New EU Organic Regulation explained

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EU Organic Regulation and new rules on organic production and labelling – explained

Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

Update

The Organic Regulation (EU) 2018/848 is the basic Act that lays down the EU rules on organic production and labelling of organic products. It revised and strengthened the controls system, trade regime and production rules, overhauling a regime that had been in place since 2007. It has the stated aims of encouraging the sustainable development of organic production in the EU, guaranteeing fair competition for EU farmers and operators, preventing fraud and unfair practices, and improving consumer confidence in organic products. While the focus is the EU organic sector, it also has significant implications for third countries. Many rules have been clarified, removing inconsistencies and ambiguities, but also adjusted to align third countries with EU organic practices.

Background

In 2007, the EU introduced Regulation (EC) 834/2007 setting out the principles, aims and overarching rules of organic production and labelling. This was complemented by several Commission Implementing Acts on the production, distribution and marketing of organic goods.

After several years of intense negotiations, on 28 June 2017 the European Parliament and the Council reached agreement to overhaul and replace those existing rules. The stated aim of the new Regulation (2018/848) is to encourage the sustainable development of organic production in the EU, guaranteeing fair competition for farmers and operators, preventing fraud and unfair practices, and improving consumer confidence in organic products. The original date of application was 1 January 2021, but this was postponed to 1 January 2022.

The first draft was introduced by the European Commission in 2014, but was not published in the Official Journal until 2018. This long process reflects the often contentious negotiations and the wide range of stakeholder opinions. The EU has aimed to achieve a balance between meeting the fundamental principles of organic production, and maintaining flexibility for operators. However, there are several issues on which it has been difficult to find a compromise acceptable

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to all parties.

This overhaul of the EU Organic Regulation accompanies the EU's Farm to Fork Strategy and Organic Action Plan, major new policy initiatives under the European Green Deal with its target of at least 25% of EU agricultural land under organic farming by 2030.

Impacted products

organic products

What is changing?

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

It brings in a fundamental change to the regulatory approach, moving from the principle of equivalence to the principle of conformity. The earlier Regulation (EC) 834/2007 recognised that organic goods could be produced in ways that were different but equivalent in terms of their outcome and alignment with organic principles. Under the new Regulation, this changes to a system of compliance. Producers in non-EU countries that do not have equivalence recognised in a trade agreement with the EU or are not recognised as an equivalent country under Regulation 834/2007 will have to conform with exactly the same set of rules as those in the EU. This is intended to be fair for all producers, as everyone will have to meet the same standards.

The Commission webpage Legislation for the organics sector lists (currently) 32 items of secondary legislation (Delegated and Implementing Acts) in application, covering trade, production, labelling and controls.

In July 2023, the European Commission issued FAQs on the provisions of Regulation (EU) 2018/848 and its secondary legislation. The FAQs summarise replies that have been prepared in response to specific questions received by the Commission. They include helpful clarifications on the composition and functioning of farmer groups, among others. The document will be regularly updated and published on the Commission's website – see Organics at a glance.

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Trade rules

Under Regulation 834/2007, there were two options for recognition and trade in organic produce. The first is the equivalence agreements, whereby an administrative arrangement was made between the EU and a third country involving mutual recognition of equivalence of their organic standards. The following were recognised as "equivalent countries": Argentina, Australia, Canada, Chile, Costa Rica, India, Israel, Japan, Republic of Korea, Switzerland, Tunisia, USA and New Zealand. In these countries, inspection and certification of organic exports are carried out by the national competent authorities.

In almost all other countries, inspection and certification have been the responsibility of "control bodies". These are independent entities appointed by the European Commission to verify that organic producers in their area of responsibility follow standards and control measures equivalent to those in the EU. Each of these has an organic standard that is recognised and authorised as being equivalent and in line with organic principles. There are around 60 recognised control bodies around the world, each operating equivalent standards. They may vary in content, as the current system provides flexibility for these standards to be adapted to local circumstances. EU operators objected to this approach, claiming that it gave an unfair advantage to producers in third countries.

