

In accordance with Article 2 (e) of the Commission Regulation (EU) 2021/1698, the translation of the production rules and control measures set out in Regulation (EU) 2018/848, and the delegated and implementing acts adopted pursuant to it in languages that are understandable for the contracted operators in the third countries for which the control authority or control body requests recognition, Başak Ekolojik prepared this document

Since Başak Ekolojik operates in the following product categories, this document has been prepared in accordance with the relevant products, it does not contain information about product categories that are not within the scope of Başak Ekolojik.

- A: unprocessed plants and plant products, including seeds and other plant reproductive material;  
D: processed agricultural products, including aquaculture products, for use as food;  
G: other products listed in Annex I to Regulation (EU) 2018/848 or not covered by the previous categories.

## DEFINITIONS

**Farmer;** means a natural or legal person, or a group of natural or legal persons, regardless of the legal status of that group and its members under national law, who exercises an agricultural activity.

**Holding;** means all the production units operated under single management for the purpose of producing live or unprocessed agricultural products, including products originating from aquaculture and beekeeping, referred to in point (a) of Article 2(1) or products listed in Annex I other than essential oils and yeast.

**Precautionary measures;** means 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 (EC) 848/2018, and to avoid the commingling of organic products with non-organic products.

**Preventive measures;** means 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.

**Organic production unit;** means a production unit, excluding during the conversion period, which is managed in compliance with the requirements applicable to organic production.

**In-conversion production unit;** means a production unit managed in compliance with the requirements applicable to organic production, during the conversion period; it may be constituted of land parcels or other assets for which the conversion period starts at different moments in time.

**Non-organic production unit;** means a production unit which is not managed in compliance with the requirements applicable to organic production.

**Stage of production, preparation and distribution;** means 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.

**Production unit;** means all assets of a holding, such as primary production premises, land parcels, pasturages, open air areas, livestock buildings or parts thereof, hives, fish ponds, containment systems and sites for algae or aquaculture animals, rearing units, shore or seabed concessions, and premises for the storage of crops, of crop products, of algae products, of animal products, of raw materials and of any other relevant inputs.

**Verification;** means actions performed to ensure that controls and other related activities are consistent and effective.

**External inspection;** means re-inspection. It is the inspection carried out by Başak Ekolojik.

**ICS;** means Internal Control System of group of operator.

**non-compliance'** means non-compliance with this Regulation or non-compliance with the delegated or implementing acts adopted in accordance with this Regulation;

**TRACES;** Trade Control and Expert System, means the computerised system referred to in Article 133(4) of Regulation (EU) 2017/625 for the purposes of exchanging data, information and documents;

**Plant reproductive material;** As defined in Article 2(1) of Regulation (EU) 1305/2013; means plants and all parts of plants, excluding seedlings, including seeds, at any stage of growth that are capable of, and intended for, producing entire plants;

**Adverse climatic event** means weather conditions, such as frost, storms and hail, ice, heavy rain or severe drought, which can be assimilated to a natural disaster;

**Environmental incident;** means a specific occurrence of pollution, contamination or degradation in the quality of the environment which is related to a specific event and is of limited geographical scope; but does not cover general environmental risks not connected with a specific event, such as climate change or atmospheric pollution;

**Natural disaster;** means a naturally occurring event of a biotic or abiotic nature that leads to important disturbances in agricultural production systems or forest structures, eventually causing important economic damage to the farming or forestry sectors;

**Catastrophic event;** means an unforeseen event of a biotic or abiotic nature caused by human action that leads to important disturbances in agricultural production systems or forest structures, eventually causing important economic damage to the farming or forestry sectors.

[\(EU\) 2018/848- \(EU\) 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](#)

## CHAPTER III PRODUCTION RULES

### Article 9 General production rules

1. Operators shall comply with the general production rules laid down in this Article.
2. The entire holding shall be managed in compliance with the requirements of this Regulation that apply to organic production.
3. For the purposes and uses referred to in Articles 24 and 25 and in Annex II, only products and substances that have been authorised pursuant to those provisions may be used in organic production, provided that their use in non-organic production has also been authorised in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law.

The following products and substances referred to in Article 2(3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic production, provided that they are authorised pursuant to that Regulation:

- (a) safeners, synergists and co-formulants as components of plant protection products;
- (b) adjuvants that are to be mixed with plant protection products

The use in organic production of products and substances for purposes other than those covered by this Regulation shall be allowed, provided that their use complies with principles of organic production.

4. Ionising radiation shall not be used in the treatment of organic food or feed, and in the treatment of raw materials used in organic food or feed.
5. The use of animal cloning, and the rearing of artificially induced polyploid animals, shall be prohibited.
6. Preventive and precautionary measures shall be taken, where appropriate, at every stage of production, preparation and distribution.
7. Notwithstanding paragraph 2, a holding may be split into clearly and effectively separated production units for organic, in-conversion and non-organic production, provided that for the non-organic production units:
  - (a) as regards livestock, different species are involved;
  - (b) as regards plants, different varieties that can be easily differentiated are involved.
8. By way of derogation from point (b) of paragraph 7, in the case of perennial crops which require a cultivation period of at least three years, different varieties that cannot be easily differentiated, or the same varieties, may be involved, provided that the production in question is within the context of a conversion plan, and provided that the conversion of the last part of the area related to the production in question to organic production begins as soon as possible and is completed within a maximum of five years.

In such cases:

- (a) the farmer shall notify the competent authority, or, where appropriate, the control authority or the control body, of the start of harvest of each of the products concerned at least 48 hours in advance;
- (b) upon completion of the harvest, the farmer shall inform the competent authority, or, where appropriate, the control authority or the control body, of the exact quantities harvested from the units concerned and of the measures taken to separate the products;

(c) the conversion plan and the measures to be taken to ensure the effective and clear separation shall be confirmed each year by the competent authority, or, where appropriate, by the control authority or the control body, after the start of the conversion plan.

9. The requirements concerning different species and varieties, laid down in points (a) and (b) of paragraph 7, shall not apply in the case of research and educational centres, plant nurseries, seed multipliers and breeding operations.

10. Where, in the cases referred to in paragraphs 7, 8 and 9, not all production units of a holding are managed under organic production rules, the operators shall:

(a) keep the products used for the organic and in-conversion production units separate from those used for the non-organic production units;

(b) keep the products produced by the organic, in-conversion and non-organic production units separate from each other;

(c) keep adequate records to show the effective separation of the production units and of the products.

11. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraph 7 of this Article by adding further rules on the splitting of a holding into organic, in-conversion and non-organic production units, in particular in relation to products listed in Annex I, or by amending those added rules.

## Article 10 Conversion

1. Farmers and operators that produce algae or aquaculture animals shall comply with a conversion period. During the whole conversion period they shall apply all rules on organic production laid down in this Regulation, in particular the applicable rules on conversion set out in this Article and in Annex II.

2. The conversion period shall start at the earliest when the farmer or the operator that produces algae or aquaculture animals has notified the activity to the competent authorities, in accordance with Article 34(1), in the Member State in which the activity is carried out and in which that farmer or operator's holding is subject to the control system.

3. No previous period may be retroactively recognised as being part of the conversion period, except where:

(a) the operator's land parcels were subject to measures which were defined in a programme implemented pursuant to Regulation (EU) No 1305/2013 for the purpose of ensuring that no products or substances other than those authorised for use in organic production have been used on those land parcels; or

(b) the operator can provide proof that the land parcels were natural or agricultural areas that, for a period of at least three years, have not been treated with products or substances that are not authorised for use in organic production.

4. Products produced during the conversion period shall not be marketed as organic products or as in-conversion products.

However, the following products produced during the conversion period and in compliance with paragraph 1 may be marketed as in-conversion products:

(a) plant reproductive material, provided that a conversion period of at least 12 months has been complied with;

(b) food products of plant origin and feed products of plant origin, provided that the product contains only one agricultural crop ingredient, and provided that a conversion period of at least 12 months before the harvest has been complied with.

5. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending point 1.2.2 of Part II of Annex II by adding conversion rules for species other than those regulated in Part II of Annex II on 17 June 2018, or by amending those added rules.

6. The Commission shall, where appropriate, adopt implementing acts specifying the documents to be supplied for the purpose of the retroactive recognition of a previous period in accordance with paragraph 3 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

## Article 11 Prohibition of the use of GMOs

1. GMOs, products produced from GMOs, and products produced by GMOs shall not be used in food or feed, or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms or animals in organic production.

2. For the purposes of the prohibition laid down in paragraph 1, with regard to GMOs and products produced from GMOs for food and feed, operators may rely on the labels of a product that have been affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003 of the European Parliament and of the Council or Regulation (EC) No 1830/2003 of the European Parliament and of the Council or any accompanying document provided pursuant thereto.

3. Operators may assume that no GMOs and no products produced from GMOs have been used in the manufacture of purchased food and feed where such products do not have a label affixed or provided, or are not accompanied by a document provided, pursuant to the legal acts referred to in paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those legal acts.

4. For the purposes of the prohibition laid down in paragraph 1, with regard to products not covered by paragraphs 2 and 3, operators using non-organic products purchased from third parties shall require the vendor to confirm that those products are not produced from GMOs or produced by GMOs.

## Article 12 Plant production rules

1. Operators that produce plants or plant products shall comply, in particular, with the detailed rules set out in Part I of Annex II.

2. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending

(a) points 1.3 and 1.4 of Part I of Annex II as regards derogations;

(b) point 1.8.5 of Part I of Annex II as regards the use of in-conversion and non-organic plant reproductive material;

(c) point 1.9.5 of Part I of Annex II by adding further provisions concerning agreements between operators of agricultural holdings, or by amending those added provisions;

(d) point 1.10.1 of Part I of Annex II by adding further pest- and weed-management measures, or by amending those added measures;

(e) Part I of Annex II by adding further detailed rules and cultivation practices for specific plants and plant products, including rules for sprouted seeds, or by amending those added rules.

## Article 16 Production rules for processed food

1. Operators that produce processed food shall comply, in particular, with the detailed production rules set out in Part IV of Annex II and in any implementing acts referred to in paragraph 3 of this Article.

2. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending:

(a) point 1.4 of Part IV of Annex II as regards precautionary measures and preventive measures to be taken by operators;

(b) point 2.2.2 of Part IV of Annex II as regards the types and composition of products and substances that are allowed for use in processed food, as well as conditions under which they may be used;

(c) point 2.2.4 of Part IV of Annex II as regards the calculation of the percentage of agricultural ingredients referred to in points (a)(ii) and (b)(i) of Article 30(5), including the food additives authorised pursuant to Article 24 for use in organic production that are considered as agricultural ingredients for the purpose of such calculations

Those delegated acts shall not include the possibility of using flavouring substances or flavouring preparations which are neither natural, within the meaning of Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council, nor organic.

3. The Commission may adopt implementing acts laying down the techniques authorised in the processing of food products.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

## Article 19 Production rules for yeast used as food or feed

1. Operators that produce yeast to be used as food or feed shall comply, in particular, with the detailed production rules set out in Part VII of Annex II.

2. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending point 1.3 of Part VII of Annex II by adding further detailed yeast production rules, or by amending those added rules.

## **Article 21 Production rules for products not falling within the categories of products referred to in Articles 12 to 19**

**1.** The Commission is empowered to adopt delegated acts in accordance with Article 54 amending Annex II by adding detailed production rules, as well as rules on the obligation to convert, for products that do not fall within the categories of products referred to in Articles 12 to 19, or by amending those added rules.

Those delegated acts shall be based on the objectives and principles of organic production laid down in Chapter II and shall comply with the general production rules laid down in Articles 9, 10 and 11 as well as existing detailed production rules laid down for similar products in Annex II. They shall lay down requirements concerning, in particular, the treatments, practices and inputs that are allowed or prohibited, or conversion periods for the products concerned.

**2.** In the absence of the detailed production rules referred to in paragraph 1:

(a) operators shall, as regards products referred to in paragraph 1, comply with the principles laid down in Articles 5 and 6, mutatis mutandis with the principles laid down in Article 7, and with the general production rules laid down in Articles 9 to 11;

(b) a Member State may, as regards products referred to in paragraph 1, apply detailed national production rules, provided that those rules are in accordance with this Regulation, and provided that they do not prohibit, restrict or impede the placing on the market of products which have been produced outside its territory and which comply with this Regulation.

## **Article 23 Collection, packaging, transport and storage**

**1.** Operators shall ensure that organic products and in-conversion products are collected, packaged, transported and stored in accordance with the rules set out in Annex III.

**2.** The Commission is empowered to adopt delegated acts in accordance with Article 54 amending:

(a) Section 2 of Annex III;

(b) Sections 3, 4 and 6 of Annex III by adding further special rules for the transport and reception of the products concerned, or by amending those added rules.

## **Article 24 Authorisation of products and substances for use in organic production**

**1.** The Commission may authorise certain products and substances for use in organic production, and shall include any such authorised products and substances in restrictive lists, for the following purposes:

(a) as active substances to be used in plant protection products;

(b) as fertilisers, soil conditioners and nutrients;

(c) as non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin;

(d) as feed additives and processing aids;

(e) as products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production;

(f) as products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding;

(g) as products for cleaning and disinfection in processing and storage facilities.

**2.** In addition to products and substances authorised in accordance with paragraph 1, the Commission may authorise certain products and substances for use in the production of processed organic food and of yeast used as food or feed, and shall include any such authorised products and substances in restrictive lists, for the following purposes:

(a) as food additives and processing aids;

(b) as non-organic agricultural ingredients to be used for the production of processed organic food;

(c) as processing aids for the production of yeast and yeast products.

**3.** The authorisation of the products and substances referred to in paragraph 1 for use in organic production shall be subject to the principles laid down in Chapter II and to the following criteria, which shall be evaluated as a whole:

(a) they are essential for sustained production and for the use for which they are intended;

(b) all of the products and substances concerned are of plant, algal, animal, microbial or mineral origin, except in cases where products or substances from such sources are not available in sufficient quantities or qualities or where alternatives are not available;

(c) in the case of products referred to in point (a) of paragraph 1:

- i. their use is essential for the control of a pest for which other biological, physical or breeding alternatives, cultivation practices or other effective management practices are not available;
- ii. if such products are not of plant, algal, animal, microbial or mineral origin and are not identical to their natural form, their conditions for use preclude any direct contact with the edible parts of the crop;

(d) in the case of products referred to in point (b) of paragraph 1, their use is essential for building or maintaining the fertility of the soil or to fulfil specific nutritional requirements of crops, or for specific soil-conditioning purposes;

**4.** The authorisation of the products and substances referred to in paragraph 2 for use in the production of processed organic food or for the production of yeast used as food or feed shall be subject to the principles laid down in Chapter II and to the following criteria, which shall be evaluated as a whole:

(a) alternative products or substances authorised in accordance with this Article or techniques compliant with this Regulation are not available;

(b) it would be impossible to produce or preserve the food or to fulfil given dietary requirements provided for on the basis of Union legislation without having recourse to those products and substances;

(c) they are to be found in nature and may only have undergone mechanical, physical, biological, enzymatic or microbial processes, except in cases where products or substances from such sources are not available in sufficient quantities or qualities;

(d) the organic ingredient is not available in sufficient quantity.

