possible.

4.3 On-site inspection

§ **Regulation 2021/1698**

Art. 9 General provisions

Art. 11 Methods and techniques for controls

Art. 14 Written records

Regulation 2021/771

Art. 2 Official controls of groups of operators (*via Regulation 2021/1698, Art 9.8*)

Frequency of on-site inspections

After the first inspection, all operators and groups of operators in non-EU countries must be inspected at least once a year to verify compliance with Regulation 2018/848 ("physical on-the-spot control").

In addition to the annual physical inspection, CBs need to plan additional risk-based controls (see the list of risk factors in Regulation 2021/1698, Art 9.2). The EU rules require that each CB performs at least 10% of additional inspections every year, and out of all on-site inspections performed, at least 10% must be unannounced (without any prior notice).

Planning the on-site inspection

If operators have several production units, including purchase and collection centres, all such sites, including those used for non-organic products, must be inspected by the CB.

The first inspection is usually scheduled shortly after the application is approved. For the planning of annual inspections, a key factor is the timing of the on-site inspection and/or sampling. This should be carried out at the most appropriate time to verify whether operators comply with the requirements. Inspectors also need to observe the production/process in place both for farming and preparation activities, and planning needs to consider that activities may be seasonal and/or done on request of the client.

The timing of inspections may need to vary over the years to cover different potentially critical periods in the production cycle, so that inspections are not predictable. Operators cannot be inspected by the same inspector for more than 3 consecutive years (Regulation 2018/848, Art 46). All of these factors need to taken into account during planning.

On-site inspection activities

During the on-site inspection, inspectors verify whether the operator or group of operators complies with all applicable requirements. They must verify that preventive and precautionary measures are implemented at every stage of production, preparation, and distribution. If an operator or group of operators handles both organic and non-organic products in the same or different locations, inspectors will verify that organic products are clearly identified and separated during all operations to prevent mixing and contamination.

Operators also need to keep records to prove that they comply with the rules at all stages. This includes, for example, records of preventive measures, application of pest control products and fertiliser, harvest activities, processing, storage, and traceability. Groups of operators must also provide members' lists and reports of internal inspections. All these records are verified during the on-site inspection; if any are unavailable, not updated, or not properly completed, this results in non-compliance.

Inspectors use various methods and information sources to verify whether an operator complies with all organic production rules in line with the CB's documented control procedures. Regulation 2021/1698, Art 11 describes the minimum methods and techniques to be applied, including:

- inspection of production units, equipment, means of transport, premises under control of the operator, fields
- inspection of animals, plants and goods, raw materials, finished products, ingredients, etc.
- check of labelling and advertising material
- check of production documents and traceability records
- interviews with operators and staff
- checking management of non-compliances identified during the previous inspection.

Organic production requirements to be checked during the inspection are indicated in Regulation 2018/848. Also see AGRINFO: Guidance for operators and groups of operators for an overview and explanation of production rules and records, and ICS procedures and records, for groups of operators.

If the inspector suspects the use of unauthorised inputs, or has been instructed to take samples based on the CB's sampling plan, they will also take samples for laboratory testing (see section 4.8).

During each annual on-site control, the inspector must also conduct traceability and mass balance checks (see below). The products and verification period selected for these are based on the risk assessment.

Group of operators: on-site inspection

The inspection and certification of a group of operators has some specific differences from the control of an individual operator. The rules are defined in Regulation 2021/771, Art. 2.

In particular, the on-site inspection of a group of operators focuses primarily on verifying the functioning of the internal control system (ICS):

- verification that the required ICS procedures and records are in place and up to date (see Regulation 2018/848, Art. 36.1 and Regulation 2021/279)
- re-inspection (full-farm inspection) of at least 5% of members to evaluate the quality of the ICS; the inspector must also witness at least one internal inspection
- verification of farm data to check coherence between the reality seen in the field and the list of members, other ICS records such as internal inspection reports, maps, and yield estimates
- evaluation of measures taken by the ICS to address any non-conformities identified during internal inspections
- sampling for residue testing from at least 2% of members
- inspection of purchase centres, central warehouse/processing, and the traceability system from members to sales.

Inspections of groups of operators are more complex than for single operators, and tend to take several days. They require the assessment of internal management systems and organic production rules (farming and preparation) across multiple units (members, purchase centres, central preparation and/or storage units). It is very important that inspectors are adequately trained and qualified for this type of inspection.

Traceability check

Traceability checks (Regulation 2021/1698, Art. 11.4) are mandatory during on-the-spot physical inspections to verify compliance with the EU Organic Regulation. Traceability verifies the origin and flow of a specific batch of product. The following is an example of what to consider for a traceability check.