This changes under the new EU Organic Regulation 2018/848. There will still be two possible systems for importing organic products from outside the EU, but they are no longer based on equivalence:

- Trade agreements. All third countries previously recognised as equivalent must renegotiate the terms as bilateral trade agreements.
- Control bodies. In the absence of a trade agreement, a list of recognised EU and non-EU control bodies/authorities will be authorised to carry out inspections and certifications in third countries.

Secondary legislation details how the new trade rules will operate, the procedures by which trade agreements are negotiated, and how control bodies are authorised. Of particular relevance for AGRINFO partners are:

- Delegated Regulation (EU) 2021/2306 with rules on issuing certificates of inspection (COI), the format of the COI, use of TRACES, official controls on consignments, and special customs procedures.
- Delegated Regulation (EU) 2021/2305 with rules on when organic and in-conversion products are exempted from official controls, and on the place of official controls. Important to note is the change of EU Point of Entry. Organic produce that requires a phytosanitary certificate will have to pass through Border Control Points (as opposed to Border Control Posts), with stricter controls and a limited number of EU ports of entry.

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- Implementing Regulation (EU) 2021/2307 on documents and notifications required for EU import. This includes amended provisions for the COI; COI and split consignments; rules for prior notification before arrival (via TRACES) with the minimum time (1 working day before arrival); and transitional rules for paper COIs.
- Delegated Regulations (EU) 2021/1697 on the criteria, and 2021/1698 on procedural requirements, for recognition of control authorities and control bodies, and their operation. Implementing Regulation (EU) 2021/2325 establishes the list of third countries and control authorities/control bodies. Of importance are the transitional periods (see timeline).
- Delegated Regulation (EU) 2021/1342 on the procedure during the transitional period for control bodies/control authorities. Until the expiry of their current recognition, organic products imported into the EU must be produced in accordance with current production rules and control arrangements (Regulations (EC) 834/2007, (EC) 889/2008 and (EC) 1235/2008). Control bodies will continue to audit according to equivalence rules until they are officially recognised.

Production and labelling rules

Chapter III of Regulation (EU) 2018/848 lays down the general production rules, and Annex II gives the detailed rules. These cover conversion; plant production; plant reproductive material; collection, packaging, transport and storage; and authorisation of products and substances. Of particular relevance to AGRINFO partners are:

- Delegated Regulation (EU) 2020/1794 which includes derogations on the use of in-conversion and non-organic plant reproductive material, and sets conditions for use of non-organic material when organic material is not available. Implementing Regulation (EU) 2020/464 lays down rules on documents needed for the retroactive recognition of periods for the purpose of conversion. Delegated Regulation (EU) 2020/2146 specifies exceptional organic production rules, including conditions and derogations (exceptions) in the case of catastrophic events.
- Delegated Regulation (EU) 2021/642 outlines certain information to be provided when labelling organic products, including compound feed. Delegated Regulation (EU) 2021/716 gives organic production rules on sprouted seeds and chicory heads, on feed for certain aquaculture animals, and on aquaculture parasite treatments.
- Implementing Regulation (EU) 2021/1165 authorises products and substances for use in organic production and establishes their lists, including the following Annexes:

Annex I: Active substances contained in plant protection products authorised for use in organic production. Substances listed in Annex I must be approved in the “horizontal” EU pesticide legislation (Regulation (EC) 1107/2009), and can only be used according to the conditions of use approved in the EU.

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Annex II: Authorised fertilisers, soil conditioners and nutrients.

Annex IV: Authorised products for cleaning and disinfection.

Annex VI: Products and substances authorised for use in organic production in certain areas of third countries (Regulation (EU) 2018/84, Art. 45(2)). Substances can be added to Annex VI for use in third countries when there are justified reasons (e.g. for a pest not present in the EU). Regulation (EU) 2021/1165 (Art. 10) outlines the procedure to obtain these authorisations. Listed substances do not need to be approved for use in the EU, but must comply with EU pesticide maximum residue limits under Regulation (EC) 396/2005.