**5.** The authorisation of the use of chemically synthesised products and substances, in accordance with paragraphs 1 and 2 of this Article, shall be strictly limited to cases where the use of external inputs referred to in point (g) of Article 5 would contribute to unacceptable impacts on the environment.

**6.** The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraphs 3 and 4 of this Article by adding further criteria for the authorisation of products and substances referred to in paragraphs 1 and 2 of this Article for use in organic production in general, and in the production of processed organic food in particular, as well as further criteria for the withdrawal of such authorisations, or by amending those added criteria.

**7.** Where a Member State considers that a product or substance should be added to or withdrawn from the lists of authorised products and substances referred to in paragraphs 1 and 2, or that the specifications of use referred to in the production rules should be amended, it shall ensure that a dossier giving the reasons for the inclusion, withdrawal or other amendments is officially sent to the Commission and to the other Member States and is made publicly available, subject to Union and national legislation on data protection.

The Commission shall publish any requests referred to in this paragraph.

**8.** The Commission shall regularly review the lists referred to in this Article. The list of non-organic ingredients referred to in point (b) of paragraph 2 shall be reviewed at least once a year.

**9.** The Commission shall adopt implementing acts concerning the authorisation or withdrawal of authorisation of products and substances in accordance with paragraphs 1 and 2 that may be used in organic production in general and in the production of processed organic food in particular, and establishing the procedures to be followed for such authorisations and the lists of such products and substances and, where appropriate, their description, compositional requirements and conditions for use.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

## Article 27 Obligations and actions in the event of suspicion of non-compliance

Where an operator suspects that a product it has produced, prepared, imported or has received from another operator does not comply with this Regulation, that operator shall, subject to Article 28(2);

- (a) identify and separate the product concerned;
- (b) check whether the suspicion can be substantiated;
- (c) not place the product concerned on the market as an organic or in-conversion product and not use it in organic production, unless the suspicion can be eliminated,
- (d) where the suspicion has been substantiated or where it cannot be eliminated, immediately inform the relevant competent authority, or, where appropriate, the relevant control authority or control body, and provide it with available elements, where appropriate;
- (e) fully cooperate with the relevant competent authority, or, where appropriate, with the relevant control authority or control body, in verifying and identifying the reasons for the suspected non-compliance.

## Article 28 Precautionary measures to avoid the presence of non-authorised products and substances

1. In order to avoid contamination with products or substances that are not authorised in accordance with the first subparagraph of Article 9(3) for use in organic production, operators shall take the following precautionary measures at every stage of production, preparation and distribution:

- (a) put in place and maintain measures that are proportionate and appropriate to identify the risks of contamination of organic production and products with non-authorised products or substances, including systematic identification of critical procedural steps;
- (b) put in place and maintain measures that are proportionate and appropriate to avoid risks of contamination of organic production and products with non-authorised products or substances;
- (c) regularly review and adjust such measures; and
- (d) comply with other relevant requirements of this Regulation that ensure the separation of organic, in-conversion and non-organic products.

2. Where an operator suspects, due to the presence of a product or substance that is not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production in a product that is intended to be used or marketed as an organic or in-conversion product, that the latter product does not comply with this Regulation, the operator shall;

- (a) identify and separate the product concerned;
- (b) check whether the suspicion can be substantiated;
- (c) not place the product concerned on the market as an organic or in-conversion product and not use it in organic production unless the suspicion can be eliminated;
- (d) where the suspicion has been substantiated or where it cannot be eliminated, immediately inform the relevant competent authority, or, where appropriate, the relevant control authority or control body, and provide it with available elements, where appropriate;
- (e) fully cooperate with the relevant competent authority, or, where appropriate, with the relevant control authority or control body, in identifying and verifying the reasons for the presence of non-authorised products or substances.

3. The Commission may adopt implementing acts laying down uniform rules to specify:

- (a) the procedural steps to be followed by operators in accordance with points (a) to (e) of paragraph 2 and the relevant documents to be provided by them;
- (b) the proportionate and appropriate measures to be adopted and reviewed by operators to identify and avoid risks of contamination in accordance with points (a), (b) and (c) of paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

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

1. Where the competent authority, or, where appropriate, the control authority or control body, receives substantiated information about the presence of products or substances that are not authorised pursuant to the first

subparagraph of Article 9(3) for use in organic production, or has been informed by an operator in accordance with point (d) of Article 28(2), or detects such products or substances in an organic or an in-conversion product:

(a) it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 with a view to determining the source and the cause in order to verify compliance with the first subparagraph of Article 9(3) and with Article 28(1);

Such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case;

(b) it shall provisionally prohibit both the placing on the market of the products concerned as organic or in-conversion products and their use in organic production pending the results of the investigation referred to in point (a).

2. The product concerned shall not be marketed as an organic or in-conversion product or used in organic production where the competent authority, or, where appropriate, the control authority or control body, has established that the operator concerned:

(a) has used products or substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production;

(b) has not taken the precautionary measures referred to in Article 28(1); or

(c) has not taken measures in response to relevant previous requests from the competent authorities, control authorities or control bodies.

3. The operator concerned shall be given an opportunity to comment on the results of the investigation referred to in point (a) of paragraph 1. The competent authority, or, where appropriate, the control authority or control body, shall keep records of the investigation it has carried out.

Where required, the operator concerned shall take such corrective measures as necessary to avoid future contamination.

## CHAPTER V CERTIFICATION

### Article 36 Group of operators

1. Each group of operators shall:

(a) only be composed of members who are farmers and who in addition may be engaged in processing, preparation or placing on the market of food;

(b) only be composed of members:

(i) of which the individual certification cost represents more than 2 % of each member's turnover or standard output of organic production and whose annual turnover of organic production is not more than EUR 25 000 or whose standard output of organic production is not more than EUR 15 000 per year; or;

(ii) who have each holdings of maximum:

— five hectares,

— 0,5 hectares, in the case of greenhouses, or

— 15 hectares, exclusively in the case of permanent grassland;

(c) be established in a Member State or a third country;

(d) have legal personality (eg. agricultural cooperative, producer association, foundation, non-governmental organization, limited company etc);

(e) only be composed of members whose production activities or possible additional activities referred to in point (a) take place in geographical proximity to each other in the same Member State or in the same third country;

(f) set up a joint marketing system for the products produced by the group; and

(g) establish a system for internal controls comprising a documented set of control activities and procedures in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group.

The system for internal controls (ICS) shall comprise documented procedures on:

- (i) the registration of the members of the group;
- (ii) the internal inspections, which include the annual internal physical on-the-spot inspections of each member of the group, and any additional risk-based inspections, in any case scheduled by the ICS manager and conducted by ICS inspectors, whose roles are defined in point (h);
- (iii) the approval of new members in an existing group or, where appropriate, the approval of new production units or new activities of existing members upon the approval by the ICS manager on the basis of the internal inspection report;
- (iv) the training of the ICS inspectors, which is to take place at least annually and to be accompanied by an assessment of the knowledge acquired by the participants;;
- (v) the training of members of the group on the ICS procedures and the requirements of this Regulation;
- (vi) the control of documents and records;
- (vii) the measures in cases of non-compliance detected during the internal inspections, including their follow-up;
- (viii) the internal traceability, which shows the origin of the products delivered in the joint marketing system of the group and allows the tracing of all products of all members throughout all stages, such as production, processing, preparation or placing on the market, including estimating and cross-checking the yields of each member of the group;

**(h)** appoint an ICS manager and one or more ICS inspectors who may be a member of the group. Their positions shall not be combined. The number of ICS inspectors shall be adequate and proportional in particular to the type, structure, size, products, activities and output of organic production of the group. The ICS inspectors shall be competent with regard to the products and activities of the group.

**The ICS manager shall:**

- (i) verify the eligibility of each member of the group regarding the criteria set out in points (a), (b) and (e);
- (ii) ensure that there is a written and signed membership agreement between each member and the group, by which the members commit themselves to:
  - comply with this Regulation,
  - participate in the ICS and comply with the ICS procedures, including the tasks and responsibilities assigned to them by the ICS manager and the obligation for records keeping,
  - permit access to production units and premises and be present during the internal inspections carried out by the ICS inspectors and official controls carried out by the competent authority or, where appropriate, the control authority or control body, make available to them all documents and records and countersign the inspection reports,
  - accept and implement the measures in cases of non-compliances in accordance with the decision of the ICS manager or the competent authority or, where appropriate, the control authority or control body, within the given time-frame,
  - immediately inform the ICS manager on suspected non-compliance.
- (iii) develop the ICS procedures and the relevant documents and records, keep them up to date and make them readily available to the ICS inspectors, and where relevant, to the members of the group;
- (iv) draw up the list of the members of the group and keep it up to date;
- (v) assign tasks and responsibilities to the ICS inspectors;
- (vi) be the liaison between the members of the group and the competent authority or, where appropriate, the control authority or control body, including requests for derogations;
- (vii) verify annually the conflict of interest statements of the ICS inspectors;
- (viii) schedule internal inspections and ensure their adequate implementation in accordance with the ICS manager's schedule referred to in point (ii) of the second paragraph of point (g);
- (ix) ensure adequate trainings for the ICS inspectors and carry out an annual assessment of ICS inspectors' competences and qualifications;
- (x) approve new members or new production units or new activities of existing members;

- (xi) decide on measures in case of non-compliance in line with the ICS measures established by documented procedures in accordance with point g and ensure the follow-up of those measures;
- (xii) decide to subcontract activities, including the subcontracting of the tasks of ICS inspectors, and sign relevant agreements or contracts.

## **The ICS inspector shall**

- (i) carry out internal inspections of the members of the group according to the schedule and the procedures provided by the ICS manager;
- (ii) draft internal inspection reports on the basis of a template and submit it within a reasonable time to the ICS manager;
- (iii) submit at appointment a written and signed statement on conflict of interest and update it annually;
- (iv) participate in trainings.

**2.** Competent authorities, or, where appropriate, control authorities or control bodies, shall withdraw the certificate referred to in Article 35 for the whole group where deficiencies in the set-up or functioning of the system for internal controls referred to in paragraph 1, in particular as regards failures to detect or address non-compliance by individual members of the group of operators, affect the integrity of organic and in-conversion products.

At least the following situations shall be considered as deficiencies in the ICS:

- (a) producing, processing, preparing or placing on the market of products from suspended/withdrawn members or production units;
- (b) placing on the market of products for which the ICS manager has prohibited the use of reference to organic production in their labelling or advertising;
- (c) adding new members to the list of members or changing the activities of existing members without following the internal approval procedure;
- (d) not carrying out the annual physical on-the-spot inspection of a member of the group in a given year;
- (e) failing to indicate the members which have been suspended or withdrawn in the list of members;
- (f) serious deviations in findings between internal inspections carried out by the ICS inspectors and official controls carried out by the competent authority or, where appropriate, the control authority or control body;
- (g) serious deficiencies in imposing appropriate measures or carrying out the necessary follow-up in response to non-compliance identified by the ICS inspectors or by the competent authority or, where appropriate, the control authority or control body;
- (h) inadequate number of ICS inspectors or inadequate competences of ICS inspectors for the type, structure, size, products, activities and output of organic production of the group.

**3.** The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraphs 1 and 2 of this Article by adding provisions, or by amending those added provisions, in particular as regards.

- (a) the responsibilities of the individual members of a group of operators;
- (b) the criteria to determine the geographical proximity of the members of the group, such as the sharing of facilities or sites;
- (c) the set-up and functioning of the system for internal controls, including the scope, content and frequency of the controls to be carried out and the criteria to identify deficiencies in the set-up or functioning of the system for internal controls.

**4.** The Commission may adopt implementing acts laying down specific rules concerning:

- (a) the composition and dimension of a group of operators;
- (b) the documents and record-keeping systems, the system for internal traceability and the list of operators;
- (c) the exchange of information between a group of operators and the competent authority or authorities, control authorities or control bodies, and between the Member States and the Commission.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

## ANNEX II

### DETAILED PRODUCTION RULES REFERRED TO IN CHAPTER III

#### Part I: Plant production rules

In addition to the production rules laid down in Articles 9 to 12, the rules set out in this Part shall apply to organic plant production.

#### 1. General requirements

**1.1.** Organic crops, except those which are naturally grown in water, shall be produced in living soil, or in living soil mixed or fertilised with materials and products allowed in organic production, in connection with the subsoil and bedrock.

**1.2.** Hydroponic production, which is a method of growing plants which do not naturally grow in water with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited.

**1.3.** By way of derogation from point 1.1, the following shall be allowed:

(a) the production of sprouted seeds, which include sprouts, shoots and cress, solely living on the nutritional reserves available in the seeds, by moistening them in clear water, provided that the seeds are organic. The use of growing medium shall be prohibited, except the use of an inert medium intended solely to keep the seeds moist when the components of that inert medium are authorised in compliance with Article 24.

(b) the obtaining of chicory heads, including by dipping them in clear water, provided that the plant reproductive material is organic. The use of a growing medium shall be allowed only when its components are authorised in compliance with Article 24.

**1.4.** By way of derogation from point 1.1, the following practices shall be allowed:

(a) growing plants for the production of ornamentals and herbs in pots to be sold together with the pot to the final consumer;

(b) growing seedlings or transplants in containers for further transplanting

**1.6.** All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment.

#### 1.7. Geçiş

**1.7.1.** For plants and plant products to be considered as organic products, the production rules laid down in this Regulation shall have been applied with respect to the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, during a period of at least two years before its use as organic feed, or, in the case of perennial crops other than forage, during a period of at least three years before the first harvest of organic products.

**1.7.2.** Where the land or one or more parcels thereof have been contaminated with products or substances not authorised for use in organic production, the competent authority may decide to extend the conversion period for the land or parcels concerned beyond the period referred to in point 1.7.1.

**1.7.3.** In the case of treatment with a product or a substance not authorised for use in organic production, the competent authority shall require a new conversion period in accordance with point 1.7.1.

**1.7.4.** In the cases referred to in points 1.7.2 and 1.7.3, the length of the conversion period shall be fixed taking into account the following requirements:

(a) the process of degradation of the product or substance concerned must guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant;

(b) the harvest following the treatment may not be placed on the market as organic or in-conversion products.

## 1.8. Origin of plants including plant reproductive material

1.8.1. For the production of plants and plant products other than plant reproductive material, only organic plant reproductive material shall be used.

1.8.2. To obtain organic plant reproductive material to be used for the production of products other than plant reproductive material, the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.

1.8.3. When choosing organic plant reproductive material, operators shall give preference to organic plant reproductive material suitable for organic agriculture.

1.8.4. For the production of organic varieties suitable for organic production, the organic breeding activities shall be conducted under organic conditions and shall focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions.

All multiplication practices except meristem culture shall be carried out under certified organic management..

