

**COMMISSION DELEGATED REGULATION (EU) 2021/716****of 9 February 2021****amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards organic production rules on sprouted seeds and chicory heads, on feed for certain aquaculture animals and on aquaculture parasite treatments****(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 12(2)(a) and Article 15(2)(b) and (c) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2020/427 <sup>(2)</sup> has recently amended point 1.3 of Part I of Annex II to Regulation (EU) 2018/848 with respect to organic sprouted seeds to ensure their production from organic seeds. Given that sprouted seeds include sprouts, shoots and cress <sup>(3)</sup>, which can use exclusively the reserves in the seeds to sprout, only water should be used for organic production. Therefore, it needs to be clarified that the derogation from soil-related cultivation for sprouted seeds is limited to moistening seeds and it should be stated explicitly that the use of a growing medium is not allowed, except the use of an inert medium to keep the seeds moist when the components of that inert medium are authorised in compliance with Article 24 of Regulation (EU) 2018/848.
- (2) With respect to chicory heads, their specific production cycle can consist of two phases one in soil and one called 'forcing phase', which can be in soil, but also in water or substrates. Therefore, it is necessary to clarify that the derogation from soil related cultivation for chicory heads includes deepening in clear water and that the use of a growing medium is allowed only when its components are authorised in compliance with Article 24 of Regulation (EU) 2018/848.
- (3) Article 25l(3)(b) of Commission Regulation (EC) No 889/2008 <sup>(4)</sup> allowed organic cholesterol to be used to supplement natural feed in the grow-out stage and earlier life stages of penaeid shrimps and freshwater prawns (*Macrobrachium* spp.). It is therefore necessary to provide for the supplementation of feed with organic cholesterol to those shrimps and prawns in point 3.1.3.4 of Part III of Annex II to Regulation (EU) 2018/848.
- (4) In 2019, when discussing the draft of Delegated Regulation (EU) 2020/427, some Member States requested the revision of other rules relating to organic aquaculture. The expert group for technical advice on organic production (EGTOP) set up by Commission Decision 2017/C 287/03 <sup>(5)</sup> assessed those requests. Taking into account the EGTOP's conclusions published <sup>(6)</sup> in January 2020, the Commission has identified a need to update the existing production rules for aquaculture animals in particular with respect to veterinary treatments.

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

<sup>(2)</sup> Commission Delegated Regulation (EU) 2020/427 of 13 January 2020 amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards certain detailed production rules for organic products (OJ L 87, 23.3.2020, p. 1).

<sup>(3)</sup> Description of their production cycles in EFSA Scientific Opinion on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds – *EFSA Journal* 2011; 9(11):2424. [101 pp] doi:10.2903/j.efsa.2011.2424.

<sup>(4)</sup> Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).

<sup>(5)</sup> Commission Decision of 30 August 2017 appointing the members of the group for technical advice on organic production and drawing up the pool list (OJ C 287, 30.8.2017, p. 3).

<sup>(6)</sup> EGTOP Final report on Aquaculture IV – 13 December 2019.

- (5) Notwithstanding the requirements related to the prevention of diseases, such as the recommendation for biological control of parasites with preference to be given to the use of cleaner fish and of freshwater, marine water and sodium chloride solutions, a limited number of treatments, in case of severe parasites occurrence, is currently allowed on a general basis for all species. Based on the abovementioned EGTOP conclusions, it is appropriate to amend the current provisions on parasite treatments set out in point 3.1.4.2 of Part III of Annex II to Regulation (EU) 2018/848 by introducing a more species-specific approach to better address the needs of aquaculture animals without compromising the organic nature of the production.
- (6) In particular, in view of the variable duration of the production cycle of species, other than salmon, and of the potential occurrence of parasites in the juvenile phase, together with the tendency of operators to postpone as far as possible any courses of treatment due to the frequency limit, in the first year of the life cycle, a high mortality rate of fry and juveniles has been reported. Therefore, for other species than salmon, it is appropriate to align the frequency and maximum number of parasite treatments with the frequency limits set for other chemically synthesised allopathic veterinary medicinal products to permit to intervene when it is really necessary and to avoid high mortality in the first stages of the life cycle.
- (7) As regards salmon, considering the duration of the production cycle and the need to guarantee the non-occurrence of sea lice within the period in freshwater, the current frequency limits and maximum number of courses for parasite treatments should be maintained.
- (8) Moreover, it is important to clarify the current provisions, by setting a clear overall limit for the maximum number of parasite treatments that may be administered, regardless of the species concerned.
- (9) Annex II to Regulation (EU) 2018/848 should therefore be amended accordingly.
- (10) 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, 9 February 2021.

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

## ANNEX

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

(1) in Part I, point 1.3 is replaced by the following:

‘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.’;

(2) Part III is amended as follows:

(a) in point 3.1.3.4. the following paragraph is added:

‘In the grow-out phase and in earlier life stages in nurseries and hatcheries, organic cholesterol may be used to supplement the diets of penaeid shrimps and freshwater prawns (*Macrobrachium* spp.), in order to secure their quantitative dietary need.’;

(b) in point 3.1.4.2. point (e) is replaced by the following:

‘(e) the use of parasite treatments, other than through compulsory control schemes operated by Member States, shall be limited as follows:

- (i) for salmon, to maximum two courses of treatment per year, or to one course of treatment per year where the production cycle is less than 18 months;
  - (ii) for all species other than salmon, to two courses of treatment per year, or to one course of treatment per year where the production cycle is less than 12 months;
  - (iii) for all species, to no more than four courses of treatment in total, regardless of the length of the production cycle of the species.’;
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