

Switching from equivalence to compliance according to the new EU Organic Regulation (Reg. (EU) 2018/848, Reg. (EU) 2021/1698)

A new EU Organic Regulation has come into force in the EU member states on 01.01.2022, while for operators in third countries, there will be a transitional period until 31.12.2024 to switch to certification according to the new regulation. The amended regulation aims at guaranteeing fair competition to producers, prevent fraud and increase consumer confidence in organic products. It consists of the basic act Regulation (EU) 2018/848, as well as secondary legislation (so called delegating and implementing acts). An overview on the applicable Regulations may be found on the website of bio.inspecta in the document [Overview New EU Organic Regulations](#).

1. Transition period for switching to the new regulation for operators in third countries

All clients of bio.inspecta, currently certified according to the bi-OS will switch to certification under the new regulation. From first January 2024, inspections will be done according to the new Regulation. Until then, COIs are issued according to Article 57 of Regulation (EU) 2018/848, as it is stated in the COIs in TRACES, box 18:

This is to certify that this certificate has been issued on the basis of the checks required under Commission Delegated Regulation (EU) 2021/1698 (2) for compliance (Article 46 of Regulation (EU) 2018/848) or Commission Delegated Regulation (EU) 2021/1342 (3) for equivalence (Article 47, 48 or 57 of Regulation (EU) 2018/848) and that the products designated above are in line with the requirements of Regulation (EU) 2018/848.

2. What are the major changes in the new EU regulation?

2.1 General provisions

- Except for countries with trade agreements, the new regulation is binding also for third countries. Certification will no longer be according to equivalent standards by certification bodies (e.g. the bi-OS), but according to the EU regulation.
- The range of products that may be certified is increased. Added are e.g., salt, beeswax, cotton, wool, silkworm cocoons, essential oils (also those not intended for human consumption).
- An operator or a group of operators may not obtain a certificate from more than one control body in relation to activities regarding the same category of products (e.g. production/processing).
- The new regulation is more specific about and gives much more importance to the duty of certified operators to take precautionary measures at every stage of production, preparation and distribution to avoid contamination and commingling with products or substances not authorized. Operators must develop a quality assurance system with measures that are proportionate and appropriate to identify and avoid risks of contamination and commingling. The measures must be regularly reviewed and adjusted.
- Operators must have a system of self-control (e.g. quality management system). Control bodies must control the system of certified operators and assess its effectiveness.

2.2 Plant production

2.2.1 Soil bound crop production

- The new regulation is more specific about requirements on soil bound crop production. Crop cultivation must be done in living soil or in soil that is mixed or fertilized with materials and products that are allowed in organic production in connection with the subsoil and bedrock (excepted are those plants which are naturally grown in water). Hydroponic production remains prohibited.
- Culture in pots is permitted for the production of ornamentals and herbs to be sold together with the pot to the final consumer and for growing seedlings or transplants in containers for further transplanting.

2.2.2. Seeds and other plant reproductive material

- Plant reproductive material (including seeds and vegetative propagating material such as cuttings, seed potatoes, rootstock) must be of organic origin, in case of proven unavailability in the country of the certified operator, a derogation to use conventional seeds may be granted by the control body (as before, approval for the derogation must be obtained before sowing). Seeds of in-conversion quality may be purchased. In such case, evidence must be obtained that no organic material is available. The evidence will be verified during inspection. No derogation is possible for seedlings with a cultivation cycle completed

in one growing season (from the transplantation of the seedling to the first harvest of the product). Such seedlings must be organic.

2.2.3 Soil management and fertilization

- It is now compulsory that a crop rotation must include leguminous crops as the main or cover crop for rotating crops and other green manure crops (grassland and perennial forage are exempted from this obligation).
- For perennial crops other than forage or greenhouse crops, short-term green manure crops and legumes must be used. In addition, the soil fertility of these areas must be maintained and increased through the diversity of cultivated plants.
- In all cases, soil fertility shall be maintained by the application of livestock manure or organic matter, both preferably composted, from organic production.
- As before, external fertilizers and soil conditioners may only be used if the nutrient requirements of the plants cannot be covered by measures of tillage and cultivation practices, crop rotation, application of livestock manure or organic matter.
- The allowed substances are listed in Reg. (EU) 2021/1165, Annex II. The list is very similar to the bi-OS Annex I.

2.2.4 Plant protection

- It is now defined that besides the listed active substances, all safeners, synergists, co-formulants and adjuvants according to Reg. (EC) 1107/2009 (general plant protection law of the EU) are allowed.
- More emphasis is given to 'preventive measures'. Production shall include the principle of maintenance of plant health by preventive measures, in particular the choice of appropriate species, varieties or heterogeneous material resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and protection of the natural enemies of pests. Only if preventive measures are not sufficient to protect the crop, allowed substances as listed in Reg. (EU) 2021/1165, Annex I may be used. The list is the same as the bi-OS Annex II.

2.2.5 Cleaning and disinfection

- A list of products for the cleaning and disinfection of buildings and installations used for plant production, including storage on an agricultural holding is planned to be published in 2024. Until then, there are no changes in the bio.inspecta procedure.

2.3 Groups of operators

2.3.1 Structure of the group

- Farmer groups must have an own legal personality.
- The requirements for a farmer to become a member are as follows: The individual certification cost represents more than 2% of each member's turnover and whose annual turnover of organic production is not more than EUR 25000 or who has a holding of maximum:
 - 5 hectares;
 - 0,5 hectares, in the case of greenhouses;
 - 15 hectares, exclusively in the case of permanent grassland.
- The maximum size of a group of operators shall be 2000 members. Larger groups will need to create new groups (maximum 2000 members, individual legal personality). Groups of operators certified according to the previous regulation for which important administrative, legal and structural changes are necessary with regard to the maximum size of the group of operators have a transition period until 31.12.2025.
- A member of a group of operators shall register to only one group of operators for a given product, also where the operator is engaged in different activities (production, processing) related to that product.
- A group of operators may not obtain a certificate from more than one control bodies in relation to activities regarding the same category of products, including cases in which that group of operators operates at different stages of production, preparation and distribution.