## 1.8.5. Use of in-conversion and non-organic plant reproductive material

1.8.5.2. Operators in third countries may use in-conversion plant reproductive material in accordance with Article 10(4), second subparagraph, point (a), or plant reproductive material authorised in accordance with point 1.8.6 when organic plant reproductive material is justified to be not available in sufficient quality or quantity in the territory of the third country in which the operator is located.

Without prejudice to relevant national rules, operators in third countries may use both organic and in-conversion plant reproductive material obtained from their own holding.

Control authorities or control bodies recognised in accordance with Article 46(1) may authorise operators in third countries to use non-organic plant reproductive material in an organic production unit, when organic or in-conversion plant reproductive material or plant reproductive material authorised in accordance with point 1.8.6 is not available in sufficient quality or quantity in the territory of the third country in which the operator is located, under the conditions laid down in points 1.8.5.3, 1.8.5.4, 1.8.5.5 and 1.8.5.8.

1.8.5.3. Non-organic plant reproductive material shall not be treated after harvest with plant protection products other than those authorised for the treatment of plant reproductive material in accordance with (EU) 2018/848. Where the non-organic plant reproductive material treated with the prescribed chemical treatment referred to in the first paragraph is used, the parcel on which the treated plant reproductive material is growing shall be subject, where appropriate, to a conversion period as provided in points 1.7.3 and 1.7.4.

1.8.5.4. The authorisation to use non-organic plant reproductive material shall be obtained before the sowing or planting of the crop.

1.8.5.5. The authorisation to use non-organic plant reproductive material shall be granted to individual users for one season at a time, and the competent authorities, control authority or body responsible for authorisations shall list the quantities of the authorised plant reproductive material.

1.8.5.8. Competent authorities shall not authorise the use of non-organic seedlings in the case of seedlings of species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product.

**1.8.6.** Competent authorities or, where appropriate, control authorities or control bodies recognised in accordance with Article 46(1) may authorise operators producing plant reproductive material for use in organic production to use non-organic plant reproductive material, when mother plants or, where relevant, other plants intended for the production of plant reproductive material and produced in compliance with point 1.8.2 are not available in sufficient quantity or quality, and to place such material on the market for use in organic production provided that the following conditions are met:

a) The non-organic plant reproductive material used has not been treated after harvest with plant protection products other than those authorised in accordance with (EU) 2018/848. Where non-organic plant reproductive material treated with such prescribed chemical treatment is used, the land parcel on which the treated plant

reproductive material is growing shall be subject, where appropriate, to a conversion period as provided in points 1.7.3 and 1.7.4;

b) the non-organic plant reproductive material used is not a seedling of species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product;

c) the plant reproductive material is grown in compliance with all other relevant organic plant production requirements;

d) the authorisation to use non-organic plant reproductive material shall be obtained before that material is sown or planted;

e) the competent authority, control authority or control body responsible for the authorisation shall grant the authorisation only to individual users and for one season at a time, and shall list the quantities of the authorised plant reproductive material.

The authorisations granted in accordance with this paragraph shall expire on 31 December 2036.

## **1.9. Soil management and fertilisation**

1.9.1. In organic plant production, tillage and cultivation practices shall be used that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion.

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

(a) except in the case of grassland or perennial forage, by the use of multiannual crop rotation including mandatory leguminous crops as the main or cover crop for rotating crops and other green manure crops,

(b) in the case of greenhouses or perennial crops other than forage, by the use of short-term green manure crops and legumes as well as the use of plant diversity; and

(c) in all cases, by the application of livestock manure or organic matter, both preferably composted, from organic production.

1.9.3. Where the nutritional needs of plants cannot be met by the measures provided for in points 1.9.1 and 1.9.2, only fertilisers and soil conditioners that have been authorised pursuant to Article 24 of the Regulation (EU) 2018/848 for use in organic production shall be used, and only to the extent necessary. Operators shall keep records of the use of those products, including the date or dates on which each product was used, the name of the product, the amount applied and the crop and parcels concerned.

1.9.4. The total amount of livestock manure, as defined in Directive 91/676/EEC, used in the in-conversion and organic production units shall not exceed 170 kg of nitrogen per year/hectare of agricultural area used. That limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrement, including poultry manure, composted farmyard manure and liquid animal excrement.

1.9.5. Operators of agricultural holdings may establish written cooperation agreements exclusively with operators of other agricultural holdings and undertakings which comply with the organic production rules, for the purpose of spreading surplus manure from organic production units. The maximum limit referred to in point 1.9.4 shall be calculated on the basis of all of the organic production units involved in such cooperation.

1.9.6. Preparations of micro-organisms may be used to improve the overall condition of the soil or to improve the availability of nutrients in the soil or in the crops.

1.9.7. For compost activation, appropriate plant-based preparations and preparations of micro-organisms may be used.

1.9.8. Mineral nitrogen fertilisers shall not be used.

1.9.9. Biodynamic preparations may be used.

## **1.10. Pest and weed management**

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

— natural enemies,

— the choice of species, varieties and heterogeneous material,

— crop rotation,

— cultivation techniques such as biofumigation, mechanical and physical methods, and

— thermal processes such as solarisation and, in the case of protected crops, shallow steam treatment of the soil (to a maximum depth of 10 cm)

1.10.2. Where plants cannot adequately be protected from pests by measures provided for in point 1.10.1 or in the case of an established threat to a crop, only products and substances authorised pursuant to Articles 9 and 24 of the Regulation (EU) 2018/848 for use in organic production shall be used, and only to the extent necessary. Operators shall keep records proving the need for the use of such products, including the date or dates on which each product was used, the name of the product, its active substances, the amount applied, the crop and parcels concerned, and the pest or disease to be controlled.

1.10.3. In relation to products and substances used in traps or in dispensers of products and substances other than pheromones, the traps or dispensers shall prevent the products and substances from being released into the environment and shall prevent contact between the products and substances and the crops being cultivated. All traps, including pheromone traps, shall be collected after use and shall be safely disposed of.

### **1.11. Products used for cleaning and disinfection**

Only those products for cleaning and disinfection in plant production authorised pursuant to Article 24 of the Regulation (EU) 2018/848 for use in organic production shall be used for that purpose. Operators shall keep records of the use of those products including the date or dates on which each product was used, the name of the product, its active substances, and the location of such use.

### **1.12. Record-keeping obligation**

Operators shall keep records regarding the parcels concerned and the amount of the harvest. In particular, operators shall keep records of any other external input used on each parcel and, where applicable, keep available documentary evidence on any derogation from production rules obtained in accordance with point 1.8.5.

### **1.13. Preparation of unprocessed products**

If preparation operations other than processing are carried out on plants, the general requirements laid down in points 1.2, 1.3, 1.4, 1.5 and 2.2.3 of Part IV shall apply *mutatis mutandis* to such operations.

## **2. Detailed rules for specific plants and plant products**

### **2.1. Rules on mushroom production**

For the production of mushrooms, substrates may be used if they are composed only of the following components:

- (a) farmyard manure and animal excrement:
  - (i) either from organic production units or from in-conversion units in their second year of conversion; or
  - (ii) referred to in point 1.9.3, only when the product referred to in point (i) is not available, provided that that farmyard manure and animal excrement do not exceed 25 % of the weight of total components of the substrate, excluding the covering material and any added water, before composting;
- (b) products of agricultural origin, other than those referred to in point (a), from organic production units;
- (c) peat, not treated with chemical products;
- (d) wood, not treated with chemical products after felling;
- (e) mineral products referred to in point 1.9.3, water and soil

### **2.2. Rules concerning the collection of wild plants**

The collection of wild plants and parts thereof growing naturally in natural areas, forests and agricultural areas is considered as organic production, provided that:

- (a) for a period of at least three years before the collection, those areas were not treated with products or substances other than those authorised pursuant to Articles 9 and 24 of the Regulation (EU) 2018/848 for use in organic production;
- (b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.

Operators shall keep records of the period and location of the collection, the species concerned and the quantity of wild plants collected..

## Part IV:

### Processed food production rules

In addition to the general production rules laid down in Articles 9, 11 and 16, the rules laid down in this Part shall apply to the organic production of processed food.

#### 1. İşlenmiş Gıda Üretimi İçin Genel Şartlar

**1.1.** Food additives, processing aids and other substances and ingredients used for processing food and any processing practice applied, such as smoking, shall comply with the principles of good manufacturing practice (means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof).

**1.2.** Operators producing processed food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.

**1.3.** The application of the procedures referred to in point 1.2 shall ensure that the produced processed products comply with this Regulation at all times.

**1.4.** Operators shall comply with and implement the procedures referred to in point 1.2, and, without prejudice to Article 28, shall in particular:

(a) take precautionary measures;

(b) implement suitable cleaning measures, monitor their effectiveness and keep records of those operations;

(c) guarantee that non-organic products are not placed on the market with an indication referring to organic production.

**1.5.** The preparation of processed organic, in-conversion and non-organic products shall be kept separate from each other in time or space. Where organic, in-conversion and non-organic products, in any combination, are prepared or stored in the preparation unit concerned, the operator shall:

a) inform the competent authority, or, where appropriate, the control authority or control body, accordingly;

b) carry out the operations continuously until the production run has been completed, separately in place or time from similar operations performed on any other kind of product (organic, in-conversion or non-organic);

c) store organic, in-conversion and non-organic products, before and after the operations, separate by place or time from each other;

d) keep available an updated register of all operations and quantities processed;

e) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges between organic, in-conversion and non-organic products;

f) carry out operations on organic or in-conversion products only after suitable cleaning of the production equipment.

**1.6.** Products, substances and techniques that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of organic food, or that otherwise may be misleading as to the true nature of products intended to be marketed as organic food, shall not be used.

**1.7.** Operators shall keep available documentary evidence on authorisations for the use of non-organic agricultural ingredients for the production of processed organic food in accordance with Article 25 of the Regulation (EU)2018/848 if they have obtained or used such authorisations.

#### 2. Detailed requirements for the production of processed food

**2.1.** The following conditions shall apply to the composition of processed organic food:

(a) the product shall be produced mainly from agricultural ingredients or products intended for use as food listed in Annex I of the Regulation (EU)2018/848 for the purpose of determining whether a product has been produced mainly from those products, added water and salt shall not be taken into account;

(b) an organic ingredient shall not be present together with the same ingredient in non-organic form;

(c) an in-conversion ingredient shall not be present together with the same ingredient in organic or non-organic form.

**2.2.** Use of certain products and substances in processing of food

**2.2.1.** Only food additives, processing aids and non-organic agricultural ingredients authorised pursuant to Article 24 or Article 25 of the Regulation (EU)2018/848 for use in organic production, and the products and substances referred to in point 2.2.2 may be used in the processing of food, with the exception of products and substances of the wine

sector, for which point 2 of Part VI shall apply, and with the exception of yeast, for which point 1.3 of Part VII shall apply.

2.2.2. In the processing of food, the following products and substances may be used:

(a) preparations of micro-organisms and food enzymes normally used in food processing, provided that food enzymes to be used as food additives have been authorised pursuant to Article 24 of the Regulation (EU)2018/848 for use in organic production;

(b) substances and products defined in points (c) and (d)(i) of Article 3(2) of Regulation (EC) No 1334/2008 that have been labelled as natural flavouring substances or natural flavouring preparations in accordance with Article 16(2), (3) and (4) of that Regulation;

(c) colours for stamping meat and eggshells in accordance with Article 17 of Regulation (EC) No 1333/2008;

(d) natural colours and natural coating substances for the traditional decorative colouring of the shell of boiled eggs produced with the intention of placing them on the market at a given period of the year;

(e) drinking water and organic or non-organic salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;

(f) minerals (trace elements included), vitamins, amino acids and micronutrients, provided that:

(i) their use in food for normal consumption is 'directly legally required', in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if those minerals, vitamins, amino acids or micronutrients are not added; or

(ii) as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers;

— in products referred to in points (a) and (b) of Article 1(1) of Regulation (EU) No 609/2013 of the European Parliament and of the Council their use is authorised by that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned, or

— in products regulated by Commission Directive 2006/125/EC, their use is authorised by that Directive.

2.2.3. Only the products for cleaning and disinfection authorised pursuant to Article 24 of the Regulation (EU)2018/848 for use in processing shall be used for that purpose.

2.2.4. For the purpose of the calculation referred to in Article 30(5) of the Regulation (EU)2018/848, the following rules shall apply:

(a) certain food additives authorised pursuant to Article 24 of the Regulation (EU)2018/848 for use in organic production shall be calculated as agricultural ingredients

(b) preparations and substances referred to in points (a), (c), (d), (e) and (f) of point 2.2.2 shall not be calculated as agricultural ingredients;

(c) yeast and yeast products shall be calculated as agricultural ingredients.

2.3. Operators shall keep records of any input used in the food production. In case of production of composite products, complete recipes/formulae showing the quantities of input and output shall be kept available for the competent authority or control body.

## ANNEX III

### COLLECTION, PACKAGING, TRANSPORT AND STORAGE OF PRODUCTS

#### 1. Collection of products and transport to preparation units

Operators may carry out the simultaneous collection of organic, in-conversion and non-organic products only where appropriate measures have been taken to prevent any possible mixture or exchange between organic, in-conversion and non-organic products and to ensure the identification of the organic and in-conversion products.

#### 2. Packaging and transport of products to other operators or units

##### 2.1. Information to be provided

2.1.1. Operators shall ensure that organic products and in-conversion products are transported to other operators or units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles closed in such a manner that alteration, including substitution, of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating, without prejudice to any other indications required by Union law:

- (a) the name and address of the operator and, where different, of the owner or seller of the product;
- (b) the name of the product;
- (c) the name or the code number of the control authority or control body to which the operator is subject; and
- (d) where relevant, the lot identification mark in accordance with a marking system either approved at national level or agreed with the control authority or control body and which permits the linking of the lot with the records referred to in Article 34(5).

## **2.2. The closing of packaging, containers or vehicles shall not be required where:**

- (a) the transport takes place directly between two operators, both of which are subject to the organic control system;
- (b) the transport includes only organic or only in-conversion products;
- (c) the products are accompanied by a document giving the information required under point 2.1; and
- (d) both the expediting and the receiving operators keep documentary records of such transport operations available for the control authority or control body.

## **5. Reception of products from other operators or units:**

On receipt of an organic or in-conversion product, the operator shall check the closing of the packaging, container or vehicle where it is required and the presence of the indications provided for in Section 2. The operator shall cross-check the information on the label referred to in Section 2 with the information on the accompanying documents. The result of those verifications shall be explicitly mentioned in the records referred to in Article 34(5) of the Regulation (EU)2018/848.

## **6. Special rules for the reception of products from a third country**

Where organic or in-conversion products are imported from a third country, they shall be transported in appropriate packaging or containers, closed in a manner that prevents the substitution of the content and bearing the identification of the exporter and any other marks and numbers that serve to identify the lot, and shall be accompanied by the certificate of control for import from third countries where appropriate.

On receipt of an organic or in-conversion product imported from a third country, the natural or legal person to whom the imported consignment is delivered and who receives it for further preparation or marketing shall check the closing of the packaging or container and, in the case of products imported in accordance with point (b)(iii) of Article 45(1) of the Regulation (EU)2018/848, shall check that the certificate of inspection referred to in that Article covers the type of product contained in the consignment.