Control rules

The organic control rules are laid out in Regulation (EU) 2018/848, Art. 38. Details on inspection and certification requirements are described in para. 3. Operators and groups of operators (with some exceptions) must be subject to an audit, including a physical on-the-spot inspection at least once a year. Audits may be less frequent (up to a maximum of 24 months) if the operator or group has been assessed as low risk of non-compliance, and previous inspections have revealed no non-compliances in the past 3 consecutive years.

Delegated and Implementing Acts on certification and controls include: checks on production and operator groups; controls and other measures on traceability and compliance; and certification/ certificate details. Of particular relevance for AGRINFO partners are:

- Delegated Regulation (EU) 2021/715 on requirements for groups of operators, including the internal control system (ICS); the responsibilities of group members, the ICS manager and ICS inspectors; and the list of situations considered deficiencies of the ICS.
- Delegated Regulation (EU) 2021/1006 introducing the model certificate of compliance for operators and groups of operators, and Delegated Regulation (EU) 2021/2304 with rules on issuing complementary certificates on the non-use of antibiotics in animal products for export.
- Delegated Regulations (EU) 2021/1691 introducing detailed requirements for record keeping by operators in organic production, and 2021/771 laying down specific criteria and conditions for documentary checks, including rules on traceability and mass balance checks during official controls, and additional requirements concerning groups of operators.
- Implementing Regulation (EU) 2021/279 on controls and other measures ensuring traceability and compliance. This includes rules on the composition and maximum size of a group of operators; documentary and record keeping requirements for the ICS; percentage of controls and sampling; mandatory use (by competent authorities) of the Organic Farming Information System (OFIS) for exchange of information with the Commission; and a transitional period (up to 1 January 2025) for groups of operators in third countries with respect to maximum group size.
- Implementing Regulation (EU) 2021/2119 on records and declarations required from operators and groups of operators, and on the means for issuing certificates in third

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countries. This includes detailed provisions on issuing electronic certificates; record-keeping requirements by operators and groups of operators; and declarations and other communications to be made available to control authorities/control bodies.

Group certification and sampling procedures

In response to concerns in the EU about the quality of group certification, particularly in the case of very large producer groups, major changes have been made in the new Regulation (EU) 2018/848. The most significant are (Art. 36):

- Certification of farmer groups is longer restricted to low-income countries, but can take place in any third country or within the EU.
- Group members must be farmers (though they may also be engaged in processing, preparing or marketing food or feed). Cooperatives, federations of cooperatives, and processors/ exporters with affiliated farms will no longer be accepted as certifiable legal group entities.
- Maximum size of a group will be 2,000 members (Regulation (EU) 2021/279, Art. 4).
- There will be strict limits to the scale of operation of group members. Each holding must be 5 ha or less (0.5 ha for greenhouses). Alternatively, the individual certification cost of each member must be more than 2% of their turnover or standard output from organic production, and they must have a turnover of organic production of no more than €25,000, or their standard output from organic production must be no more than €15,000 per year.
- The farmer group must have its own legal entity.
- Each group must operate a joint marketing system.
- All farmers within the group must be operating in the same geographical location.
- Each group must implement its own ICS, with a nominated person or body responsible for ensuring that all members of the group are in compliance.

Changes have also been introduced on the level of controls and sampling that will be done under third party inspections of farmer groups (Regulation (EU) 2021/279, Art. 7(e)). For every group, a minimum of 5% of its members (and not fewer than 10) must be subject to third party inspection every year. Where a group has 10 members or fewer, all members must be inspected every year. Produce sampling and laboratory analysis must be applied to 2% of the total number of members.

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Why?

An overhaul of the EU organic rules was considered justified for several reasons. Many existing provisions were over 20 years old and no longer fit for purpose given the major changes that have taken place in organic production and trade. The “patchwork of rules and derogations in place did not give sufficient certainty and security to this highly important sector of European agriculture” (European Commission 2017).