- Select a specific lot of finished product (using sales invoice or shipping document) and verify the chain of product flows.
- Verification of flow: identify the origin of the raw material. Match the finished product lot to specific incoming purchase invoices or harvest records.
- Check certification status:
    - check if the organic certificate of the supplier was valid at the time of delivery; ensure the certificate covers the specific category of products supplied
    - for harvest records, check if the field was in the organic production unit (for organic product) or in the in-conversion unit (for in-conversion product)
    - in a group of operators, check that all members have organic status.
- Check reception checks for any incoming organic products from suppliers.
- Linking lots: verify that the lot ID on the sales invoice matches the internal production/processing records, and that these records link to the specific lot ID of the incoming raw material. If a lot number changes (e.g. raw material Lot A becomes finished good Lot B), there must be a documented log.
- Where there is both organic and non-organic production, ensure separation of product in time or space by checking production and cleaning records.

Mass balance check

A mass balance check (Regulation 2021/1698, Art. 11.5) is compulsory during the on-site inspection. Using the operator's records (financial, stock, production, and transport records), the objective is to calculate the balance between inputs and outputs over a set period to ensure no non-organic product was sold as organic.

If everything is correct, then:

$$\text{closing stock} = (\text{opening stock} + \text{inputs} + \text{production}) - (\text{outputs} + \text{losses})$$

It is important to compare theoretical stock vs. actual physical stock.

The following is an example of what to consider for a mass balance check.

- Select a product and timeframe for the calculation (e.g. 1 January to 31 March). The end of the period should match the date of the inspection, in order to check if the theoretical stock matches the physical stock.
- Opening stock: the quantity of product in the warehouse at the start of the selected period.
- Input: calculate the sum of all organic raw products purchased/received during the period. For crops, verify that the yield per hectare/total harvest quantity matches the agronomic reality of the land area (compare estimated vs. actual yield).
- Output: sum of all organic products sold/dispatched (during the period).

- Losses: subtract the documented spoilage, processing waste (moisture loss, peeling, etc.), or shrinkage. If processing takes place, apply the technical conversion/processing factor.
- Calculate: theoretical closing stock = (opening stock + inputs + production) – (outputs + losses).
    - Actual closing stock: count the physical stock currently present in the warehouse.
    - Does the calculated remaining stock match the actual physical stock? If there is more stock than expected, it may indicate undeclared purchases or mixing with non-organic. If there is less stock than expected, it may indicate poor record-keeping or undeclared sales.

Closing the on-site inspection

At the end of the on-site inspection, the inspector presents the findings and the inspection report, which must be signed by the operator, or the manager of the group of operators. If non-compliances have been identified, these are listed in the report together with an overview of the corrective actions that must be implemented by the operator or group of operators (with deadlines).

In the event of major and critical non-conformities, the inspector must immediately inform the certification office for further action by the CB. On review of the findings, the certification office may need to impose immediate sanction measures (see sections 4.5 and 4.9).

Control bodies must set up standardised inspection checklists to verify applicable production rules, and inspection report formats for different types of operators or groups of operators. The minimum inspection report content is described in Regulation 2021/1698, Art. 14.

4.4 Control of subcontracted activities

§ Regulation 2021/1698

Art. 10 Checks for the certification of operators or groups of operators

Art. 21 Exchange of information between the European Commission, control authorities, control bodies, and competent authorities

In certain situations, certified operators (A) subcontract part of their activity to third parties (B); examples of this are cool warehousing of harvested products, or contract processing (e.g. drying, milling, oil extraction). Under these circumstances there are two options for certification.

- The operator (third party, B) to whom an activity has been subcontracted by the certified operator (A) is certified organic independently, in its own right; *or*
- The operator (third party, B) to whom an activity has been subcontracted by the certified operator (A), is *not* itself organic certified; instead the certified operator (A) remains responsible for the organic production that takes place at the level of the subcontractor (B). In this case, the CB of the certified operator (A) must verify that activities carried out by the subcontractor (B) comply with EU rules. Subcontractors are listed in the scope of the organic certificate of the certified operator (A).

Operators must inform their CB of any subcontracting of organic production or preparation activities, and provide any relevant information. If subcontractors are certified by another CB, entities must exchange relevant information.

4.5 Certification

§

Regulation 2018/848

Art. 45 Import of organic and in-conversion products

Regulation 2021/1698

Art. 9 General provisions

Art. 10 Checks for the certification of operators or groups of operators

Regulation 2021/1378

Art. 1 Certificate for operators, groups of operators, and exporters in third countries

Annex I Model of the certificate

The CB reviews the results of the on-site inspection and takes a decision on certification, based on its standard procedures and catalogue of measures (often known as "catalogue of sanctions"). Details on the requirements for a CB's catalogue of measures are described in section 4.9. The certification decision is always made by someone other than the person who conducted the on-site inspection.

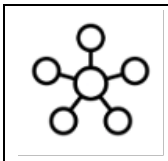
If the organic operator or group of operators' certificate can be issued, the CB issues it electronically in the TRACES system using a standardised format (see Regulation 2021/1378, Annex I). According to the template provided, some elements are mandatory (e.g. activities, category of products, directory of products, list of members in a group of operators) and some are optional (e.g. quantity of products, list of premises).

Control bodies generally send a notification letter to the operator or group of operators with further details on the certified products and areas, together with a final list of required corrective measures, and the approved version of the inspection report.