The result of this verification shall be explicitly mentioned in the records referred to in Article 34(5) of the Regulation (EU)2018/848.

## **7. Storage of products**

**7.1.** Areas for the storage of products shall be managed in such a way as to ensure identification of lots and to avoid any mixing or contamination with products or substances not in compliance with the organic production rules. Organic and in-conversion products shall be clearly identifiable at all times.

**7.2.** No input products or substances other than those authorised pursuant to Articles 9 and 24 of the Regulation (EU)2018/848 for use in organic production shall be stored in organic or in-conversion plant and livestock production units.

**7.3.** Allopathic veterinary medicinal products, including antibiotics, may be stored in agricultural and aquaculture holdings provided that they have been prescribed by a veterinarian in connection with the treatment referred to in points 1.5.2.2 of Part II and 3.1.4.2(a) of Part III of Annex II, that they are stored in a supervised location and that they are entered in the records referred to in Article 34(5) of the Regulation (EU)2018/848.

**7.4.** Where operators handle organic, or in-conversion or non-organic products in any combination and the organic or in-conversion products are stored in storage facilities in which also other agricultural products or foodstuffs are stored:

- (a) the organic or in-conversion products shall be kept separate from the other agricultural products or foodstuffs;
- (b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges between organic, in-conversion and non-organic products;
- (c) suitable cleaning measures, the effectiveness of which has been checked, shall have been carried out before the storage of organic or in-conversion products and the operators shall keep records of those operations.

7.5. Only the products for cleaning and disinfection authorised pursuant to Article 24 of the Regulation (EU)2018/848 for use in organic production shall be used in storage facilities for that purpose.

[\(EU\) 2020/464-Commission Implementing Regulation of 26 March 2020](#)

[laying down certain rules for the application of Regulation \(EU\) 2018/848 of the European Parliament and of the Council as regards the documents needed for the retroactive recognition of periods for the purpose of conversion, the production of organic products and information to be provided by Member States](#)

## CHAPTER IV

### PROCESSED FOOD AND FEED

#### Article 23 Techniques authorised in the processing of food products

1. Only techniques complying with the principles laid down in Chapter II of Regulation (EU) 2018/848, in particular the relevant specific principles applicable to the processing of organic food laid down in Article 7, with the relevant rules of Chapter III of that Regulation and with the detailed production rules set out in Part IV of Annex II thereto are authorised in the processing of food products in organic production.

2. Without prejudice to point 3 of Part VI of Annex II to Regulation (EU) 2018/848, ion exchange and adsorption resin techniques are authorised when used for the preparation of organic raw materials:

(a) for products referred to in points (a) and (b), respectively, of Article 1(1) of Regulation (EU) No 609/2013, provided that using those techniques is necessary to meet the requirements of that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned; or

(b) for products regulated by Directive 2006/125/EC, provided that using those techniques is necessary to meet the requirements of that Directive.

Buna göre;

Aşağıdaki ürünlerin hammaddelerinin hazırlanmasında iyon değiştirme ve adsorpsiyon reçinesi teknikleri kullanılabilir;

(i) infant formula and follow-on formula;

(ii) processed cereal-based food and baby food

(iii) processed cereal-based foods;

(iv) baby foods' other than processed cereal-based foods.

Operators using the techniques for the above products are required to prove that the practice is necessary to meet the requirements of Regulation (EU) No 609/2013 or Directive 2006/125/EC.

[\(EU\) 2020/2146-Commission Delegated Regulation of 24 September 2020 supplementing Regulation \(EU\) 2018/848 of the European Parliament and of the Council as regards exceptional production rules in organic production](#)

#### Article 3 Specific derogations from Regulation (EU) 2018/848

1. By way of derogation from point 1.8.1 of Part I of Annex II to Regulation (EU) 2018/848, for the production of plants and plant products other than plant reproductive material, non-organic plant reproductive material may be used when the use of organic or in conversion plant reproductive material is not possible, provided that point 1.8.5.3 of Part I of that Annex and, where appropriate, the requirements set out in point 1.7 of Part I of that Annex are complied with.

[\(EU\) 2021/279-Commission Implementing Regulation of 22 February 2021 laying down detailed rules for the implementation of Regulation \(EU\) 2018/848 of the European Parliament and of the Council on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products](#)

**Article 1 Procedural steps to be followed by the operator in case of a suspicion of non-compliance due to the presence of non-authorised products or substances**

1. In order to check whether the suspicion can be substantiated in accordance with Article 28(2)(b) of Regulation (EU) 2018/848, the operator shall take into account the following elements:

(a) where the suspicion of non-compliance concerns an incoming organic or in-conversion product, the operator shall check whether:

(i) the information on the label of the organic or in-conversion product and the information on the accompanying documents match;

(ii) the information on the certificate provided by the supplier relates to the product actually purchased;

(b) where there is a suspicion that the cause of the presence of the non-authorized products or substances lies under the control of the operator, the operator shall examine any possible cause for the presence of non-authorized products or substance.

2. When the operator informs the competent authority or, where appropriate, the control authority or control body in accordance with Article 28(2)(d) of Regulation (EU) 2018/848 about a substantiated suspicion or when the suspicion cannot be eliminated, the operator shall provide, if relevant and where available, the following elements:

(a) information and documents about the supplier (delivery note, invoice, certificate of the supplier, Certificate of Inspection for organic products (COI));

(b) the traceability of the product with the lot identification, stock quantity, and quantity of product sold;

(c) laboratory results, from accredited laboratory when relevant and available;

(d) the sampling sheet detailing the time, place and method used to take the sample;

(e) any information about any previous suspicion with regard to the specific non-authorized product or substance;

(f) every other relevant document to clarify the case.

## Article 2 Methodology of an official investigation

1. Without prejudice to Article 38(2) of Regulation (EU) 2018/848, when carrying out an official investigation referred to in Article 29(1)(a) of that Regulation, the competent authorities or, where appropriate, control bodies or control authorities shall determine at least the following:

a. the name, lot identification, ownership and physical location of the organic or in-conversion products concerned;

b. whether the products concerned are still placed on the market as organic or in-conversion products or used in organic production;

c. the type, name, quantity and other relevant information of the present non-authorized products or substances;

d. Information from other control bodies in the supply chain and from these organizations;

e. at which stage of production, preparation, storing or distribution and where exactly the presence of non-authorized products or substances has been detected, in particular for plant production, whether the sample was taken pre-harvest or post-harvest;

f. whether other operators in the supply chain are affected;

g. the results of previous official investigations on the organic or in-conversion products and operators concerned.

2. The official investigation shall be pursued by using appropriate methods and techniques.

3. The official investigation shall at least conclude on:

(a) the integrity of organic and in-conversion products;

(b) the source and the cause of the presence of non-authorized products or substances;

(c) the elements provided in Article 29(2)(a), (b) and (c) of Regulation (EU) 2018/848.

4. The competent authorities or, where appropriate, control authorities or control bodies shall draw up a final report for each official investigation. That final report shall contain:

(a) the records of the specific elements required pursuant to this Article;

(b) the records of the information exchanged with the competent authority, other control authorities and control bodies and the Commission related to this official investigation.

## Article 4 Composition and dimension of a group of operators

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 related to that product.

The maximum size of a group of operators shall be 2 000 members.

Groups of operators in third countries complying with Regulations (EC) No 834/2007, (EC) No 889/2008 and (EC) No 1235/2008 before the date of entry into application of the Regulation (EU) 2021/279 and for which important administrative, legal and structural changes are necessary with regard to the maximum size of the group of operators laid down in the second paragraph, complies with that provision from 1 January 2025 at the latest.

## Article 5 Documents and records of a group of operators

The group of operators shall keep the following documents and records for the purposes of the system for internal controls (ICS):

(a) the list of members of the group of operators based on their registration of each member and consisting of the following elements for each member of the group of operators:

(i) name and identification (code number);

(ii) contact details;

(iii) date of registration;

(iv) total land surface under the management of the member and whether it is part of an organic, in-conversion or non-organic production unit;

(v) information on each production unit and/or activity: size, location, including a map where available, product, date of the beginning of the conversion period and yield estimates;

(vi) date of the last internal inspection with the name of the ICS inspector;

(vii) date of the last official control performed by the competent authority or, where appropriate, control authority or control body with the name of the inspector;

(viii) date and version of the list

(b) the signed membership agreements between the member and the group of operators as legal person, which shall include the rights and responsibilities of the member;

(c) the internal inspection reports signed by the ICS inspector and the inspected member of the group of operators and including at least the following elements:

(i) (the name of the member and the location of the production unit or premises, including purchase and collection centres where the activities referred to in Article 36(1)(a) of Regulation (EU) 2018/848 subject to the inspection take place;

(ii) the date and starting and ending hour of the internal inspection;

(iii) the findings of the inspection;

(iv) the audit scope/perimeter;

(v) the date of issue of the report;

(vi) the name of the internal inspector.

(d) the training records of the ICS inspectors consisting of:

(i) the dates of the training;

(ii) the subject matter of the training;

(iii) the name of the trainer;

(iv) the signature of the trainee;

(v) where appropriate, an assessment of the knowledge acquired.

(e) the training records of the members of the group of operators;

(f) the records of the measures taken in case of non-compliance by the ICS manager, which shall include:

- (i) the members subject to measures in case of non-compliance, including those suspended, withdrawn or required to comply with a new conversion period;
- (ii) documentation of identified non-compliance;
- (iii) documentation of follow-up of the measures

(g) traceability records, including information on the quantities, on the following activities, where relevant:

- (i) purchase and distribution of farm inputs including plant reproductive material by the group;
- (ii) production including harvest;
- (iii) storing;
- (iv) preparation;
- (v) delivery of products from each member to the joint marketing system;
- (vi) placing on the market of products by the group of operators

(h) the written agreements and contracts between the group of operators and subcontractors including information on the nature of the subcontracted activities;

(i) the appointment of the ICS manager;

(j) the appointment of the ICS inspectors as well as the list of ICS inspectors.

The list of members referred to in point (a) of the first paragraph shall be updated by the ICS manager after any modification of the elements listed in point (a)(i) to (viii) and it shall be indicated whether any of the members has been suspended or withdrawn due to measures in case of non-compliance resulting from internal inspections or official controls.

## **Article 6 Notifications from the ICS manager**

The ICS manager shall immediately notify the competent authority or, where appropriate, the control authority or control body of the following information:

- (a) any suspicion of major and critical non-compliance;
- (b) any suspension or withdrawal of a member or a production unit or premises, including purchase and collection centres, from the group;
- (c) 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.

[\(EU\) 2021/771-Commission Delegated Regulation of 21 January 2021 supplementing Regulation \(EU\) 2018/848 of the European Parliament and of the Council by laying down specific criteria and conditions for the checks of documentary accounts in the framework of official controls in organic production and the official controls of groups of operators](#)

## **Article 2 Official controls of groups of operators**

1. In order to certify and verify the compliance of a group of operators, the competent authority or, where appropriate, the control authority or control body, shall assign inspectors competent to assess systems for internal controls (ICS).

2. For the purpose of evaluating the set-up, functioning and maintaining of the ICS of a group of operators, the competent authority or, where appropriate, the control authority or control body, shall determine at least that:

- (a) the documented procedures of the ICS that have been put in place comply with the requirements established in Regulation (EU) 2018/848;

- (b) the list of members of the group of operators with the required information for each member is continuously updated and aligned with the scope of the certificate;
- (c) all members of the group of operators comply with the criteria set out in Article 36(1)(a), (b) and (e) of Regulation (EU) 2018/848 throughout their participation in the group of operators;
- (d) the number, training and competence of ICS inspectors are proportionate and adequate and ICS inspectors are without conflicts of interest;
- (e) the internal inspections of all members of the group of operators and their activities and production units or premises including purchase and collection centres have been carried out at least annually and are documented;
- (f) new members or new production units and new activities of existing members, including new purchase and collection centres, have been accepted only after they have been approved by the ICS manager on the basis of the internal inspection report according to the ICS documented procedures that have been put in place;
- (g) the ICS manager takes appropriate measures in case of non-compliance, including their follow up, according to the ICS documented procedures that have been put in place;
- (h) the ICS manager's notifications to the competent authority or, where appropriate, the control authority or control body, are appropriate and sufficient;
- (i) the internal traceability for all products and members of the group of operators is ensured by estimating quantities and by cross-checking the yields of each member of the group of operators;
- (j) the members of the group of operators receive adequate training on the ICS procedures and the requirements of Regulation (EU) 2018/848.

**3.** The competent authority or, where appropriate, the control authority or control body, shall apply risk assessment to select the sample of the members of the group of operators for the re-inspections in accordance with Article 38(4)(d) of Regulation (EU) 2018/848. In doing so, it shall take into account at least the volume and the value of the production and the assessment of the likelihood of non-compliance with the provisions of Regulation (EU) 2018/848. Re-inspections shall be carried out physically on the spot with the presence of the members selected.

**4.** The competent authority or, where appropriate, the control authority or control body, shall allocate reasonable time for the control of a group of operators, proportional to the type, structure, size, the products, the activities and output of organic production of the group of operators.

**5.** The competent authority or, where appropriate, the control authority or control body, shall carry out witness audits in order to verify the competence and knowledge of ICS inspectors.

**6.** The competent authority or, where appropriate, the control authority or control body, shall assess whether there is a failure of the ICS based on the number of non-compliances undetected by the ICS inspectors and the result of the investigation of the cause and the nature of the non-compliances.

**(EU) 2021/1698-Commission Delegated Regulation of 13 July 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with procedural requirements for the recognition of control authorities and control bodies that are competent to carry out controls on operators and groups of operators certified organic and on organic products in third countries and with rules on their supervision and the controls and other actions to be performed by those control authorities and control bodies**

## CHAPTER III

### CONTROLS IN RESPECT OF OPERATORS AND GROUPS OF OPERATORS BY THE CONTROL AUTHORITIES AND CONTROL BODIES

#### Article 9 General provisions

**1.** Controls performed by control authorities and control bodies for the verification of compliance with Regulation (EU) 2018/848 by operators and groups of operators in third countries shall include:

a. the verification of the application of preventive and precautionary measures, as referred to in Article 9(6) and in Article 28 of Regulation (EU) 2018/848, at every stage of production, preparation and distribution;

b. where the holding includes non-organic or in-conversion production units, the verification of the records and of the measures or procedures or arrangements in place to ensure the clear and effective separation between organic, in-conversion and non-organic production units as well as between the respective products produced by those units, and of the substances and products used for organic, in-conversion and non-organic production units.

Such verification shall include checks on parcels for which a previous period was recognised retroactively as part of the conversion period, and checks on the non-organic production units.

c. where organic, in-conversion and non-organic products are collected simultaneously by operators, are prepared or stored in the same preparation unit, area or premises, or are transported to other operators or units, the verification of the records and of the measures, procedures or arrangements in place to ensure that operations are carried out separated by place or time, that suitable cleaning measures and measures to prevent substitution of products are implemented, that organic products and in-conversion products are identified at all times, that organic, in-conversion and non-organic products are stored, before and after the preparation operations, separated by place or time from each other, and that traceability of each lot from the individual land parcels to the collection centre has been ensured.