This lack of clarity led to a growing number of requests for legal interpretations, and to inconsistencies in the application of the rules between Member States. There was also an increasing risk of formal complaints on the grounds of unfair competition.

The new regime introduced one set of rules covering the whole EU organic sector, applying to both EU farmers and non-EU farmers exporting to the EU. It replaced the 60+ equivalent standards previously in operation, with the aim of ensuring greater fairness for EU organic farmers, and assurance for consumers.

Timeline

The new Organic Regulation was applied on 1 January 2022, with varying transitional periods.

Existing recognition of equivalent countries will expire on 31 December 2026. Existing recognition of equivalent control bodies will expire on 31 December 2024 (control bodies/control authorities can apply for accreditation against the new regulation at any time between 1 January 2022 and 31 December 2024).

Control authorities/bodies continue to audit according to the equivalence rules until they are officially recognised under the new Regulation.

What are the major implications for exporting countries?

While the focus of the new Regulation is the EU organic sector, it also has significant implications for third countries. Rules have been clarified, removing inconsistencies and ambiguities, but also adjusted to align third countries with EU organic practices. The aim is to strengthen the integrity of organic production, especially for imported products, by setting the same rules for operators in EU and worldwide. However, there may be challenges for operators in third countries as they adapt to the new rules.

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Trade rules

The shift from a system of equivalence to a system of compliance creates a uniform set of requirements and standards. This may limit the possibility of adapting requirements to locally specific conditions and organic practices.

Production rules

The loss of the equivalence provision also has implications for production practices, if these primarily correspond with European conditions. For example, substances approved for use as plant protection products (Implementing Regulation (EU) 2021/1165, Annex I) may not cover needs in countries where pests, pest pressure, and socio-economic and agroecological conditions are very different from those in Europe. The provision (Annex VI) to include products and substances authorised for use in certain areas of third countries addresses this, but there are concerns about the timescale and complexity involved in the process, and the potentially limited duration and geographical scope of each application.

Farmer groups and sampling

Concerns have been expressed about the potential impact of the new rules on farmer groups and sampling procedures (e.g. Fairtrade International 2020). Historically, provisions for group certification have been very important in enabling small-scale farmers in low-income countries to access the EU organic market.

Changes to group certification will potentially create additional technical, administrative and cost burdens. Groups with more than 2,000 members will have to split into two or more groups. Farmers who do not meet the criteria because they exceed the farm size or financial limits will have to leave a group and be individually certified. Many small-scale growers (e.g. in organic fruit and vegetable production) currently operate in groups run by processors/ traders, and benefit from their administrative and technical support. These will also have to separate and run their own independent groups.

Whenever new groups are established, they must create and register as a separate legal entity. The legislation does not stipulate what a legal entity means, recognising that this will vary according to the regulations in each third country. New groups must put in place and implement their own Internal Control System (ICS), and nominate a person or body responsible to manage it. Groups of over 400 will face increased certification costs due to the new rules on external controls.

The Commission recognises that there will be significant administrative, legal and structural changes with regard to the maximum size of the group, so there is a transition period for operators to adapt to the new requirements. Groups that were already certified on 1 January 2022 have 3 years to comply with changes to group size (Regulation (EU) 2021/279, Art. 10). This means that they must have their own legal entity and ICS by 1 January 2025.

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There is no specific reference to transitional provisions for the processor/ trader groups that must reorganise. While their control body continues to operate under the equivalence system (see timeline), a group can continue to operate as a processor/ trader group (potentially to December 2024).

Resources

Online resources from the European Commission:

- Legislation for the organics sector
- The new organic Regulation. Press release, 20 November
- Organics at a Glance including FAQs

Fairtrade International (2020) Changes to EU organic rules threaten farmers' livelihoods.

Organic Farming Information System (OFIS)

Sources

Regulation (EU) 2018/848 (New EU Organic Regulation)

Visit the AGRINFO website to view the latest AGRINFO Update newsletters and search the database.

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