

Brussels, **XXX**
[...] (2021) **XXX** draft

COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the requirements for record-keeping for operators in organic production

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Following the adoption of Regulation (EU) 2018/848, which will enter into application on 1 January 2022, it is necessary to adopt a delegated regulation amending that Regulation in order to lay down additional rules for operators, groups of operators and subcontractors to keep records concerning their organic production to demonstrate compliance with organic production rules. The organic sector needs to have legal certainty on the rules that will apply for these issues and Member States need to have enough time to integrate these rules into their national legislation.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The act was discussed thoroughly with the Member States at the Group of Experts on Organic Production as well as with the main organisations representing the organic sector, namely IFOAM, COPA-COGECA and EOCC. DG AGRI cooperated closely with other DGs in the field of their specific expertise when drafting these rules. WTO partners were notified and general public consultations were carried out.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This delegated act lays down additional rules amending Annex II to Regulation (EU) 2018/848 as regards the requirements for keeping records to demonstrate compliance with organic production rules by operators, groups of operators and sub-contractors in the organic production chain.

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(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 834/2007¹, and in particular Article 34(8) thereof,

Whereas:

- (1) Annex II to Regulation (EU) 2018/848 sets out some requirements to keep records concerning certain specific production rules. Records can be relevant for traceability purposes, internal quality control and for the assessment of compliance with the detailed organic production rules set out in that Annex.
- (2) Notwithstanding the provisions on keeping records set out in Article 9(10), point (c), Article 34(5) and Article 39(1) point (a) of Regulation (EU) 2018/848, it is necessary to detail further the minimum record-keeping requirements in each production area covered by the various parts of Annex II to that Regulation.
- (3) It is also necessary to introduce certain specific elements to ensure consistency and a harmonised basis for record-keeping, which is considered crucial to allow operators to provide evidence of the effective application of the organic production rules.
- (4) The amendments made by this Regulation are without prejudice to the record-keeping requirements set out in other Union acts such as those concerning food and food safety, feed and feed safety, animal health and welfare, plant health, plant protection and plant reproductive material. Hence, for the purposes of Regulation (EU) 2018/848, only the complementary elements which allow verification of compliance with the organic production rules will have to be recorded by those operators already fulfilling the record-keeping requirements under other Union acts, without the need to duplicate them. Nevertheless, certain record-keeping requirements are repeated in Annex II to Regulation (EU) 2018/848 as amended by this Regulation, because they are relevant for operators in third countries.
- (5) As regards plant production rules, for the purpose of recording data on the use of fertilisers and soil conditioners, it is necessary to include certain application parameters given that the use of fertilisers in organic production is subject to both quantitative and qualitative restrictions, which have to be taken into account when agronomical measures are not sufficient to fulfil the nutritional needs of plants.

¹ OJ L 150, 14.6.2018, p. 1.

- (6) The use of plant protection products and of cleaning and disinfection products, such as biocides and detergents, is subject to restrictions in organic production and is limited to cases where preventive measures did not impede the occurrence and spread of pests and diseases and in all cases to products and substances approved pursuant to Article 24 of Regulation (EU) 2018/848. Without prejudice to the requirements on record-keeping set out in Regulations (EC) No 1107/2009² and (EC) No 852/2004³ of the European Parliament and of the Council, it is necessary to require that operators record the detailed application conditions when having to resort to the use of a plant protection product, a biocide or a detergent in order to demonstrate, where relevant, compliance with the applicable restrictions, the respect of the recommended frequency and the pre-harvest period.
- (7) As land parcels can have different characteristics and host different crops, agronomic conditions can vary. This implies that, when external inputs are applied, their use differs from parcel to parcel. Therefore, external inputs should be recorded in relation to the parcel where the input is used to allow operators to monitor the efficacy and provide appropriate records for traceability purposes and, where relevant, documentary evidence related to any derogation from plant production rules obtained in accordance with point 1.8.5 of Part I of Annex II to Regulation (EU) 2018/848.
- (8) When collecting wild plants and their products, it is necessary to require operators to keep records of the species concerned and quantities and periods of collection in a specific natural habitat to allow traceability and verification of compliance with natural habitat conditions.
- (9) As regards livestock production rules, in view of possible derogations from those rules granted under points 1.3.4.3, 1.3.4.4, 1.7.5, 1.7.8, 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II to Regulation (EU) 2018/848, operators should keep documentary evidence related to such derogations to allow for traceability and control of compliance with the applicable conditions.
- (10) Without prejudice to the requirements of Regulation (EC) No 852/2004 and Regulation (EU) 2016/429 of the European Parliament and of the Council⁴, operators should keep detailed records on the origin of animals introduced in the holding and their relevant former veterinary records in order to be able to ensure traceability and to demonstrate compliance with the specific conditions set out in Parts II and III of Annex II to Regulation (EU) 2018/848.
- (11) In addition, in order to document compliance with the species-specific nutritional needs and the relevant nutrition rules set out for the different groups of animals in Part II of Annex II to Regulation (EU) 2018/848, operators should keep detailed records of the feeding regime and the grazing periods.

² Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

³ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

⁴ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (Animal Health Law) (OJ L 84, 31.03.2016, p. 1).

- (12) Without prejudice to the record-keeping and identification requirements set out in Regulations (EC) No 852/2004 and (EU) 2016/429, Regulation (EC) No 1760/2000 of the European Parliament and Council⁵ and Directive 2001/82/EC of the European Parliament and Council⁶, in view of the specific limitations set under organic production rules, it is appropriate to lay down some specific requirements for record-keeping of the veterinary treatments and of cleaning and disinfection of the buildings, installations and animals in order to enable operators to demonstrate to the competent authority or control body that the relevant requirements are being fulfilled while allowing to verify efficacy and the respect of specific withdrawal periods.
- (13) Without prejudice to the traceability requirements set out in Regulation (EC) No 178/2002 of the European Parliament and of the Council⁷, in order to allow traceability and verification of compliance with organic production rules, including those on the conversion periods for the various species, it is necessary that operators keep detailed records on any animal coming to or leaving the holding.
- (14) Among the housing and husbandry requirements for poultry, there are specific requirements that apply to certain rearing systems as regards the respect of a period of emptiness. The relevant documentary evidence should be kept to allow proper monitoring.
- (15) Given the relevance of the position of apiaries in areas that should ensure availability of nectar and pollen from organically produced crops or from natural uncontaminated areas or from crops under low environmental impact methods to avoid any contamination of apiaries, it is necessary that operators keep a map of the areas used as well as records of any external input used and operations performed on the beehives.
- (16) As regards production rules for aquaculture animals, in view of possible derogations from those rules granted under points 3.1.2.1(d) and (e) of Part III of Annex II to Regulation (EU) 2018/848, operators should keep documentary evidence related to such derogations to allow for traceability and control of compliance with the applicable conditions.
- (17) In particular, the use of external inputs is subject to restrictions under Regulation (EU) 2018/848 and is to be recorded as in the case of fertilisers or nutrients used in organic algae production, which can only be used when authorised pursuant to Article 24 of that Regulation and which are limited to indoor facilities and to be applied under certain conditions. Therefore, operators should record such uses to demonstrate compliance with the applicable conditions.
- (18) It is also necessary to set record-keeping requirements in respect of the specific provisions for juveniles for breeding and on-growing purposes, in particular as regards

⁵ Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) no 820/97 (OJ L 204, 11.08.2000, p. 1).

⁶ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p.1.)

⁷ 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).

the precise time of their occurrence during the cycle of production of animals and an initial period of conversion.

- (19) The feeding regimes of aquaculture animals are intended to address the specific nutritional needs of each species at the various stages of development. Therefore, considering the detailed provisions on authorised feed materials, including when from non-organic origin, records of the feeding regime should be kept for each species concerned, with data for the various stages of development.
- (20) The health care of aquaculture animals is based on prevention and monitoring the wellbeing of the animals. Therefore, it is necessary to keep records of the various actions put in place to limit as much as possible the recourse to veterinary treatments, which are subject to strict limitations in terms of frequency and number depending on the duration of the life cycle of the species concerned. The corresponding record-keeping requirements need to be laid down.
- (21) Proper husbandry practices determine the wellbeing of animals. In the context of aquaculture, the quality of water and the limits for stocking densities and relevant chemical-physical parameters are fundamental for animal welfare. Therefore, it is necessary to have records of such data as well as of the type and time of interventions carried out to monitor the maintaining of the best conditions for aquaculture animals and the measures taken to respect organic production rules in the different stages of development of those animals. In organic aquaculture, the use of aeration is allowed, but oxygen use is limited to specific cases. Therefore, records should be kept on these types of intervention.
- (22) Without prejudice to the record-keeping requirements under Regulation (EC) No 852/2004, operators producing organic processed food and/or organic processed feed should keep detailed records to demonstrate compliance with organic production rules, in particular concerning precautionary measures put in place to ensure the integrity of organic products, the specific conditions for the use of external inputs and of cleaning and disinfection products. Moreover, to allow the proper verification of input and output balance, operators should keep available data on the input used and in case of composite products, the complete recipes/formulae as well as, where applicable, documentary evidence on authorisations for the use of non-organic agricultural ingredients in accordance with Article 25 of Regulation (EU) 2018/848.
- (23) Without prejudice to the record-keeping requirements under Regulation (EC) No 852/2004, operators producing organic wine should keep detailed records to demonstrate compliance with the organic production rules, in particular with respect to any external product and substance used in the wine production and for cleaning and disinfection.
- (24) Without prejudice to the record-keeping requirements under Regulation (EC) No 852/2004, operators producing organic yeast should keep detailed records to demonstrate compliance with the organic production rules, in particular with respect to the products and substances used in the yeast production and for cleaning and disinfection.
- (25) Annex II to Regulation (EU) 2018/848 should therefore be amended accordingly.
- (26) 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