**2.** Controls by control authorities and control bodies for the verification of compliance with Regulation (EU) 2018/848 shall be performed on all operators and groups of operators in third countries regularly, on a risk basis and with appropriate frequency, throughout the entire process at all stages of production, preparation and distribution on the basis of the likelihood of non-compliance as defined in point (57) of Article 3 of Regulation (EU) 2018/848, which shall be determined taking into account the following elements:

(a) the type, size, including newly added land parcels, and structure of the operators and groups of operators, as well as the number of new members joining the group of operators;

(b) location and complexity of the activities or operations of operators and groups of operators;

(c) the length of time during which operators and groups of operators have been involved in organic production, preparation and distribution;

(d) the results of the controls performed in accordance with this Article, in particular as regards compliance with Regulation (EU) 2018/848;

(e) in the case of a group of operators, the results of the internal inspections carried out in accordance with the documented procedures of the system for internal controls of the group of operators;

(f) whether the holding includes non-organic or in-conversion production units;

(g) the type, quantity and value of products;;

(h) the risk of commingling of products or contamination with non-authorized products or substances;

(i) the application of derogations or exceptions to the rules by operators and groups of operators;

(j) the critical points for non-compliance at every stage of production, preparation and distribution;

(k) subcontracting activities;

(l) whether operators or groups of operators have changed their certifying control authority or control body;

(m) any information indicating the likelihood that consumers might be misled;

(n) any information that might indicate non-compliance with Regulation (EU) 2018/848.

**3.** Article 2 of Commission Delegated Regulation (EU) 2021/771 ve and Articles 4, 5 and 6 of Commission Implementing Regulation (EU) 2021/279 shall apply *mutatis mutandis* to controls in respect of groups of operators in third countries.

**4.** The control authority or control body shall carry out a verification of compliance with Regulation (EU) 2018/848 for all operators and groups of operators at least once a year. The verification of compliance shall include a physical on-the-spot inspection.

5. The control authority or control body shall ensure that it carries out every year at least 10 % of additional controls to those referred to in paragraph 4. Of all physical on-the-spot inspections carried out by the control authority or control body, at least 10 % shall be without prior notice.
6. Controls carried out as a follow-up on a suspected or established non-compliance shall not count towards the additional controls referred to in paragraph 5.
7. Every year, the control authority or control body shall re-inspect at least 5 % of the members of a group of operators, but not less than 10 members. Where the group of operators has 10 members or less, all members shall be re-inspected.
8. The physical on-the-spot inspection and the sampling shall be carried out by the control authority or control body at the most appropriate times in order to verify compliance on critical control points. For the high-risk products referred to in Article 8, the control authority or control body shall carry out, at least, two physical on-the-spot inspections per year of operators or groups of operators. One of these physical on-the-spot inspections shall be without prior notice.
9. Where operators or groups of operators run several production units or premises, including purchase and collection centres, all production units or premises, including purchase and collection centres, used for non-organic products shall also be subject to the control requirements set out in paragraph 4.
10. The delivery or renewal of the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 shall be based on the results of the verification of compliance referred to in this Article.

## Article 11 Methods and techniques for controls

1. Control methods and techniques applied by a control authority or control body shall include the following:
  - (a) a check whether the maps or sketches with cardinal directions and geo-location of the production units and premises to be physically inspected, as provided by the operators or groups of operators, is up-to-date;
  - (b) an inspection of, as appropriate:
    - (i) the production units, equipment, means of transport, premises and other places under the control of the operator or group of operators;
    - (ii) animals, plants and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals, and substances authorised for use in organic production;
    - (iii) traceability, labelling, presentation, advertising and relevant packaging materials;
  - (c) an examination of documents, traceability records and other records and practices and procedures that are relevant for the assessment of compliance with Regulation (EU) 2018/848. This includes documents accompanying food, feed and any substance or material entering or leaving an establishment;
  - (d) interviews with operators and their staff;
  - (e) sampling and laboratory analysis;
  - (f) the examination of the control system that operators and groups of operators have put in place, including an evaluation of its effectiveness;
  - (g) the examination of non-compliances found during previous inspections and the measures taken by the operators or by the groups of operators to address them;
  - (h) any other action required to identify cases of non-compliance..
2. The annual physical on-the-spot inspection referred to in Article 9(4) shall include a traceability check and a mass balance check of the operators or groups of operators, carried out by means of checks of documentary accounts and of any other relevant element deemed necessary by the control authority or control body.
3. For the purpose of the traceability check and the mass balance check, the selection of products, groups of products and period under verification shall be based on a risk assessment by the control authority or control body.
4. Besides any other relevant element deemed necessary by the control authority or control body, the traceability check shall cover the following elements justified by appropriate documents including stock and financial records:

- (a) the name and address of the supplier and, where different, of the owner or the seller, or the exporter of the products;
- (b) the name and address of the consignee and, where different, of the buyer or importer of the products;
- (c) the certificate of the supplier in accordance with an implementing act adopted pursuant Article 45(4) of Regulation (EU) 2018/848;
- (d) the information referred to in the first paragraph of point 2.1 of Annex III to Regulation (EU) 2018/848
- (e) the appropriate lot identification;
- (f) in the case of processors, the necessary information to allow internal traceability and guarantee the organic status of ingredients.

**5.** The mass balance check shall cover the following elements justified by appropriate documents including stock and financial records, where relevant:

- (a) the nature and the quantities of products delivered to the unit and, where relevant, of materials bought and the use of such materials, and, where relevant, the composition of products;
- (b) the nature and the quantities of products held in storage at the premises including at the time of the physical on-the-spot inspection;
- (c) the nature and quantities of the products that have left the unit of the operators or groups of operators to the consignee's premises or storage facilities;
- (d) in case of operators or groups of operators who buy or sell the product(s) without storing or physically handling the product(s), the nature and the quantities of products that have been bought and sold;
- (e) the yield of the products obtained, collected or harvested over the previous year;
- (f) the estimated or actual yield of the products obtained, collected or harvested over the current year;
- (g) the number and/or weight of livestock managed over the current and previous year;
- (h) any losses, increase or decrease in quantity of products at any stage of production, preparation and distribution;
- (i) the total output of the holding in terms of organic and non-organic products.

## **Article 12 Sampling, methods used for sampling and selection of laboratories for sample analysis**

1. The control authority or control body shall take and analyse samples for detecting the use of non-authorized products and substances for organic production, for checking production techniques not in compliance with the organic production rules or for detecting possible contamination by non-authorized products and substances for organic production.
2. The control authority or control body shall carry out sampling on at least 5 % of the number of individual operators under its control. For a group of operators, the control authority or control body carry out sampling on at least 2 % of the members of each group.
3. The selection of the operators and groups of operators where samples have to be taken shall be based on risk assessment including the likelihood of non-compliance with the organic production rules, taking into account all stages of production, preparation and distribution.
4. In addition to the minimum sampling rate set in paragraph 2, the control authority or control body shall take and analyse samples in each case where the use of non-authorized products and substances or techniques for organic production is suspected, unless the control authority or control body considers that sufficient evidence is available without sampling.
5. For the high-risk products referred to in Article 8, the control authority or control body shall take, in addition to the sampling rate set in paragraphs 2 and 3 of this Article, at least one field sample of the crop each year. That sample shall be taken from crops in the field, at the most appropriate moment to detect potential use of non-authorized substances according to the assessment of the control authority or control body. For operators not growing crops, a relevant sample of incoming raw material or intermediate product or processed product shall be taken.
6. The control authority and control body shall ensure that the laboratories used comply with the following:
  - (a) they are accredited laboratories that meet the applicable requirements of ISO standard ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';

(b) their accreditation bodies are signatory of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;

(c) they have sufficient capacity for analysis and testing and they can ensure that samples are always tested with relevant methods included in the scope of their accreditation;

(d) as regards residue pesticide testing, they are accredited for gas and liquid spectrometry in order to be able to cover the list of pesticide residues monitored under the coordinated multi-annual control programme of the Union set out in Commission Implementing Regulation (EU) 2019/533.

7. The control authority or control body may delegate sampling tasks to other control authorities or control bodies recognised by the Commission or bodies accredited in accordance with ISO standard ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'.

## **Article 16 Verification of consignments intended for import into the Union**

1. The relevant control authority or control body shall verify consignments intended for import into the Union with regard to the compliance with Regulation (EU) 2018/848 and this Regulation. This verification shall include systematic documentary checks and, as appropriate according to a risk assessment, physical checks, before the consignment leaves the third country of export or of origin.

2. For the purposes of this Article, the relevant control authority or control body shall be:

(a) the control authority or control body of the producer or the processor of the product concerned; or

(b) where the operator or group of operators carrying out the last operation for the purpose of preparation is different from the producer or processor of the product, the control authority or control body of the operator or group of operators carrying out the last operation for the purpose of preparation as defined in point (44) of Article 3 of Regulation (EU) 2018/848.

The relevant control authority or control body shall be recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 for the products concerned and for the third country in which the products have their origin, or, where applicable, in which the last operation for the purpose of preparation has been carried out.

3. The documentary checks referred to in paragraph 1 shall aim at verifying:

(a) the traceability of the products and ingredients;

(b) that the volume of the products included in the consignment is in line with the mass balance checks of the respective operators or groups of operators according to the assessment carried out by the control authority or control body;

(c) the relevant transport documents and commercial documents (including invoices) of the products;

(d) in case of processed products, that all organic ingredients of such products have been produced by operators or groups of operators certified in a third country by a control authority or control body recognised in accordance with Article 46(1) or referred to in Article 57 of Regulation (EU) 2018/848 or by a third country recognised in accordance with Articles 47 and 48 of Regulation (EU) 2018/848, or have been produced and certified in the Union in accordance with that Regulation.

Those documentary checks shall be based on all relevant documents, including the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848, the latest record of the inspections, the production plan for the product concerned and records kept by the operators or groups of operators, available transport documents, commercial and financial documents and any other documents deemed relevant by the control authority or control body.

4. In relation to the risk assessment preceding physical checks as referred to in paragraph 1, the relevant control authority or control body shall take into account the following criteria:

(a) the relevant criteria listed in Article 9(2);

(b) whether there are several operators involved in the distribution chain of the products who do not store or physically handle organic products;

(c) high-risk products referred to in Article 8;

(d) any criteria deemed relevant by the control authority or control body.

5. For consignments made out of bulk organic products, the relevant control authority or control body shall draw up a travel plan in the Trade Control and Expert System (TRACES), including all the premises to be used during the travel from the third country of origin or export to the Union.
6. For consignments of high-risk products referred to in Article 8, the relevant control authority or control body shall carry out systematic physical checks and take at least one representative sample of each consignment. Moreover, the control authority or control body shall have complete documentation of the traceability of the operators or groups of operators and the product, including transport and commercial documents, including invoices. At the request of the Commission or the competent authority of a Member State, the control authority or control body shall send this traceability documentation as well as the results of the sampling analysis to the control authority or control body of the importer and to the competent authority of the Member State where the consignment is verified.
7. In case of suspicion of non-compliance, the Commission or the competent authority of a Member State may request the relevant control authority or control body to make available without delay the list of all operators and all groups of operators in the organic production chain of which the consignment is part, and of their control authorities or control bodies.

## **Article 21 Exchange of information between the Commission, control authorities, control bodies and competent authorities**

1. The control authority or control body shall immediately share information with the Commission, with other control authorities and control bodies, and with the competent authorities of the Member States and of the third countries concerned on any suspicion of non-compliance that affects the integrity of organic or in-conversion products.
2. Where a control authority or control body is notified by the Commission, after the Commission has received a notification from a Member State in accordance with Article 9 of Implementing Regulation (EU) 2021/279 as regards suspected or established non-compliance affecting the integrity of imported organic or in-conversion products, it shall carry out an investigation in accordance with Article 22 of this Regulation. The control authority or control body shall inform the Commission and the Member State that sent the initial notification (notifying Member State), using the template set out in Annex III to this Regulation. The control authority or control body shall reply within 30 calendar days from the date of receiving that notification and shall inform about the actions and measures taken, including the results of the investigation and provide any other information when available and/or required by the notifying Member State.
3. The notified control authority or control body shall provide further necessary information if requested by the notifying Member State.
4. Where operators or groups of operators and/or their subcontractors are subject to controls by different control authorities or control bodies, those control authorities or control bodies shall exchange the relevant information on the operations covered by their control activities.
5. Where operators or groups of operators and/or their subcontractors change their control authority or control body, the new control authority or control body shall request the control file of the operator or group of operators concerned from the previous control authority or control body. The previous control authority or control body shall, within 30 days, provide to the new control authority or control body the control file of the operator or group of operators concerned and the written records referred to in Article 14 of the Regulation (EU) 2021/1698, the status of the certification, the list of non-compliances and the corresponding measures taken by the previous control authority or control body.  
The new control authority or control body shall ensure that non-compliances noted in the report of the previous control authority or control body have been addressed by the operators or groups of operators.
6. Where operators or groups of operators are subject to a traceability check and a mass balance check, control authorities and control bodies shall exchange the relevant information allowing finalisation of these checks.

## **Article 22 Additional rules on actions to be taken in case of non-compliance**

1. In addition to the measures referred to in Article 29(1), (2) and (3) of Regulation (EU) 2018/848 and Article 2 of Implementing Regulation (EU) 2021/279, where a control authority or control body suspects or receives substantiated information, including information from other control authorities or control bodies, that a product, which may not be in compliance with Regulation (EU) 2018/848, is intended to be imported from a third country for the purpose of

placing that product on the market within the Union, but which bears terms referring to the organic production, or where such a control authority or control body has been informed by an operator of a suspicion of non-compliance in accordance with Article 27 of that Regulation:

(a) it shall immediately carry out an investigation with a view to verifying compliance with Regulation (EU) 2018/848 or with the delegated or implementing acts adopted pursuant to that Regulation; such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case;

(b) it shall prohibit the import from that third country for the purpose of placing the product concerned on the market within the Union as organic or in-conversion product pending the results of the investigation referred to in point (a). Before taking such a provisional decision, the control authority or control body, shall give the operator or group of operators an opportunity to comment.

2. In the event that the results of the investigation referred to in point (a) of paragraph 1 do not show any non-compliance affecting the integrity of organic or in-conversion products, those products shall be allowed to be used and labelled as organic or in-conversion products.