If the result of the inspection is a suspected or established non-compliance that affects the integrity of organic/in-conversion products (e.g. the presence of a non-authorised substance, or commingling of organic products), measures must be taken immediately as described in detail in section 4.9. These may include:

- provisionally prohibit the sale/delivery/export of the products in question, and ensure that they are kept identified and segregated (quarantined) until the results of the investigation are available
- begin an official investigation to determine the source and cause, and to confirm or eliminate the suspicion of non-compliance
- depending on the outcome of the investigation, either downgrade the product lot in question to non-organic and take additional measures, or release the product to be marketed as organic
- exchange information with the European Commission, EU Member States, and CBs via the OFIS 2 system.

The first certification of an operator or group of operators is particularly important, as products can only be marketed as organic or in-conversion from the first certification onwards.



Additional requirements for certification of a group of operators

The list of members with details on all the holdings, production units, and products is one of the most important documents. Section 10 of the organic certificate will contain the names of members. Many control bodies also send the complete approved members' list with the certification documents to confirm which areas, crops, and yield estimates are covered under the group's certificate for that year.

The group of operator certification is only valid for organic sales through the group's joint marketing system; individual sales by members are not certified organic.

If deficiencies in the setup or functioning of the internal control system (ICS) are identified that affect the integrity of the organic system (in particular, if the ICS fails to detect or address non-compliances by individual members), certification for the entire group must be withdrawn. In evaluating deficiencies (as listed in Regulation 2018/848, Art. 36.2), the CB must also consider the number of non-compliances undetected by the ICS, and the results of any investigation into the cause and nature of the non-compliances.

4.6 Verification of consignments and issue of certificates of inspection

§

Regulation 2021/1698

Art. 16 Verification of consignments intended for import into the European Union

Regulation 2021/2306

Art. 2 Definitions

Art. 3 Verification in third country

Art. 4 Issuance of the certificate of inspection (COI)

Art. 5 Format of the COI and use of TRACES

Art. 6 Official controls on consignments

Annex Part I Certificate of inspection template; Part II Notes for completion

Verification of consignments

Each consignment of organic products intended for export to the EU must be accompanied by a certificate of inspection (COI). The COI is issued by the CB of the operator that carried out the last operation before exporting the product to the EU (e.g. packing, labelling, storing).

To issue the COI, the CB verifies if each consignment complies with the EU organic rules by checking the relevant documents and, based on risk assessment, taking samples.

When controlling the documents, the CB:

- checks the traceability of the product and its ingredients
- verifies that the volume of the product included in the consignment is in line with the mass balance checks
- checks the transport documents and commercial documents (including invoices) of the product

- checks that, for processed products, all organic ingredients are certified and comply with the Organic Regulation
- verifies the certificate, last inspection record, and production plan of the product.

All checks carried out must be recorded. CBs have developed dedicated checklists to track mass balance checks and ensure that the quantities match the availability of the certified product.

To decide whether to take a sample from the consignment, the risk assessment must must take into account the sampling considerations mentioned in section 4.8 of this document; the list of high-risk products (section 4.10); whether there are other operators involved in the supply chain who do not store or physically handle the product; and any other risk factors deemed necessary.

All these checks need to be carried out in order to issue the COI, and hence before the consignment leaves the exporting country.

Issuing the certification of inspection

Once all the checks mentioned above have been carried out, the CB issues the COI in TRACES before the consignment leaves the country of export.

The COI is issued using a specific form (Regulation 2021/2306, Annex Part I). Regulation 2021/2306 also contains notes on how to fill in each section of the COI. The CB is responsible for the information in the first 18 boxes (e.g. exporter data, country of origin, product description including CN code, lot, quantity), and for signing box 18 with the electronic seal. The other information is added in TRACES by the importer and by the competent authority in the EU (e.g. EU customs).

When issuing the COI, the CB also uploads supporting documents into TRACES, for example laboratory reports of samples taken, bills of lading, invoices, packing lists, and other commercial and transport documents.

Once the consignments arrive at customs in the EU, the relevant EU Member State competent authority checks the consignments before release into free circulation. This includes verifying the documents (documentary checks), verifying that the imported product corresponds with the documents (identity checks), and potentially taking samples (physical checks). For all consignments, a documentary check is obligatory, while identity and physical checks are carried out based on risk assessment. If the checks are positive, customs release the imported product for free circulation as organic, and sign the COI in TRACES.

If the consignment is presented without a COI issued in TRACES, or with a COI issued after the consignment left the exporting country, the product will not be cleared as organic. For further information about the activities carried out by the competent authorities in the EU Member States at a border control post or at a point of release for free circulation, see Regulation 2021/2306, Art. 6.

Certificate of inspection user guidelines for organic importers, exporters and control bodies: European Commission: TRACES NT Documentation: Complete and submit

4.7 Maintaining certification (surveillance)

§ Regulation 2021/1698
Art. 9 General provisions
Art. 13 Documented control procedures

The CB ensures that every year all operators and groups of operators receive at least one on-site inspection (physical, on-the-spot) to verify compliance with the requirements of Regulation 2018/848 (see section 4.3 of this document). If they are found to (still) comply, an updated certificate is issued. If they no longer meet the requirements, their certification might be suspended or withdrawn (section 4.5).