Annex II to Regulation (EU) 2018/848 is amended in accordance with the Annex to this Regulation.

Article 2

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,

For the Commission
The President
Ursula VON DER LEYEN



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[...] (2021) **XXX** draft

ANNEX

ANNEX

to the

COMMISSION DELEGATED REGULATION (EU)

**amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the
Council as regards the requirements for record-keeping for operators in organic
production**

ANNEX

Annex II to Regulation (EU) 2018/848 is amended as follows:

(1) Part I is amended as follows:

(a) in point 1.9.3, the second sentence is replaced by the following:

‘Operators shall keep records of the use of those products, including the date or dates on which each product was used, the type and name of the product, the amount applied and the crop and parcels concerned.’;

(b) in point 1.10.2, the second sentence is replaced by the following:

‘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 type and name of the product, its active substances, the amount applied, the crop and parcels concerned, and the pest or disease to be controlled.’;

(c) in point 1.11, the following sentence is added:

‘Operators shall keep records of the use of those products including the date or dates on which each product was used, the type and name of the product, its active substances, and the location of such use.’;

(d) in point 1.12, the following sentence is added:

‘In particular, operators shall keep records of any other external input used on each parcel and, where applicable, keep documentary evidence on any derogation from production rules obtained in accordance with point 1.8.5.’;

(e) in point 2.2, the following paragraph is added:

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

(2) Part II is amended as follows:

(a) in point 1.1, the following paragraph is added:

‘Operators shall keep documentary evidence on any derogation from livestock production rules obtained in accordance with points 1.3.4.3, 1.3.4.4, 1.7.5, 1.7.8, 1.9.3.1(c) and 1.9.4.2(c).’;

(b) the following point 1.3.4.5 is inserted:

‘1.3.4.5. Operators shall keep records or documentary evidence of the origin of animals, identifying the animals in accordance with appropriate systems (per animal or by batch/flock/hive), of the veterinary records of the animals introduced in the holding, the date of arrival, and the conversion period.’;

(c) the following point 1.4.4 is inserted:

‘1.4.4. Record-keeping of the feeding regime

Operators shall keep records of the feeding regime and, where relevant, the grazing period. In particular, they shall keep records of the name of the feed, including feed supplements, proportions of various feed materials of rations and proportion of feed from their own holding or the same region and, where relevant, periods of access to grazing areas, periods of transhumance where restrictions apply and documentary evidence of the application of points 1.4.2 and 1.4.3.’;

(d) in point 1.5.1.6, the following sentence is added:

‘Operators shall keep records of the use of those products including the date or dates on which the product was used, the type and name of the product, its active substances, and the location of such use.’;

(e) the following point 1.5.2.7. is inserted:

‘1.5.2.7. Operators shall keep records or documentary evidence of any treatment applied and, in particular, the identification of the animals treated, the date of treatment, diagnosis, the posology, the type and name of the treatment product and, where applicable, the veterinary prescription for veterinary care, and the withdrawal period applied before livestock products can be marketed and labelled as organic.’;

(f) the following point 1.7.12 is inserted:

‘1.7.12. Operators shall keep records or documentary evidence of any specific operation applied and justifications for the application of point 1.7.5, 1.7.8, 1.7.9 or 1.7.10. As regards animals leaving the holding, the following data shall be recorded, where relevant: age, number of animals, weight of slaughter animals, appropriate identification (per animal or by batch/flock/hive) date of departure and destination.’;

(g) in point 1.9.4.4, point (c) is replaced by the following:

‘(c) buildings shall be emptied of livestock between each batch of poultry that has been reared. The buildings and fittings shall be cleaned and disinfected during this time. In addition, when the rearing of each batch of poultry has been completed, runs shall be left empty during a period to be established by the Member States in order to allow vegetation to grow back. The operator shall keep records or documentary evidence of the application of such period. Those requirements shall not apply where poultry are not reared in batches, are not kept in runs and are free to roam throughout the day;’;

(h) the following point 1.9.6.6 is inserted:

‘1.9.6.6. Record-keeping obligations

Operators shall keep a map on an appropriate scale or geographic coordinates of the location of hives to be provided to the control authority or control body demonstrating that the areas accessible to the colonies meet the requirements of this Regulation.