3. The control authority or control body shall develop a catalogue of measures to be taken in case of established non-compliance. That catalogue of measures shall be based on the elements specified in Annex IV to this Regulation and shall cover at least:

(a) a list of non-compliances with reference to the specific rules of Regulation (EU) 2018/848 or of the delegated or implementing acts adopted pursuant to that Regulation. That list shall include, at least the non-compliances listed in Part B of Annex IV to this Regulation;

(b) the classification of the non-compliances into three categories: minor, major and critical as set out in Part A of Annex IV to this Regulation, taking into account at least the following criteria:

(i) the application of precautionary measures referred to in Article 28(1) of Regulation (EU) 2018/848, the practical measures referred in point (a)(ii) of Article 10(1) of this Regulation and the reliability of own controls carried out by the operator or group of operators in line with point (f) of Article 11(1) of this Regulation;

(ii) the impact on the integrity of the organic or in-conversion of products;

(iii) the ability of the traceability system to locate the affected product(s) in the supply chain and prohibition of importing from a third country for the purpose of placing the product(s) on the market within the Union with reference to organic production;

(iv) the response of the operator or group of operators to previous requests from the control authority or control body;

(c) the measures to be applied for each non-compliance.

4. The control authority or control body shall document the results of the investigations referred to in point (a) of Article 29(1) of Regulation (EU) 2018/848.

## **Article 23 Additional rules on measures in the event of non-compliance**

1. In the event of non-compliance affecting the integrity of organic or in-conversion products throughout any of the stages of production, preparation and distribution, for example as a result of the use of non-authorized products, substances or techniques, or commingling with non-organic products, the control authority or control body shall ensure, in addition to the measures to be taken in accordance with paragraphs 2 and 3 of this Article, that no reference is made to organic production as set out in Chapter IV of Regulation (EU) 2018/848, in the labelling and advertising of the entire lot or production run of the product intended to be imported from a third country for the purpose of placing that product on the market within the Union.

2. Where the non-compliance is established, the control authority or control body shall:

a. take any action necessary to determine the origin and extent of the non-compliance and to establish the responsibilities of the operator or group of operators; and

b. take appropriate measures to ensure that the operator or group of operators remedies the non-compliance and prevents further occurrences of such non-compliance.

When deciding which measures to take, the control authority or control body shall take account of the nature of that non-compliance and the past record of the operator or of the group of operators with regard to compliance.

3. When acting in accordance with paragraph 2 of this Article, the control authority or control body shall take any measure it deems appropriate to ensure compliance with Regulation (EU) 2018/848 and the delegated and implementing acts adopted pursuant that Regulation, including:

- (a) applying the catalogue of measures referred to in Article 22(3) of this Regulation;
- (b) ensuring that the operator or group of operators increases the frequency of own controls;
- (c) ensuring that certain activities of the operator or of the group of operators are subject to increased or systematic controls by the control authority or control body.

4. In the event of serious, or repetitive or continued non-compliance, the control authority or control body shall ensure that the operator or group of operators, in addition to the measures laid down in paragraphs 2 and 3, is prohibited from placing on the market within the Union for a given period products which refer to organic production, and that its certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 be suspended or withdrawn, as appropriate.

5. The control authority or control body shall provide the operator or group of operators with a written notification of its decision concerning the action or measure to be taken in accordance with this Article, together with the reasons for that decision.

## **Article 24 Checks to be carried out for the purpose of the retroactive recognition of a previous period**

1. Before granting retroactive recognition of a previous period as part of the conversion period for the purposes of point (b) of Article 10(3) of Regulation (EU) 2018/848, the control authority or control body shall ensure that the operator submits the following documents proving that the land parcels were natural or agricultural areas that, for a period of at least 3 years, have not been treated or have not been contaminated with products or substances that are not authorised for use in organic production in accordance with Regulation (EU) 2018/848:

- (a) maps identifying clearly each land parcel covered by the request for retroactive recognition and information on the total surface of those land parcels and, if relevant, on the nature and the volume of the ongoing production and their geolocation coordinates;
- (b) any other relevant documents deemed necessary by the control authority or control body to assess the request for retroactive recognition:

2. In addition, the control authority or control body shall take the following steps:

- (a) it shall carry out a detailed risk analysis based on documentary evidence to assess whether any land parcel covered by the request for retroactive recognition has been treated with products or substances that are not authorised for use in organic production for a period of at least 3 years, taking into account in particular the size of the total surface to which the request relates and the agronomic practices carried out during that period on each land parcel subject to the request. The control authority or control body shall keep documents on the risk analysis;
- (b) it shall take samples on soil and/or plant from each land parcel in line with the results of the risk analysis referred to in point (a), including those land parcels identified as presenting the risk of being contaminated;
- (c) it shall draw up an inspection report in one of the official languages of the Union, including photographs of the parcels, following a physical inspection of the operator, including the land parcels covered by the request for retroactive recognition for the purpose of verifying the consistency of the information collected, but before any cultivation measures have been taken by the operator.

3. Based on the information provided by the operator in accordance with paragraph 1 and after having completed the steps set out in paragraph 2, the control authority or control body shall draw up a final written report. The final written report shall include a justification why the previous period can be recognised retroactively as part of the conversion period. This final written report shall also indicate the starting period considered as organic for each land parcel concerned as well as the total surface of the land parcels benefiting from this retroactive recognition of a period.

4. The control authority or control body shall immediately notify the Commission, the Member States and in case of a control body its accreditation body of any retroactive recognition granted. For each retroactive recognition granted, the control authority or control body shall provide the final written report referred to in paragraph 3.

5. The control authority or control body shall ensure that the operator to whom the granted retroactive recognition applies keeps documentary evidence relating to that recognition, as well as documentary evidence on the use of the land parcels covered by that recognition, for 3 years.

## Article 25 Authorisations for the use of non-organic plant reproductive material

1. Before granting authorisations for the use of non-organic plant reproductive material as set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848, the control authority or control body shall assess the following information and draw up a justification for each derogation granted:

- scientific and common name (common and Latin name);
- variety;
- total weight of seeds or number of plants concerned;
- the availability of organic or in-conversion plant reproductive material;
- documentation or a statement from the operator proving that the requirements set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848 have been fulfilled.

2. For each authorisation for the use of non-organic plant reproductive material as set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848, the control authority or control body shall include the relevant information in the annual report referred to in Article 4 of this Regulation.

## Article 27 Reporting on provisional authorisation for the use of non-organic agricultural ingredients for processed organic food

The control authority or control body shall immediately notify the Commission, the Member States, accreditation bodies and other control authorities and control bodies recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 of any provisional authorisation granted for the use of non-organic agricultural ingredients for processed organic food in accordance with Article 25(4) of that Regulation. That notification shall include the justification, presented in the dedicated form made available by the Commission, that such authorisation has been granted in accordance with Article 25(1) of Regulation (EU) 2018/848.

## Article 28 Recognition of catastrophic circumstances

In order for a situation to qualify as catastrophic circumstances deriving from an 'adverse climatic event', 'animal diseases', an 'environmental incident', a 'natural disaster' or a 'catastrophic event', as well as any comparable situation, the control authority or control body may recognise a situation as catastrophic circumstances based on a statement issued by the relevant authorities of the third country in which the situation occurs, where available. If such a statement is not available, any such recognition by the control authority or control body shall be based on data provided by official organisations justifying the catastrophic circumstances.

## Article 29 Conditions for derogations

1. Following the recognition referred to in Article 28, a control authority or control body may, upon identification of the operators affected in the area concerned or upon request from the individual operator or the member of the group of operators concerned, grant the relevant derogations set out in Article 3 of Delegated Regulation (EU) 2020/2146 and the conditions related thereto, provided that those derogations and conditions apply:

- for a limited period and no longer than necessary, and in no case longer than 12 months, to continue or recommence organic production as carried out before the date of application of those derogations;
- in relation to specifically affected types of production or, where relevant, land parcels; and
- to the individual operator or the member of the group of operators concerned.

2. The application of the derogations referred to in paragraph 1 shall be without prejudice to the validity of the certificates referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 during the period where the derogations apply, provided that the operator or operators concerned fulfil the conditions under which derogations were granted.

3. Control authorities and control bodies shall immediately notify the Commission, the Member States and, in case of a control body their accreditation body, of the derogations granted by them pursuant to this Regulation via the system referred to in Article 20(1). In particular, the control authority or control body shall indicate the name of the operator or operators concerned, the time period for the derogation, the type of production or, where relevant, land parcels, the justification for the derogation and include a statement from the relevant authority of the third country as referred to in Article 28. Where such a statement is not available, the control authority or control body shall justify the non-inclusion of such a statement and provide the relevant data on which the recognition is based.

4. The control authority or control body shall ensure that any operator to whom the granted derogations apply keep documentary evidence relating to the granted derogations as well as documentary evidence on the use of those derogations during the period where those derogations apply. The control authority or control body shall verify the compliance of the operator or operators with the conditions of the granted derogations.

## ANNEX IV

### Catalogue of measures referred to in Article 22(3)

#### PART A

#### Elements for the development and application of the catalogue of measures

1. Subject to Part B, the control authority or control body may classify cases of non-compliance as minor, major or critical, on the basis of the classification criteria in point (b) of Article 22(3) of the Regulation (EU)2021/2698 when one or more of the following situations apply:

(a) the case of non-compliance is minor when:

- i. the precautionary measures put in place by the operator are proportionate and appropriate, and the controls that the operator has put in place are efficient according to the assessment by the control authority or control body;
- ii. the non-compliance does not affect the integrity of the organic or in-conversion product;
- iii. the traceability system can locate the affected product(s) in the supply chain and the product can be prevented from being imported from a third country for the purpose of placing that product on the market within the Union with reference to organic production;

(b) the case of non-compliance is major when:

- i. the precautionary measures are not proportionate and appropriate and the controls that the operator has put in place are inefficient according to the assessment by the control authority or control body;
- ii. the non-compliance affects the integrity of the organic or in-conversion product;
- iii. the operator did not correct in a timely manner a minor non-compliance;
- iv. the traceability can locate the affected product(s) in the supply chain and the product can be prevented from being imported from a third country for the purpose of placing that product on the market within the Union with reference to organic production.

(c) the case of non-compliance is critical when:

- i. the precautionary measures are not proportionate and appropriate and the controls that the operator has put in place are inefficient according to the assessment by the control authority or control body;
- ii. the non-compliance affects the integrity of the organic or in-conversion product;
- iii. the operator fails to correct previous major non-compliances or repeatedly fails to correct other categories of non-compliances; and
- iv. there is no information from the traceability system to locate the affected product(s) in the supply and the products cannot be prevented from being imported from a third country for the purpose of placing that product on the market within the Union with reference to organic production.

#### 2. Measures

Control authorities or control bodies may apply one or more of the following measures in a proportionate manner to the listed categories of cases of non-compliance:

Category of non-compliance	Measure
Minör	Submission by the operator of an action plan within a time limit setting on the

	correction of the non-compliance(s)
Major	<ul style="list-style-type: none"> <li>- No reference to organic production in the labelling and advertising of the entire lot or production run concerned (crop(s) or animal(s) affected) according to Article 42(1) of Regulation (EU) 2018/848</li> <li>- Prohibition of import from a third country for the purpose of placing that product on the market within the Union as organic production for a given period according to Article 42(2) of Regulation (EU) 2018/848</li> <li>- New conversion period required</li> <li>- Limitation of the certificate's scope</li> <li>- Improvement of the implementation of the precautionary measures and the controls that the operator has put in place to ensure compliance</li> </ul>
Critical	<ul style="list-style-type: none"> <li>- No reference to organic production in the labelling and advertising of the entire lot or production concerned (crop(s) or animal(s) affected) according to Article 42(1) of Regulation (EU) 2018/848</li> <li>- Prohibition of import from a third country for the purpose of placing that product on the market within the Union as organic production for a given period according to Article 42(2) of Regulation (EU) 2018/848</li> <li>- New conversion period required</li> <li>- Limitation of the certificate's scope</li> <li>- Suspension of the certificate</li> <li>- Withdrawal of the certificate</li> </ul>

## PART B

### List of cases of non-compliance and the corresponding classification mandatory to be included in the catalogue of measures

Non-compliance	Category
Significant deviation between input and output calculation (mass balance)	Major
Absence of records and financial records showing the compliance with Regulation (EU) 2018/848	Critical
Intentional omission of information leading to incomplete records	Critical
Falsification of documents connected with the certification of organic products	Critical
Intentional re-labelling of downgraded products as organic	Critical
Intentional mixing organic with in-conversion or non-organic products	Critical
Intentional use of non-authorized substances or products within the scope of the Regulation (EU) 2018/848	Critical
Intentional use of GMOs	Critical
The operator refuses the control authority or the control body access to premises subject to controls, or to its book keepings, including financial records, or refuses to allow the control authority or control body to take samples	Critical

[\(EU\) 2021/2119-\(EU\) Commission Implementing Regulation of 1 December 2021 laying down detailed rules on certain records and declarations required from operators and groups of operators and on the technical means for the issuance of certificates in accordance with Regulation \(EU\) 2018/848 of the European Parliament and of the Council](#)

### Article 2 Records to be kept by operators and groups of operators

1. Operators and groups of operators shall keep all the necessary documents, including stock and financial records, that will enable competent authorities or, where appropriate, control authorities or control bodies to carry out, in particular, the following checks:

(a) checks on the preventive and precautionary measures taken in accordance with Article 9(6) and Article 28 of Regulation (EU) 2018/848;

- (b) the traceability check in accordance with Article 1(4) of Delegated Regulation (EU) 2021/771;  
(c) the mass balance check in accordance with Article 1(5) of Delegated Regulation (EU) 2021/771.

2. The documents to be kept for the purposes of the checks referred to in paragraph 1, point (a), shall include, in particular, documents confirming that the operator or group of operators has taken the proportionate and appropriate measures in order to:

- (a) prevent pests and diseases;  
(b) avoid contamination with products and substances that are not authorised for use in organic production in accordance with Regulation (EU) 2018/848 and the commingling with non-organic products.

[\(EU\) 2021/1165-Commission Implementing Regulation of 15 July 2021 authorising certain products and substances for use in organic production and establishing their list](#)

## ANNEX I

[Active substances contained in plant protection products authorised for use in organic production as referred to in point \(a\) of Article 24\(1\) of Regulation \(EU\) 2018/848](#)

The active substances listed in this Annex may be contained in plant protection products used in organic production as set out in this Annex, provided that these plant protection products are authorised pursuant to Regulation (EC) No 1107/2009. These plant protection products shall be used in compliance with the conditions set out in the Annex to Implementing Regulation (EU) No 540/2011 and in accordance with the conditions specified in the authorisations granted by the Member States where they are used. More restrictive conditions for use in organic production are specified in the last column of each table below.

In accordance with Article 9(3) of Regulation (EU) 2018/848, safeners, synergists and co-formulants as components of plant protection products, and adjuvants that are to be mixed with plant protection products shall be allowed for use in organic production, provided that they are authorised pursuant to Regulation (EC) No 1107/2009. The substances in this Annex may only be used for the control of pests as defined in Article 3(24) of Regulation (EU) 2018/848.

In accordance with point 1.10.2 of Part I of Annex II to Regulation (EU) 2018/848, these substances may only be used where plants cannot be adequately protected from pests by measures provided for in point 1.10.1 of that Part I, in particular by the use of biological control agents, such as beneficial insects, mites and nematodes complying with the provisions of Regulation (EU) No 1143/2014<sup>(1)</sup> of the European Parliament and of the Council.

