

## II

(Non-legislative acts)

## REGULATIONS

**COMMISSION DELEGATED REGULATION (EU) 2021/715**

**of 20 January 2021**

**amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the requirements for groups of operators**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 <sup>(1)</sup>, and in particular Article 36(3) thereof,

Whereas:

- (1) Article 36(1) of Regulation (EU) 2018/848 sets out certain requirements for groups of operators. In the interest of a harmonised interpretation of the geographical proximity of the members of a group of operators, it should be stated explicitly that the activities of the members are to take place in the same country.
- (2) For the purpose of establishing minimum requirements regarding the set-up and functioning of the system for internal controls (ICS), the following aspects should be defined: registration of members, internal inspections, approval of new members or new production units or activities of existing members, training of ICS inspectors, measures in cases of non-compliances and internal traceability.
- (3) In that context, the requirement to appoint an ICS manager and one or more ICS inspectors should be added in order to ensure the proper implementation of the ICS by the competent personnel.
- (4) In addition, in order to provide for a harmonised assessment framework for the ICS, it is appropriate to include a list of situations that are to be considered as deficient.
- (5) Regulation (EU) 2018/848 should therefore be amended accordingly.
- (6) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Amendments to Regulation (EU) 2018/848**

Article 36 of Regulation (EU) 2018/848 is amended as follows:

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<sup>(1)</sup> OJ L 150, 14.6.2018, p. 1.

(1) paragraph 1 is amended as follows:

(a) point (e) is replaced by the following:

‘(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’;

(b) in point (g), the following paragraph is added:

‘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.’;

(c) the following point (h) is added:

‘(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) in paragraph 2, the following subparagraph is added:

'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 of 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.'

*Article 2***Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 January 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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