The following information shall be entered in the register of the apiary with regard to feeding: name of the product used, dates, quantities and hives where the product is used.

The zone where the apiary is situated shall be recorded together with the identification of the hives and the period of moving.

All the measures applied shall be recorded in the register of the apiary, including the removals of the supers and the honey extraction operations. The amount and dates of the collection of honey shall also be recorded.’;

(3) Part III is amended as follows:

(a) the following point 1.11 is inserted:

‘1.11. Operators shall keep documentary evidence on any derogation from production rules for aquaculture animals obtained in accordance with points 3.1.2.1(d) and (e).’;

(b) in point 2.2.2(c), the following sentence is added:

‘Operators shall keep records of the use of those products, including the date or dates on which the product was used, the type and name of the product, and the amount applied, with information on the lots/tanks/basins concerned.’;

(c) in point 2.3.2, the following sentence is added:

‘Operators shall keep records of the use of those products, including the date or dates on which the product are used, the name of the product, and the amount applied with information on the lots/tanks/basins concerned.’;

(d) the following point 3.1.2.4 is inserted:

‘3.1.2.4. Operators shall keep records of the origin of animals, identifying the animals/batches of animals, the date of arrival and type of species, the quantities, the organic or non-organic status, and the conversion period.’;

(e) the following point 3.1.3.5 is inserted:

‘3.1.3.5. Operators shall keep records of specific feeding regimes, in particular, on the name and quantity of feed and the use of additional feed, and the respective animals/batches of animals fed.’;

(f) the following point 3.1.4.3 is inserted:

‘3.1.4.3. Record-keeping of disease prevention

Operators shall keep records of the disease prevention measures applied giving details of fallowing, cleaning and water treatment, and of any veterinary and other parasite treatment applied and in particular, the date of treatment, diagnosis, the posology, the type and name of the treatment product, and veterinary prescription for veterinary care, where applicable, and withdrawal periods applied before aquaculture products can be marketed and labelled as organic.’;

(g) in point 3.1.5.3, the following paragraph is added:

‘Operators shall keep records of monitoring and maintenance measures concerning animal welfare and water quality. In case of fertilisation of ponds and lakes, the operators shall keep records of the application of fertilisers and soil conditioners, including the date of application, the type and name of the product, the amount applied, and the location of the application concerned.’;

(h) in point 3.1.6.5, the following paragraph is added:

‘Operators shall keep records of such uses, indicating whether applied under point (a) (b) or (c).’;

(4) Part IV is amended as follows:

(a) in point 1.4, point (a) is replaced by the following:

‘(a) take precautionary measures and keep records of those measures;’;

(b) the following point 1.7 is inserted:

‘1.7. Operators shall keep documentary evidence on authorisations for the use of non-organic agricultural ingredients for the production of processed organic food in accordance with Article 25 if they have obtained or used such authorisations.’

(c) in point 2.2.3, the following sentence is added :

‘Operators shall keep records of the use of those products, including the date or dates on which the product was used, the type and name of the product, its active substances and the location of such use.’;

(d) the following point 2.3 is inserted:

‘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.’;

(5) Part V is amended as follows:

(a) in point 1.4, point (a) is replaced by the following:

‘(a) take precautionary measures and keep records of those measures;’;

(b) in point 2.4, the following sentence is added :

‘Operators shall keep records of the use of those products, including the date or dates on which the products was used, the type and name of the product, its active substances, and the location of such use.’;

(c) the following point 2.5 is inserted:

‘2.5. Operators shall keep records of any input used in the feed production. In the 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.’;

(6) in Part VI, the following point 2.3 is inserted:

‘2.3. Operators shall keep records of the use of any product and substance used in the wine production and for cleaning and disinfection, including the date or dates on which the product was used, the type and name of the product, its active substances, and where applicable, the location of such use.’;

(7) in Part VII, the following point 1.5 is inserted:

‘1.5. Operators shall keep records of any product and substance used for yeast production and for cleaning and disinfection, including the date or dates on which the product was used, the type and name of the product, its active substances, and the location of such use.’.