2.3.2 Tasks of ICS manager and ICS inspectors

- The tasks of an ICS manager and ICS inspectors are now clearly defined in the Regulation. ICS manager and ICS inspectors may be a member of the group, but the ICS manager may not be an ICS inspector.

2.3.3 Notification of the group to the control body

- The ICS manager shall immediately notify the control body in case of:
any suspicion of major and critical non-compliance;
any suspension or withdrawal of a member or a production unit or premises, including purchase and collection centres, from the group;
any prohibition of the placing on the market of a product as organic or in-conversion, including the name of the member or members concerned, the relevant quantities and lot identification.

2.3.4 ICS group controls by the control body

- Control bodies must at least annually visit 5% of the members of a group and take annually at least sample for analysis from 2% of the members.

2.3.5 Measures in case of the ICS not being effective

- If deficiencies in the setup or functioning of the ICS system are found, in particular as regards failures to detect or address non-compliance by individual members of the group affect the integrity of organic products, the certificate of the group must be withdrawn.

2.4 Processed food

2.4.1 Engineered nanomaterials

- Prohibition of intentionally engineered nanomaterials (particle size <100 nm). Naturally occurring nanomaterials are not concerned.

2.4.2 Non-organic agricultural product ingredients

- The list of non-organic agricultural ingredients allowed has been reduced to very few products (as before, these products may be only up to 5% of total agricultural ingredients in the certified product). The products are listed in Reg. (EU) 2021/1165, Annex V, Part B.

2.4.3 Flavours

- The kind of conventional flavours allowed is more restricted. Allowed are products labelled as natural flavouring substances and natural flavouring preparations. The flavouring part of the flavour must be obtained exclusively or by at least 95% (w/w) from the source material used in the name, e.g. «natural lemon flavour» from lemons. The max. 5% not obtained from the source material in the name can only be used for standardisation or to give a specific note.

2.4.4 Cleaning and disinfection

- A list of products for the cleaning and disinfection in processing and storage facilities is planned to be published in 2024. Until then, there are no changes in the bio.inspecta procedure.

2.5 Livestock

2.5.1 Scope

- Cervines and rabbits have been added to the certifiable species.

2.5.2 Herbivores

- Minimum requirement for feed from the own farm in the ration will increase from 60% to 70% as of 01.01.2024.
- Externally purchased maximum in-conversion year 2 feed allowed in the ration is reduced from 30% to 25%.
- If animal feeding with maternal milk is not possible, the milk replacer must be 100% organic.

2.5.3 Poultry

- Non-organic pullets purchased must be <3 days old (no more option for purchasing pullets <18 weeks).
- Minimum requirement for feed from the own farm in the ration increases from 20% to 30%.
- Externally purchased maximum in-conversion year 2 feed allowed in the ration is reduced from 30% to 25%.
- For poultry for fattening other than Gallus gallus: complete physical separation of compartments from the floor to the roof is required. For Gallus gallus: compartments must be separated by means of solid or semi-solid partitions, nets or meshes. Open air areas of each single compartment shall be separate in order to ensure that birds from different flocks cannot mix.
- It is still possible to convert open air area in just 1 year, but no longer a conversion in 6 months is possible.

- A wide variety of plants, trees and shrubs must be distributed throughout the area.
- The open-air area should not extend beyond 150 m from the nearest entry/exit pop-hole. An extension of up to 350 m will be acceptable if the space has enough shelters from weather and predators, distributed at regular intervals (minimum 4 shelters/ha).
- The new regulation defines the use of verandas. Verandas are defined as an additional, roofed, uninsulated, outdoor part of a building intended for poultry, the longest side usually being equipped with wire fencing or netting, with an outdoor climate, natural and, where necessary, artificial illumination, and a littered floor. The veranda is not an open-air area. It is therefore not considered in the calculation of stocking densities and minimum outdoor areas. For fattening poultry, the surface of the veranda is not to be considered in the total usable surface of the poultry houses (1600 m² maximum)

2.5.4 Beekeeping

- Maximum allowed purchase of non-organic animals to apiaries is increased from 10% to 20% per year of non-organic queens and swarms.
- Moving of hives to non-conforming areas for pollination purposes is no more allowed. Moving of hives to non-conforming areas may only be possible based on a derogation granted by the control body in the event of catastrophic circumstances that drastically reduce the sources of nectar and pollen and threaten the survival of the colony (earthquakes, fires, etc.).

2.6 Control System

2.6.1 Official investigation

- As before, in case of a suspicion about unallowed substances in organic products, an investigation must be conducted. As before, marketing products concerned and their use in organic production shall be provisionally prohibited until end of the investigation. New, this is called official investigation. If a control body receives substantiated information about unallowed substances in organic products, it must immediately do an official investigation. The investigation must find the source and the cause of the unallowed substance.
- The new regulation describes in more detail in which cases a product shall be decertified. This is the case if the investigation finds the following:
 - Active application of unallowed substances
 - No sufficient precautionary measures (not proportionate and appropriate)
 - Certified operator did not take measures regarding previous non-compliances identified by the control body

2.6.2 Non-compliances and catalogue of measures

- The sanction categories, categorizing the severity of non-compliances according to the bi-OS will be replaced by a catalogue of measures, with a classification of non-compliances as minor, major and critical.

For any questions, please do not hesitate to contact us (contact@bio-inspecta.al).