For the purposes of this Annex, active substances are divided into following subcategories:

### 1. Basic Substances

Basic substances listed in Part C of the Annex to Implementing Regulation (EU) No 540/2011, from plant or animal origin and based on food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>1</sup> may be used for plant protection in organic production. Such basic substances are marked with an asterisk in the table below. They shall be used in accordance with the uses, conditions and restrictions set in the relevant review reports<sup>2</sup> and taking into account the additional restrictions, if any, in the last column of the table below.

Other basic substances listed in Part C of the Annex to Implementing Regulation (EU) No 540/2011 may be used for plant protection in organic production only when they are listed in the table below. Such basic substances shall be used in accordance with the uses, conditions and restrictions set in the relevant review reports and taking into account the additional restrictions, if any, in the right column of the table below.

Basic substances shall not be used as herbicides.

<sup>(1)</sup> Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species (OJ L 317, 4.11.2014, p. 35).

<sup>1</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>2</sup> Available in the Pesticides Database: <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as>

Number and Part of Annex <sup>(1)</sup>	CAS	Name	Specific conditions and limits
1C		Equisetum arvense L.*	
2C	9012-76-4	Chitosan hydrochloride*	obtained from Aspergillus or organic aquaculture or from sustainable fisheries, as defined in Article 2 of Regulation (EU) No 1380/2013 of the European Parliament and of the Council <sup>(2)</sup>
3C	57-50-1	Sucrose*	
4C	1305-62-0	Calcium Hydroxide	
5C	90132-02-8	Vinegar*	
6C	8002-43-5	Lecithins*	
7C	-	Salix spp. Cortex*	
8C	57-48-7	Fructose*	
9C	144-55-8	Sodium hydrogen carbonate	
10C	92129-90-3	Whey*	
11C	7783-28-0	Diammonium phosphate	only in traps
12C	8001-21-6	Sunflower oil*	
14C	84012-40-8 90131-83-2	Urtica spp. (Urtica dioica extract) (Urtica urens extract)*	
15C	7722-84-1	Hydrogen peroxide	
16C	7647-14-5	Sodium chloride	
17C	8029-31-0	Beer*	
18C	-	Mustard seeds powder*	
19C	14807-96-6	Magnesium hydrogen metasilicate silicate mineral (Talc E553b)	food grade in conformity with Commission Regulation (EU) No 231/2012 <sup>(3)</sup>
20C	8002-72-0	Onion oil*	
21C	52-89-1	L-cysteine (E 920)	
22C	8049-98-7	Cow milk*	
23C	--	Allium cepa* L. bulb extract	
		Other basic substances from plant or animal origin and based on food*	

<sup>(1)</sup> Listing according to Implementing Regulation (EU) No 540/2011, numbers and which category: Part A active substances deemed to have been approved under Regulation (EC) No 1107/2009, B, active substances approved under Regulation (EC) No 1107/2009, C basic substances, D low-risk active substances and E candidates for substitution.

<sup>(2)</sup> Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

<sup>(3)</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

## 2. Low risk active substances

Low risk active substances, other than micro-organisms, listed in Part D of the Annex to Implementing Regulation (EU) No 540/2011 may be used for plant protection in organic production when they are listed in the table below or elsewhere in this Annex. Such low risk active substances shall be used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) No 1107/2009 and taking into account the additional restrictions, if any, in the last column of the table below.

Number and Part of Annex <sup>(1)</sup>	CAS	Name	Specific conditions and limits
2D		COS-OGA	

3D		Cerevisane and other products based on fragments of cells of micro-organisms	Not from GMO origin
5D	10045-86-6	Ferric phosphate (iron (III) orthophosphate)	
12D	9008-22-4	Laminarin	Kelp shall be obtained from organic aquaculture or collected in a sustainable way in accordance with point 2.4 of Part III of Annex II to Regulation (EU) 2018/848.
16D	CAS not allocated	ABE-IT 56 (components of lysate of <i>Saccharomyces cerevisiae</i> strain DDSF623)	GDO menşeli olmayan, GDO menşeli yetiştirme ortamları kullanılarak üretilmemiş
20D	10058-44-3	Ferric pyrophosphate	
28D		Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i>	

<sup>(1)</sup> Listing according to Implementing Regulation (EU) No 540/2011, numbers and which category: Part A active substances deemed to have been approved under Regulation (EC) No 1107/2009, B, active substances approved under Regulation (EC) No 1107/2009, C basic substances, D low-risk active substances and E candidates for substitution.

### 3. Micro-organisms

All micro-organisms listed in Parts A, B and D of the Annex to Implementing Regulation (EU) No 540/2011 may be used in organic production, provided that they are not from GMO origin and only when used in accordance with the uses, conditions and restrictions set in the relevant review reports. Micro-organisms including viruses are biological control agents that are considered as active substances by Regulation (EC) No 1107/2009.

### 4. Active substances not included in any of the above categories

The active substances as approved pursuant to Regulation (EC) No 1107/2009 and listed in the table below may be used as plant protection products in organic production only when they are used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) No 1107/2009 and taking into account the additional restrictions, if any, in the right column of the table below.

Number and part of Annex <sup>(1)</sup>	CAS	Name	Specific conditions and limits
139A	131929-60-7 131929-63-0	Spinosad	
225A	124-38-9	Carbon dioxide	
227A	74-85-1	Ethylene	only on bananas and potatoes; however, it may also be used on citrus as part of a strategy for the prevention of fruit fly damage
230A	Örn. 67701-09-1	Fatty acids	all uses authorised, except herbicide
231A	8008-99-9	Garlic extract ( <i>Allium sativum</i> )	
234A	CAS No not allocated CIPAC No 901	Hydrolysed proteins excluding gelatine	
244A	298-14-6	Potassium hydrogen carbonate	
249A	98999-15-6	Repellents by smell of animal or plant origin/sheep fat	

255A and others		Pheromones and other semiochemicals	Sadece tuzaklarda ve dağıtıcılarda
220A	1332-58-7	Aluminium silicate (kaolin)	
236A	61790-53-2	Kieselgur (diatomaceous earth)	
247A	14808-60-7 7637-86-9	Quartz sand	
343A	11141-17-6 84696-25-3	Azadirachtin (Margosa extract)	extracted from Neem tree seeds ( <i>Azadirachta indica</i> )
240A	8000-29-1	Citronella oil	all uses authorised, except herbicide
241A	84961-50-2	Clove oil	all uses authorised, except herbicide
242A	8002-13-9	Rape seed oil	all uses authorised, except herbicide
243A	8008-79-5	Spearmint oil	all uses authorised, except herbicide
56A	8028-48-6 5989-27-5	Orange oil	all uses authorised, except herbicide
228A	68647-73-4	Tea tree oil	all uses authorised, except herbicide
246A	8003-34-7	Pyrethrins extracted from plants	
292A	7704-34-9	Sulphur	
294A 295A	64742-46-7 72623-86-0 97862-82-3 8042-47-5	Paraffin oils	
345A	1344-81-6	Lime sulphur (calcium polysulphide)	
44B	9050-36-6	Maltodextrin	
45B	97-53-0	Eugenol	
46B	106-24-1	Geraniol	
47B	89-83-8	Thymol	
10E	20427-59-2	Copper hydroxide	in accordance with Implementing Regulation (EU) No 540/2011 only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years may be authorised
10E	1332-65-6 1332-40-7	Copper oxychloride	
10E	1317-39-1	Copper oxide	
10E	8011-63-0	Bordeaux mixture	
10E	12527-76-3	Tribasic copper sulphate	
40A	52918-63-5	Deltamethrin	only in traps with specific attractants against <i>Bactrocera oleae</i> , <i>Ceratitis capitata</i> and <i>Rhagoletis completa</i>
5E	91465-08-6	Lambda-cyhalothrin	

<sup>(1)</sup> Listing according to Implementing Regulation (EU) No 540/2011, numbers and which category: Part A active substances deemed to have been approved under Regulation (EC) No 1107/2009, B, active substances approved under Regulation (EC) No 1107/2009, C basic substances, D low-risk active substances and E candidates for substitution.

## ANNEX II

### Authorised fertilisers, soil conditioners and nutrients referred to in point (b) of Article 24(1) of Regulation (EU) 2018/848

Fertilisers, soil conditioners and nutrients<sup>(1)</sup>, listed in this Annex may be used in organic production, provided that they are compliant with.

—the relevant Union and national legislations on fertilising products, in particular, where applicable, Regulation (EC) No 2003/2003 and Regulation (EU) 2019/1009; and

— Union legislation on animal by-products, in particular Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011, in particular Annexes V and XI.

# TRANSLATION FORM OF THE PRODUCTION RULES AND CONTROL MEASURES

In accordance with point 1.9.6 of Part I of Annex II to Regulation (EU) 2018/848, preparations of micro-organisms may be used to improve the overall condition of the soil or to improve the availability of nutrients in the soil or in the crops.

They may only be used according to the specifications and restrictions of use of those respective Union and national legislations. More restrictive conditions for use in organic production are specified in the right column of the tables.

<sup>(1)</sup> Covering in particular all the product function categories listed in Part I of Annex I to Regulation (EU) 2019/1009.

Name Compound products or products containing only materials listed hereunder	Description, specific conditions and limits
Farmyard manure	product comprising a mixture of animal excrements and vegetable matter (animal bedding and feed material) factory farming origin forbidden
Dried farmyard manure and dehydrated poultry manure	factory farming origin forbidden
Composted animal excrements, including poultry manure and composted farmyard manure included	factory farming origin forbidden
Liquid animal excrements	use after controlled fermentation and/or appropriate dilution factory farming origin forbidden
Composted or fermented mixture of household waste	product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production  only vegetable and animal household waste  only when produced in a closed and monitored collection system, accepted by the Member State  maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable
Peat	use limited to horticulture (market gardening, floriculture, arboriculture, nursery)
Mushroom culture wastes	the initial composition of the substrate shall be limited to products of this Annex
Dejecta of worms (vermicompost) and insect frass-substrate mixture	where relevant in accordance with Regulation (EC) No 1069/2009
Guano	
Composted or fermented mixture of vegetable matter	product obtained from mixtures of vegetable matter, which have been submitted to composting or to anaerobic fermentation for biogas production
Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex	animal by-products (including by-products of wild animals) of category 3 and digestive tract content of category 2 (categories as defined in Regulation (EC) No 1069/2009) factory farming origin forbidden the processes have to be in accordance with Regulation (EU) No 142/2011 not to be applied to edible parts of the crop
Products or by-products of animal origin as below: Blood meal Hoof meal Horn meal Bone meal or degelatinised bone meal Fish meal Meat meal	(1) Maximum concentration in mg/kg of dry matter of chromium (VI): not detectable (2) Not to be applied to edible parts of the crop

Feather, hair and skin meal ('chiquette') Wool Fur (1) Hair Dairy products Hydrolysed proteins (2)	
Products and by-products of plant origin for fertilisers	e.g.: oilseed cake meal, cocoa husks, malt culms
Hydrolysed proteins of plant origin	
Algae and algae products	as far as directly obtained by: (i) physical processes including dehydration, freezing and grinding (ii) extraction with water or aqueous acid and/or alkaline solution (iii) fermentation only from organic or collected in a sustainable way in accordance with point 2.4 of Part III of Annex II to Regulation (EU) 2018/848
Sawdust and wood chips	wood not chemically treated after felling
Composted bark	wood not chemically treated after felling
Wood ash	from wood not chemically treated after felling
Soft ground rock phosphate	product obtained by grinding soft mineral phosphates and containing tricalcium phosphate and calcium carbonate as essential ingredients minimum content of nutrients (percentage by weight): 25 % P2O5 phosphorus expressed as P2O5 soluble in mineral acids, at least 55 % of the declared content of P2O5 being soluble in 2 % formic acid particle size: — at least 90 % by weight able to pass through a sieve with a mesh of 0,063 mm  — at least 99 % by weight able to pass through a sieve with a mesh of 0,125 mm  until 15 July 2022, cadmium content less than or equal to 90 mg/kg of P2O5;  from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply
Aluminium-calcium phosphate	product obtained in amorphous form by heat treatment and grinding, containing aluminium and calcium phosphates as essential ingredients minimum content of nutrients (percentage by weight): 30 % P2O5 phosphorus expressed as P2O5 soluble in mineral acids, at least 75 % of the declared content of P2O5 being soluble in alkaline ammonium citrate (Joulie) particle size: — at least 90 % by weight able to pass through a sieve with a mesh of 0,160 mm  — at least 98 % by weight able to pass through a sieve with a mesh of 0,630 mm

	<p>until 15 July 2022, cadmium content less than or equal to 90 mg/kg of P2O5;          from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply          use limited to basic soils (pH &gt; 7,5)</p>
Basic slag (Thomas phosphates or Thomas slag)	<p>product obtained in iron-smelting by treatment of the phosphorus melts and containing calcium silicophosphates as its essential ingredients          minimum content of nutrients (percentage by weight):              12 % P2O5              phosphorus expressed as phosphorus pentoxide soluble in mineral acids, at least 75 % of the declared content of phosphorus pentoxide being soluble in 2 % citric acid          or              10 % P2O5              phosphorus expressed as phosphorus pentoxide soluble in 2 % citric acid</p> <p>particle size:              — at least 75 % able to pass through a sieve with a mesh of 0,160 mm              — at least 96 % able to pass through a sieve with a mesh of 0,630 mm</p> <p>from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply</p>
Crude potassium salt	<p>product obtained from crude potassium salts          minimum content of nutrients (percentage by weight):              9 % K2O              potassium expressed as water- soluble K2O              2 % MgO              magnesium in the form of water- soluble salts, expressed as magnesium oxide</p> <p>from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply</p>
Potassium sulphate, possibly containing magnesium salt	product obtained from crude potassium salt by a physical extraction process, containing possibly also magnesium salts
Stillage and stillage extract	ammonium stillage excluded
Calcium carbonate, for instance: chalk, marl, ground limestone, Breton ameliorant (maerl), phosphate chalk	only of natural origin
Mollusc waste	only from organic aquaculture or from sustainable fisheries, in accordance with Article 2 of Regulation (EU) No 1380/2013
Egg shells	factory farming origin forbidden
Magnesium and calcium carbonate	only of natural origin  e.g. magnesian chalk, ground magnesium, limestone
Magnesium sulphate (kieserite)	only of natural origin
Calcium chloride solution	only for foliar treatment of apple trees, to prevent deficit of calcium
Calcium sulphate (gypsum)	product of natural origin containing calcium sulphate at various degrees of hydration minimum content of nutrients (percentage per weight):