In addition to the annual on-the-spot physical inspection, the CB needs to plan additional risk-based controls.

Additional inspections

The EU organic rules require that every year CBs carry out at least 10% of additional controls (on-site inspections). Of all on-site inspections, at least 10% must be unannounced (without prior notice).

Example

On-site and additional inspections

If a control body has 1,000 operators under its control at the end of 2025, then for 2026 it must plan:

- 1,000 on-site inspections (regular annual control)
- 100 additional on-site inspections (1,000 operators × 10% = 100)

The total of on-site inspections in 2026 will be 1,100 (1,000 annual + 100 additional). Of the total inspections, 110 (10%) need to be carried out unannounced (often the additional inspections).

The selection of operators for additional inspections is based on a risk-based approach. Regulation 2021/1698, Art. 9 provides a list of the minimum elements to consider for the risk assessment, for example:

- the type and size of operation (including newly added land parcels) and the structure of the operators, as well as the number of new members joining a group of operators
- the location and complexity of activities or operations
- in the case of a group of operators, results of the internal inspections
- whether the holding includes non-organic or in-conversion production units
- the risk of commingling of products or contamination with non-authorised products or substances
- subcontracting activities
- whether operators or groups of operators have changed their CB
- any information that might indicate non-compliance with the EU Organic Regulation.

Usually CBs work with three risk classes (low, medium, high), and classify operators and groups of operators based on an assessments of each applicable risk factor. Given that risk factors may change over time, it is

common practice to conduct a risk assessment each year. If there are significant changes during the year (for example, an operator is subject to an OFIS notification due to residue findings, or a critical non-compliance was detected during the last inspection), the risk assessment and control plan may need to be adjusted.

Control bodies must have documented procedures that describe how they assess risk, and how they carry out on-site inspection and sampling accordingly (Regulation 2021/1698, Art. 13).

Notification of changes and suspected non-compliance

Certified operators must notify the CB of any significant changes that take place during the year: for example, in the case of a group of operators, if members are suspended or excluded; or in the case of individual operators, if a new production site is added. Depending on the nature of the change, the CB or control authority will decide if an on-site inspection is needed.

Any suspected non-compliance or use of unauthorised substances must also be notified to the CB, in line with Regulation 2018/848, Arts. 27 and 28 and the procedural steps in Regulation 2021/279, Art. 1.

4.8 Sampling and analysis

§ Regulation 2021/1698
Art. 13 Documented control procedures
Art. 12 Sampling, methods used for sampling, and selection of laboratories for sample analysis

Sampling

Sampling forms part of the controls that CBs perform to verify that operators comply with the EU organic requirements. Documented sampling procedures must be in place covering the sampling strategy, procedures and methodology, laboratory analysis, testing and interpretation, evaluation of results, and decisions taken as a consequence.

Sampling is the only task that CBs can delegate to other recognised CBs, or to entities accredited according to ISO 17025 (General requirements for the competence of testing and calibration laboratories). This is especially relevant for CBs that do not have local staff in all the countries where they have clients.

Samples are taken to detect the use of non-authorised products and substances, to identify any production techniques that are not in compliance with the organic production rules, or to detect possible contamination by non-authorised substances. Samples may be taken from the certified products (e.g. from pineapples in a container prior to shipment to the EU), but may also be from tree leaves (to detect possible use of insecticides), or even liquid remaining in a sprayer tank dedicated to organic production.

The EU Organic Regulation establishes a minimum number of samples that must be taken each year by the CB:

- individual operators: at least 5% of the total number of individual operators controlled by the CB
- group of operators: at least 2% of the members of each group of operators.

Selection of the individual operator/group member, or the stage at which samples are to be taken (e.g. purchase centre), is made by the CB based on a risk assessment. When there is a suspicion that unauthorised substances are being used, the CB must take additional samples (above the minimum sampling rate).

Example

Sampling requirements

By the end of 2025, a control body certifies 10 groups of operators (three groups with 1,000 members and seven groups with 250 members) plus 10 individual operators (farm or export) in Côte d'Ivoire; and 40 individual operators in Togo.

The minimum sampling activity for 2026 must be as follows.

- Samples must be taken in all 10 groups of operators:
  - for groups with 1,000 members, samples must be taken from a minimum of 20 members *from each group* (2%)
  - for groups with 250 members, samples must be taken from a minimum of five members per group (2%).
- For individual operators, the CB must sample 5% of all operators under its control. In this example, the CB controls 50 individual operators in total. This means that at least three operators (5% of 50 = 2.5 → rounded up) must be sampled in Togo and/or Côte d'Ivoire.

The samples need to be representative (e.g. of the field, lot, or product stored in bulk), and collected using correct and adequate methodology and tools.[7] The activity must be documented using a sampling form providing all relevant information about the sample taken. It is also useful to include the traceability information of the sample in case further investigations are needed. Training inspectors in correct sampling methods is fundamental.