	<p>25 % CaO 35 % SO<sub>3</sub> calcium and sulphur expressed as total CaO + SO<sub>3</sub></p> <p>fineness of grind: — at least 80 % to pass through a sieve with a 2 mm mesh width, — at least 99 % to pass through a sieve with a 10 mm mesh width</p> <p>from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply</p>
Industrial lime from sugar production	by-product of sugar production from sugar beet and sugar cane
Industrial lime from vacuum salt production	by-product of the vacuum salt production from brine found in mountains
Elemental sulphur	<p>until 15 July 2022: as listed in accordance with Part D of Annex I to Regulation (EC) No 2003/2003</p> <p>from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply</p>
Inorganic Micronutrient Fertilisers	<p>until 15 July 2022: as listed in accordance with Part E of Annex I to Regulation (EC) No 2003/2003;</p> <p>from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply</p>
Sodium chloride	
Stone meal, clays and clay minerals	
Leonardite (Raw organic sediment rich in humic acids)	only if obtained as a by-product of mining activities
Humic and fulvic acids	only if obtained by inorganic salts/solutions excluding ammonium salts; or obtained from drinking water purification
Xylite	only if obtained as a by-product of mining activities (e.g. by-product of brown coal mining)
Chitin (Polysaccharide obtained from the shell of crustaceans)	obtained from organic aquaculture or from sustainable fisheries, in accordance with Article 2 of Regulation (EU) No 1380/2013
Organic <sup>(1)</sup> rich sediment from fresh water bodies formed under exclusion of oxygen  (e.g. sapropel)	<p>only organic sediments that are by-products of fresh water body management or extracted from former freshwater areas when applicable, extraction should be done in a way to cause minimal impact on the aquatic system</p> <p>only sediments derived from sources free from contaminations of pesticides, persistent organic pollutants and petrol like substances</p> <p>until 15 July 2022: maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable</p> <p>from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply</p>
Biochar – pyrolysis product made from a wide variety of organic materials of plant origin and applied as a soil conditioner	<p>only from plant materials, when treated after harvest only with products included in Annex I</p> <p>until 15 July 2022: maximum value of 4 mg polycyclic aromatic hydro-carbons (PAHs) per kg dry matter (DM)</p> <p>from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply</p>

Recovered struvite and precipitated phosphate salts	products must meet the requirements laid down in Regulation (EU) 2019/1009 animal manure as source material cannot have factory farming origin.
Sodium nitrate	only for algae production on land in closed systems
Potassium chloride (muriate of potash)	only of natural origin

<sup>(1)</sup> Here 'organic' is used in the sense of organic chemistry, not organic farming

## ANNEX IV

### Authorised products for cleaning and disinfection referred to in points (e), (f) and (g) of Article 24(1) of Regulation (EU) 2018/848

#### PART A

Products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production

#### PART B

Products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding

#### PART C

Products for cleaning and disinfection in processing and storage facilities

#### PART D

##### Products referred to in Article 12(1) of this Regulation

Cleaning and disinfection products listed in Annex VII of Regulation (EC) 889/2008 may continue to be used until 31 December 2023 for cleaning and disinfection of pools, cages, tanks, canals, buildings or facilities used for animal production.

The following products or products containing the following active substances as listed in Annex VII to Regulation (EC) No 889/2008 cannot be used as biocidal products:.

- caustic soda;
- caustic potash;
- oxalic acid;
- natural essences of plants with the exception of linseed oil, lavender oil and peppermint oil;
- nitric acid;
- phosphoric acid;
- sodium carbonate;
- copper sulphate;
- potassium permanganate;
- tea seed cake made of natur
- peroxyacetic acids with the exception of peracetic acid.
- al camelia seed;
- humic acid

## ANNEX V

Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed

### PART A

Authorised food additives and processing aids referred to in point (a) of Article 24(2) of Regulation (EU) 2018/848

#### SECTION A1 – FOOD ADDITIVES, INCLUDING CARRIERS

The organic foodstuffs to which food additives may be added are within the limit of authorisations given in accordance with Regulation (EC) No 1333/2008.

The specific conditions and restrictions set out here are to be applied in addition to the conditions of the authorisations under Regulation (EC) No 1333/2008.

For the purpose of the calculation of the percentages referred to in Article 30(5) of Regulation (EU) 2018/848, food additives marked with an asterisk in the column of the code number shall be calculated as ingredients of agricultural origin.

Code	Name	Organic foodstuffs to which it may be added	Specific conditions and limits
E 153	Vegetable carbon	edible cheese rind of ashy goat cheese Morbier cheese	
E 160b(i)*	Annatto bixin	Red Leicester cheese Double Gloucester cheese Cheddar Mimolette cheese	
E 160b(ii)*	Annatto norbixin	Red Leicester cheese Double Gloucester cheese Cheddar Mimolette cheese	
E 170	Calcium carbonate	products of plant and animal origin	shall not be used for colouring or calcium enrichment of products
E 220	Sulphur dioxide	fruit wines (wine made from fruits other than grapes, including cider and perry) and mead with and without added sugar	100 mg/l (maximum levels available from all sources, expressed as SO <sub>2</sub> in mg/l)
E 223	Sodium metabisulphite	crustaceans	
E 224	Potassium metabisulphite	fruit wines (wine made from fruits other than grapes, including cider and perry) and mead with and without added sugar	100 mg/l (maximum levels available from all sources, expressed as SO <sub>2</sub> in mg/l)
E250	Sodium nitrite	meat products	may only be used, if it has been demonstrated to the satisfaction of the competent authority that no technological alternative, giving the same guarantees and/or allowing to maintain the specific features of the product, is available not in combination with E252

			maximum ingoing amount expressed as NaNO <sub>2</sub> : 80 mg/kg, maximum residual amount expressed as NaNO <sub>2</sub> : 50 mg/kg
E252	Potassium nitrate	meat products	may only be used, if it has been demonstrated to the satisfaction of the competent authority that no technological alternative, giving the same guarantees and/or allowing to maintain the specific features of the product, is available  not in combination with E250 maximum ingoing amount expressed as NaNO <sub>3</sub> : 80 mg/kg, maximum residual amount expressed as NaNO <sub>3</sub> : 50 mg/kg
E 270	Lactic acid	products of plant and animal origin	
E 290	Carbon dioxide	products of plant and animal origin	
E 296	Malic acid	products of plant origin	
E 300	Ascorbic acid	products of plant origin meat products	
E 301	Sodium ascorbate	meat products	may only be used in connection with nitrates and nitrites
E 306*	Tocopherol-rich extract	products of plant and animal origin	antioxidant
E 322*	Lecithins	products of plant origin milk products	only from organic production
E 325	Sodium lactate	products of plant origin milk-based and meat products	
E 330	Citric acid	products of plant and animal origin	
E 331	Sodium citrates	products of plant and animal origin	
E 333	Calcium citrates	products of plant origin	
E 334	Tartaric acid (L(+)-)	products of plant origin mead	
E 335	Sodium tartrates	products of plant origin	
E 336	Potassium tartrates	products of plant origin	
E 341(i)	Monocalcium phosphate	self-raising flour	raising agent
E 392*	Extracts of Rosemary	products of plant and animal origin	only from organic production
E 400	Alginic acid	products of plant origin milk products	
E 401	Sodium alginate	products of plant origin milk products sausages based on meat	
E 402	Potassium alginate	products of plant origin milk-based products	

# TRANSLATION FORM OF THE PRODUCTION RULES AND CONTROL MEASURES

E 406	Agar	products of plant origin milk-based products and meat products	
E 407	Carrageenan	products of plant origin milk-based products	
E 410*	Locust bean gum	products of plant and animal origin	only from organic production
E 412*	Guar gum	products of plant and animal origin	only from organic production
E 414*	Arabic gum	products of plant and animal origin	only from organic production
E 415	Xanthan gum	products of plant and animal origin	
E 417	Tara gum	products of plant and animal origin	thickener only from organic production
E 418	Gellan gum	products of plant and animal origin	high-acyl form only only from organic production, applicable as of 1 January 2026
E 422	Glycerol	plant extracts flavourings	only from plant origin solvent and carrier in plant extracts and flavourings humectant in gel capsules surface coating of tablets only from organic production
E 440(i)*	Pectin	products of plant origin milk-based products	
E 460	Cellulose	gelatine	
E 464	Hydroxypropyl methyl cellulose	products of plant and animal origin	encapsulation material for capsules
E 500	Sodium carbonates	products of plant and animal origin	
E 501	Potassium carbonates	products of plant origin	
E 503	Ammonium carbonates	products of plant origin	
E 504	Magnesium carbonates	products of plant origin	
E 509	Calcium chloride	Milk-based products	coagulation agent
E 516	Calcium sulphate	products of plant origin	carrier
E 524	Sodium hydroxide	'Laugengebäck' flavourings	surface treatment acidity regulator
E 551	Silicon dioxide	cocoa, herbs and spices in dried powdered form flavourings propolis	for cocoa, only for use in automated dispensing machines
E 553b	Talc	products of plant origin sausages based on meat	For sausages based on meat, only surface treatment
E901	Beeswax	confectionery	glazing agent only from organic production
E903	Carnauba wax	confectionery	glazing agent

		citrus fruit	mitigating method for mandatory extreme cold treatment of fruit as a mandatory quarantine measure against harmful organisms in accordance with Commission Implementing Directive (EU) 2017/1279 <sup>(1)</sup> only from organic production
E 938	Argon	products of plant and animal origin	
E 939	Helium	products of plant and animal origin	
E941	Nitrogen	products of plant and animal origin	
E 948	Oxygen	products of plant and animal origin	
E968	Erythritol	products of plant and animal origin	only from organic production without using ion exchange technology

<sup>(1)</sup> Commission Implementing Directive (EU) 2017/1279 of 14 July 2017 amending Annexes I to V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 184, 15.7.2017, p. 33).

## SECTION A2 – PROCESSING AIDS AND OTHER PRODUCTS, WHICH MAY BE USED FOR PROCESSING OF INGREDIENTS OF AGRICULTURAL ORIGIN FROM ORGANIC PRODUCTION

The specific conditions and restrictions set out here are to be applied in addition to the conditions of the authorisations under Regulation (EC) No 1333/2008.

Name	Only authorised for the processing of the following organic foodstuffs	Specific conditions and limits
Water	products of plant and animal origin	drinking water within the meaning of Council Directive 98/83/EC <sup>(1)</sup>
Calcium chloride	products of plant origin sausages based on meat	coagulation agent
Calcium carbonate	products of plant origin	
Calcium hydroxide	products of plant origin	
Calcium sulfate	products of plant origin	coagulation agent
Magnesium chloride (or nigari)	products of plant origin	coagulation agent
Potassium carbonate	Grapes	drying agent
Sodium carbonate	products of plant and animal origin	
Lactic acid	Cheese	for the regulation of the pH of the brine bath in cheese production
L(+)-lactic acid from fermentation	plant protein extracts	
Citric acid	products of plant and animal origin	
Sodium hydroxide	Sugar(s) oil from plant origin excluding olive oil plant protein extracts	
Sulphuric acid	gelatine sugar(s)	
Hop extract	products of plant origin	only for antimicrobial purposes from organic production, if available
Pine rosin extract	products of plant origin	only for antimicrobial purposes from organic production, if available
Hydrochloric acid	gelatine	gelatine production in compliance with Regulation (EC) No 853/2004 of the

# TRANSLATION FORM OF THE PRODUCTION RULES AND CONTROL MEASURES

	Gouda-, Edam and Maasdammer cheeses, Boerenkaas, Friese and Leidse Nagelkaas	European Parliament and of the Council (2) for the regulation of the pH of the brine bath in the processing of cheeses
Ammonium hydroxide	Gelatine	gelatine production in compliance with Regulation (EC) No 853/2004
Hydrogen peroxide	Gelatine	gelatine production in compliance with Regulation (EC) No 853/2004
Carbon dioxide	products of plant and animal origin	
Nitrogen	products of plant and animal origin	
Ethanol	products of plant and animal origin	solvent
Tannic acid	products of plant origin	filtration aid
Egg white albumin	products of plant origin	
Casein	products of plant origin	
Gelatin	products of plant origin	
Isinglass	products of plant origin	
Vegetable oils	products of plant and animal origin	greasing, releasing or antifoaming agent only from organic production
Silicon dioxide gel or colloidal solution	products of plant origin	
Activated carbon (CAS-7440-44-0)	products of plant and animal origin	
Talc	products of plant origin	in compliance with the specific purity criteria for food additive E 553b
Bentonite	products of plant origin mead	sticking agent for mead
Cellulose	products of plant origin gelatine	
Diatomaceous earth	products of plant origin gelatine	
Perlite	products of plant origin gelatine	
Hazelnut shells	products of plant origin	
Rice meal	products of plant origin	
Beeswax	products of plant origin	releasing agent only from organic production
Carnauba wax	products of plant origin	releasing agent only from organic production
Acetic acid/vinegar	products of plant origin; fish	only from organic production from natural fermentation
Thiamin hydrochloride	fruit wines, cider, perry and mead	
Diammonium phosphate	fruit wines, cider, perry and mead	
Wood fibre	products of plant and animal origin	the source of timber should be restricted to certified, sustainably harvested wood wood used must not contain toxic components (post-harvest treatment, naturally occurring toxins or toxins from micro-organisms)

- (1) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).
- (2) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)

## PART B

**Authorised non-organic agricultural ingredients to be used for the production of processed organic food referred to in point (b) of Article 24(2) of Regulation (EU) 2018/848**

Name	Specific conditions and limits
Alga Arame ( <i>Eisenia bicyclis</i> ), unprocessed as well as products of first-stage processing directly related to this alga	
Alga Hijiki ( <i>Hizikia fusiforme</i> ), unprocessed as well as products of first-stage processing directly related to this alga	
Bark of the Pau d'arco tree <i>Handroanthus impetiginosus</i> ('lapacho')	only for use in Kombucha and tea mixtures
Casings	from natural raw materials of animal or from plant origin material
Gelatin	from other sources than porcine
Milk mineral powder/liquid	only when used for its sensory function to replace wholly or partly sodium chloride
Wild fishes and wild aquatic animals, unprocessed as well as products derived therefrom by processes	only from fisheries that have been certified as sustainable under a scheme recognised by the competent authority in line with the principles laid down in Regulation (EU) No 1380/2013, in accordance with point 3.1.3.1(c) of Part III of Annex II to Regulation (EU) 2018/848 only when not available in organic aquaculture

## PART C

**Authorised processing aids and other products for the production of yeast and yeast products referred to in point (c) of Article 24(2) of Regulation (EU) 2018/848**

Name	Primary yeast	Yeast production/confection/formulation	Specific conditions and limits
Calcium chloride	X		
Carbon dioxide	X	X	
Citric acid	X		for the regulation of the pH in yeast production
Lactic acid	X		for the regulation of the pH in yeast production
Nitrogen	X	X	
Oxygen	X	X	
Potato starch	X	X	for filtering only from organic production
Sodium carbonate	X	X	for the regulation of the pH
Vegetable oils	X	X	greasing, releasing or anti-foaming agent only from organic production

## ANNEX VI

**Products and substances authorised for use in organic production in certain areas of third countries pursuant to Article 45(2) of Regulation (EU) 2018/848**

*Although every possible effort has been made to ensure the accuracy of the translations; Başak Ekolojik declares that it has no responsibility for any errors, omissions or incompatibility of purpose that may be included in these translations or that may arise from these translations, and that it cannot be held responsible, without any limitation, for any direct or indirect damages or losses that may arise from them.*