Laboratories

In most cases, CBs subcontract the analysis of samples to external laboratories. A contract is required for this purpose. It is important to remember that the CB is responsible for all outsourced activities and must maintain a list of all approved laboratories used (ISO 17065:2012, 6.2.2).

According to Regulation 2021/1698, Art. 12, laboratories that are used to analyse for the presence of non-authorised substances (e.g. herbicides such as glyphosate, pesticides such as cypermethrin, genetically modified organisms) must be accredited to ISO 17025:2018 by an International Laboratory Accreditation Cooperation (ILAC) signatory accreditation body. As the CB is responsible for selecting laboratories, it is important that they take these considerations into account. In addition, laboratories must ensure that samples are always tested using the appropriate methods, and within the scope of their accreditation.

A very important requirement is that laboratories testing for pesticide residues must be accredited for gas and liquid spectrometry to cover the list of pesticide residues included in the EU monitoring programme (multiannual control programme).[8] (Chromatography is not foreseen as it cannot identify all relevant substances.) Note also that some substances (e.g. glyphosate, ethylene oxide) may not be included in the

7 The DG AGRI working document on additional official controls on products originating from certain third countries indicates that sampling should be done by using the methods as described in Regulation 691/2013 and Directive 2002/63/EC.

8 Commission Implementing Regulation (EU) 2023/731 concerning a coordinated multiannual control programme of the Union for 2024, 2025 and 2026 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

laboratory's pesticide multi-residue testing package, in which case they need to be requested as an additional analysis (provided the laboratory is accredited for the substances concerned).

For CBs operating in multiple countries, it is recommended that when possible they identify qualified laboratories in each country of operation. This avoids the process of exporting the samples (when there might be issues of customs clearance or phytosanitary problems) and enables the report to be produced more rapidly, which is critical when the results are needed to issue a COI. Responsibility for the chain of custody of the sample remains with the CB.

For more information about sampling, laboratories, and common sources of contamination, see:

BÖL (2024) A Vade Mecum on Official Investigation in Organic Products. Good Implementation Practices for Articles 28 and 29 of Regulation (EU) 2018/848. Bundesprogramm Ökologischer Landbau.

4.9 Measures in the event of non-compliances affecting the organic integrity of products

§

Regulation 2018/848

Art. 27 Obligation and actions in the event of suspicion of non-compliance

Art. 28 Precautionary measures to avoid the presence of non-authorised products and substances

Art. 29 Measures to be taken in the event of the presence of non-authorised products or substances

Regulation 2021/1698

Art. 21 Exchange of information between the European Commission, control authorities, control bodies, and competent authorities

Art. 22 Additional rules on actions to be taken in case of non-compliance

Art. 23 Additional rules on measures in the event of non-compliance

Annex III Organic Farming Information System (OFIS) template

Annex IV Catalogue of measures

Regulation 2021/279

Art. 2 Methodology of an official investigation

Regulation 2021/2306

Art. 10 Information to be provided by a competent authority, control authority, or control body in a third country on suspected or established non-compliances on consignments

Procedure in the event of non-compliances that affect organic integrity

If a CB has a suspicion of non-compliance that affects the integrity of organic/in-conversion products for export to the EU, it must immediately inform the European Commission, other CBs, and competent authorities in EU Member States using the OFIS system. The CB must also inform the national competent authority (NCA) in the country concerned, if one is nominated, via letter or email (Regulation 2021/1698, Art. 21).

Information about a suspected or established non-compliance due to the presence of a non-authorised substance may be provided to the CB by the operator (see operators' obligations in Regulation 2018/848, Arts. 27 and 28) or by other CBs, or may be detected during the CB's own control activities. In each case, the CB immediately (without any delay) performs an official investigation. This will identify the source and the cause of the presence of a non-authorised substance and will verify compliance with the organic production rules.

When a CB receives information from the European Commission (via OFIS) about a suspected or established non-compliance due to the presence of unauthorised substances in a consignment, it must similarly carry out an official investigation. It must then provide feedback to the Commission within 30 calendar days from the date of the notification, informing them of the result of the investigation and the actions and measures taken (using the template provided in Regulation 2021/1698, Annex III).

While an investigation is in progress, the operator is prohibited from selling, delivering, or exporting the products as organic until the investigation is completed.

Official investigation in the event of a suspected or established non-compliance

An investigation must be completed as soon as possible. This means that a CB must be prepared for such an eventuality, with all relevant information to hand (e.g. traceability details of the product, inspection report, production records), and qualified staff available at short notice to carry out a follow-up on-site inspection, take samples, etc..

The methodology to be used by CBs for official investigations due to the presence of unauthorised substances is described in Regulation 2021/279, Art. 2. This indicates the minimum elements that must be determined, including:

- name, lot identification, ownership
- physical location of the organic products concerned
- whether the products are still placed on the market as organic, or used in organic production
- type, name, quantity, and any other relevant information about the unauthorised substances
- stage of production, preparation, storing, or distribution, and the exact location where the unauthorised substances were detected
- whether other operators in the supply chain are affected.

The official investigation must reach a conclusion on the following elements (as a minimum):

- the integrity of organic and in-conversion products
- the source and cause of the presence of unauthorised products or substances
- if the operator has used unauthorised products or substances
- if the operator has taken precautionary measures
- if the operator has addressed previous non-compliances.

Control bodies also prepare a report describing the activities carried out, the outcome of the investigation, and the measures taken.

If the result of an investigation determines that the operator has used unauthorised products, has not taken adequate precautionary measures, or has not addressed previous non-compliances, the product is downgraded and cannot be sold, delivered, or used as organic; the certification status of the operator might also be suspended or withdrawn.

If the results of the official investigation do not show any non-compliance affecting the organic integrity of products, they are allowed to be used and labelled as organic (or in-conversion) products.

For more information about sampling, laboratories, and common sources of contamination, see:

BÖL (2024) A Vade Mecum on Official Investigation in Organic Products. Good Implementation Practices for Articles 28 and 29 of Regulation (EU) 2018/848. Bundesprogramm Ökologischer Landbau.

Requirements for the control body's catalogue of measures

Control bodies/authorities must develop a catalogue of measures (commonly known as a catalogue of sanctions) to be taken in the event of an established non-compliance. The catalogue must be developed and applied based on the requirements specified in Regulation 2021/1698, Annex IV.

The catalogue must include at least three elements.

- List of non-compliances:
  - with reference to the production rules set in Regulation 2018/848
  - mandatory non-compliances listed in Annex IV include e.g. a significant deviation in the mass balance check, falsification of documents, and refusal to provide access to premises and records, or to take samples.
- Classification of non-compliances:
  - non-compliances are classified into three categories – minor, major, and critical – based on the key factors provided in Annex IV, e.g. the potential impact on the integrity of organic products; the ability of the traceability system to locate the affected product in the supply chain; or the implementation of appropriate precautionary measures
  - mandatory non-compliances listed in Annex IV include the corresponding classification, e.g. a significant deviation in the mass balance check is a "major non-compliance"; falsification of documents and refusal to provide access to premises and records or to take a sample are "critical non-compliances".
- Measures to be applied for each non-compliance:
  - Annex IV indicates the type of measures/actions that must be taken for minor, major, and critical non-compliances
  - in the case of a minor non-compliance, the operator must submit an action plan to correct the non-compliance; in the case of a major non-compliance, no reference to organic production can be made in the labelling of the product; in the case of a critical non-compliance, the operator may be suspended or the certificate scope may be restricted.

If non-compliance is established, the CB verifies the origin and extent of the non-compliance (e.g. other operators that might be affected). It also ensures that the operator addresses the non-compliances by implementing corrective action to avoid recurrence of the problem in the future. The operator's risk assessment is reassessed, and the CB must ensure that it carries out increased or systematic controls on the operator.

In all cases, the CB's decisions and justification must be notified in writing to the operator.

4.10 List of high-risk third (non-EU) countries and products

§

Regulation 2021/1698

Art. 8 List of high-risk third countries and high-risk products

Art. 9 General provisions

Art. 12 Sampling, methods used for sampling, and selection of laboratories for sample analysis

Art. 16 Verification of consignments intended for import into the European Union

Regulation 2021/2306

Art. 6 Official controls on consignments

For certain combinations of products and non-EU (third) countries of origin, the EU establishes a list of "high risk products and third countries" (as defined in Regulation 2021/1698, Art 8 and recently updated by Regulation 2025/2651), with rules on additional controls on both consignments and operators/groups of operators involved in the supply chain:

- "high risk consignments": a representative sample[9] of physical checks must be carried out by the CB of the exporter and/or by the competent authorities of the EU Member State where the consignment is customs cleared, based on a specified percentage of consignments. The CB must have complete documentation for traceability of the operators and the product, including transport and commercial documents and invoices.
- Operators involved in the "high risk supply chain":
    - At least two physical on-the-spot inspections must be made per year per operator, one of which must be unannounced (without prior notice).
    - At least one field sample must be taken each year, taken from crops in the field at the most appropriate moment to detect potential use of non-authorised substances. For operators not growing crops, a relevant sample of incoming raw material or intermediate product or processed product must be taken.

These sampling activities do not count towards the minimum sampling rate of 5% of operators under control (see section 4.8).

Samples are analysed for the presence of non-authorised substances in a laboratory that is accredited to ISO 17025:2018 for the methods used, which should include all relevant non-authorised substances and ethylene oxide. The COI should not be issued before the results of the analysis have been received and evaluated. The report must be uploaded in TRACES with reference to the respective COI (see section 4.6).

9 Sampling should be done as described in Regulation 691/2013 and Directive 2002/63/EC.

In July 2026, the EU issued a public consultation on its Draft Regulation proposing the list of high-risk organic and in-conversion products from non-EU countries for 2027. Prior to this, from 2015 onwards, the list has been published as an annual letter and working document.[10] This is sent to recognised CBs in non-EU countries and to EU Member States, specifying the additional control measures to be carried out for the coming year.

Example

Bananas from Ecuador and Peru – additional control measures for a high-risk product in 2025

In 2025, 5% of consignments for bananas had to be sampled in Ecuador and in Peru.

In both these countries, CBs have to perform two physical inspections every year for all EU organic operators producing, preparing, trading, storing, or exporting bananas (one of which has to be unannounced), taking at least one sample of bananas from the fields and one sample from bananas in stock.

4.11 Transfer of operators between control bodies

§ Regulation 2021/1698

Art. 10 Checks for the certification of operators or groups of operators

Art. 21 Exchange of information between the European Commission, control authorities, control bodies, and competent authorities

In the event that an operator changes its CB, before certifying the operator, the new CB must verify relevant information that has to be provided by the previous CB. This includes, for example, the inspection reports from the preceding 3 years, the list of any non-compliances, and any derogations granted (see the complete list in Regulation 2021/1698, Art. 10). These documents are part of the "control file" that the previous CB must provide to the new CB within 30 calendar days of the request.

If the previous CB does not provide the requested information, or if there are any doubts, the new CB must not issue any certificate while waiting for clarifications.

Before issuing the certificate, the new CB must ensure that any non-compliances noted in the report of the previous entity have been addressed by the operator.

There may be temporary disruptions to the export of organic products when operators change CB. For example, the previous CB may stop issuing COIs as soon as the operator applied to another CB, even though the latter has not yet completed the audit and certification process allowing them to begin issuing COIs for export consignments. It is recommended that, wherever possible, the two CBs find agreement on an orderly change from one CB to the other.

10 The "Working document on additional official controls on products originating from certain third countries" and "Letter to control bodies and authorities on the import of organic products from certain countries" can be downloaded from the Commission's Trade in organics webpage.

Operators or groups of operators whose certification has been withdrawn are not entitled to receive certification again for at least 2 years after the decision for withdrawal. Note that the CB is legally obliged to maintain public information about the withdrawal of organic certification of operators and groups of operators for no less than 5 years.

4.12 Database of operators

§	**Regulation 2021/1698** Art. 18 Database of operators and groups of operators

The CB must keep and update an electronic database of operators, providing all details required by Regulation 2021/1698, Art. 18. This database can be an Excel file (it does not need to use complex software). The most important consideration is that the relevant information is present and up to date.

5. FINDING MORE INFORMATION

5.1 The EU organic regulatory system: finding Regulations

The new Organic Regulation (EU) 2018/848 replaced the previous Regulation (EC) 834/2007 that had been in place since 2009. The Basic Act was published in 2018 and came into force in January 2022. It is supplemented by numerous "implementing" and "delegated" acts. "Delegated Amending Regulations" modify either the Basic Act or secondary regulations, and these changes are later incorporated into "consolidated versions" to make it easier to check the rules in application at a given time. However, the original amending regulations remain the legally binding text.

Many secondary acts contain key rules for non-EU producers. It is important to read and comply with these, in addition to the consolidated version of Regulation 2018/848. In particular, Regulation 2021/1698 sets the requirements for recognition of CBs and control procedures in non-EU countries.

For more information on Regulation 2018/848 and the secondary legislation, see New EU Organic Regulation explained. All regulations are available in EUR-Lex in all EU languages, and can be easily found using an internet search for the relevant Regulation number. Following the link to the "current consolidated version" is always recommended, if available. The European Commission also provides an overview of all Legislation for the organics sector with summary of each legal act.

The Commission has produced Frequently Asked Questions on organic rules clarifying some requirements. EGTOP Reports on organic production by the Expert Group for Technical Advice on Organic Production provide technical advice for ongoing development of the organic legal framework.

5.2 Guides, training materials, and information sources

The AGRINFO guidance document *Production, preparation, and export of organic plant products into the European Union: Guidance for operators and groups of operators* explains the new rules that apply to non-EU countries under the compliance regime.

Many organisations – including IFOAM Organics Europe, Better Training for Safer Food (BTSF), FiBL, Anti-fraud Initiative, and others – publish training materials and guides on the EU Organic Regulation and specific topics within the Regulation.

As with this guidance document, such third-party materials can help operators and authorities to better understand what is expected. However, certification in non-EU countries is based solely on the EU's legal texts, and on the assessment of compliance by each recognised CB based on its approved policies and procedures.

Some key resources that may be helpful for operators and groups of operators in non-EU countries are listed below.

Training materials, guides, and other information sources

AGRINFO: *New EU Organic Regulation explained* (2023). In addition, use AGRINFO's Search page > Select topics and tick "organic production" to see the most up-to-date information and explanations of recent changes.

FiBL: *Training Handbook: The New EU Organic Regulation (2018/848) for Producer Groups* (2024).

Naturland: *Internal Control Systems* – ICS Manual and ICS Infosheet.

BÖL: *A Vade Mecum on Official Investigation in Organic Products. Good Implementation Practices for Articles 28 and 29 of Regulation (EU) 2018/848* (2024). Report on common contaminants, laboratory analysis, potential sources and pathways of contamination, and official investigation in organic products according to the new EU Regulation.

ANNEX I EU DEFINITIONS – ORGANIC CONTROL WITHIN THE EU

For explanation of some of these terms in the non-EU organic control context, see section 1.2.

Term	Definitions in Regulations 2018/848 (Art. 3), 2017/625 (Art. 3), and 2021/2306 (Art. 3)
Competent authorities	As defined by Regulation 2017/625 (the Official Controls Regulation), a competent authority is: (a) the central authorities of a Member State responsible for the organisation of official controls and of other official activities (b) any other authority to which that responsibility has been conferred (c) where appropriate, the corresponding authorities of a third country.
Control authority	As defined by Regulation 2017/625, a control authority is a public administrative organisation for organic production and labelling of organic products of a Member State to which the competent authorities have conferred, in whole or in part, their competences in relation to Regulation 2018/848, or an authority recognised by the European Commission or by a third country recognised by the European Commission for the purposes of carrying out controls in third countries for the import of organic and in-conversion products into the EU.
Control body	A delegated body as defined by EU Regulation 2017/625 (a separate legal person to which the competent authorities have delegated certain official control tasks or certain tasks related to other official activities), or a body recognised by the European Commission or by a third country recognised by the European Commission for the purposes of carrying out controls in third countries for the import of organic and in-conversion products into the EU.
Consignment	A consignment of products intended to be placed on the market within the EU as organic products or in-conversion products; it means a quantity of products under one or more Combined Nomenclature codes, covered by a single certificate of inspection, conveyed by the same means of transport and imported from the same third country.
Documentary check	The examination of the official certificates, official attestations and other documents, including documents of a commercial nature, which are required to accompany the consignment.
Identity check	A visual inspection to verify that the content and labelling of a consignment, including the marks on animals, seals, and means of transport, correspond to the information provided in the official certificates, official attestations, and other documents accompanying it.
Physical check	A check on animals or goods and, as appropriate, checks on packaging, the means of transport, labelling, and temperature, the sampling for analysis, testing, or diagnosis, and any other check necessary to verify compliance.
Group of operators	A “group of operators” is defined in Art 36.1 of Regulation 2018/848.
Operator	The natural or legal person responsible for ensuring that the Organic Regulation is complied with at every stage of production, preparation, and distribution under that person’s control.
Integrity of organic or in-conversion products	The fact that the product does not exhibit non-compliance which: (a) in any stage of production, preparation, and distribution affects the organic or in-conversion characteristics of the product; or (b) is repetitive or intentional.
Non-compliance	Non-compliance with Regulation 2018/848 or non-compliance with the Delegated or Implementing Acts adopted in accordance with this Regulation.
Preventive measures	Measures that are to be taken by operators at every stage of production, preparation, and distribution in order to ensure the preservation of biodiversity and soil quality; measures for the prevention and control of pests and diseases; and measures that are to be taken to avoid negative effects on the environment, animal health, and plant health.

Term	Definitions in Regulations 2018/848 (Art. 3), 2017/625 (Art. 3), and 2021/2306 (Art. 3)
Precautionary measures	Measures that are to be taken by operators at every stage of production, preparation, and distribution to avoid contamination with products or substances that are not authorised for use in organic production in accordance with the Organic Regulation, and to avoid the commingling of organic products with non-organic products.
Product categories	EU product categories (as defined in Regulation 834/200): A: unprocessed plants and plant products, including seeds and other plant reproductive material B: livestock and unprocessed livestock products C: algae and unprocessed aquaculture products D: processed agricultural products, including aquaculture products, for use as food E: feed F: wine G: other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories (e.g. cotton, wool, essential oils, plant-based traditional herbal preparations).
Stage of production, preparation, and distribution	Any stage from the primary production of an organic product through its storage, processing, transport, and sale or supply to the final consumer, including, where relevant, labelling, advertising, import, export, and subcontracting activities.
Traceability	The ability to trace and follow food, feed, or any product referred to in Art. 2(1) of the Organic Regulation, and any substance intended or expected to be incorporated into food, feed, or any product referred to in Art. 2(1), through all stages of production, preparation, and distribution.
Review audit	The inspection of operators or groups of operators to verify compliance with the standard control and risk assessment procedures of the control authority or control body and to verify its effectiveness, taking into account the evolution of the operators' situation from the last inspection of the control authority or control body.
Witness audit	The evaluation of the performance of the physical on-the-spot inspection carried out by an inspector of the control authority or control body.
Preparation	The operations of preserving or processing of organic or in-conversion products, or any other operation that is carried out on an unprocessed product without altering the initial product, such as slaughtering, cutting, cleaning, or milling, as well as packaging, labelling, or alterations made to the labelling relating to organic production (Regulation 852/2004). Preparation may also include processing activities.
Processing	Processing is any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion, or a combination of those processes; this includes the use of substances (allowed ingredients according to Arts 24 and 25 of Regulation 2018/848) but does not include packaging or labelling operations.
Processed products	Processed products means foodstuffs resulting from the processing of unprocessed products (Regulation 852/2004).
Unprocessed products	Foodstuffs that have not undergone processing; includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen, or thawed, irrespective of packaging or labelling operations.

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