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<sup>(1)</sup> Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.



## 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 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.'.

*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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**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 25(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.’;
-

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/717****of 26 April 2021****registering a geographical indication of a spirit drink under Article 30(2) of Regulation (EU) 2019/787 of the European Parliament and of the Council ('Nagykunsági szilvapálinka')**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 <sup>(1)</sup>, and in particular Article 30(2) thereof,

Whereas:

- (1) In accordance with Article 17(5) of Regulation (EC) No 110/2008 of the European Parliament and of the Council <sup>(2)</sup>, the Commission has examined Hungary's application of 14 October 2016 for the registration of the geographical indication 'Nagykunsági szilvapálinka'.
- (2) Regulation (EU) 2019/787, which replaces Regulation (EC) No 110/2008, entered into force on 25 May 2019. Under Article 49(1) thereof, Chapter III of Regulation (EC) No 110/2008 on geographical indications is repealed with effect from 8 June 2019.
- (3) After concluding that the application complied with Regulation (EC) No 110/2008, the Commission published the main specifications of the technical file in the *Official Journal of the European Union* <sup>(3)</sup> as required by Article 17(6) of that Regulation, in accordance with the first subparagraph of Article 50(4) of Regulation (EU) 2019/787.
- (4) No notice of opposition has been received by the Commission under Article 27(1) of Regulation (EU) 2019/787.
- (5) The name 'Nagykunsági szilvapálinka' should therefore be registered as a geographical indication,

HAS ADOPTED THIS REGULATION:

*Article 1*

The geographical indication 'Nagykunsági szilvapálinka' is hereby entered in the register. This Regulation grants the name 'Nagykunsági szilvapálinka' the protection referred to in Article 21 of Regulation (EU) 2019/787 in accordance with Article 30(4) of that 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*.

<sup>(1)</sup> OJ L 130, 17.5.2019, p. 1.

<sup>(2)</sup> Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

<sup>(3)</sup> OJ C 14, 13.1.2021, p. 3.

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

Done at Brussels, 26 April 2021.

*For the Commission,  
On behalf of the President,  
Janusz WOJCIECHOWSKI  
Member of the Commission*

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**COMMISSION IMPLEMENTING REGULATION (EU) 2021/718****of 30 April 2021****amending Implementing Regulation (EU) No 371/2011 as regards the name of the holder of the authorisation of dimethylglycine sodium salt as feed additive****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 13(3) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) Taminco BVBA has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation as regards Commission Implementing Regulation (EU) No 371/2011 <sup>(2)</sup>. The applicant claimed that Belgium has reformed its Companies and Associations Code ('Wetboek van Vennootschappen en Verenigingen'), bringing change to all Belgian entities. As part of the changed legislation the company type 'besloten vennootschap met beperkte aansprakelijkheid' ('BVBA'), under which Taminco is doing business, has been converted to 'besloten vennootschap' ('BV'). The company remains a private limited liability company under the laws of Belgium. This means that Taminco will trade as 'Taminco BV' as of 1 January 2021. The application was accompanied by the relevant supporting data.
- (3) That proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The European Food Safety Authority was informed of the application.
- (4) To allow the applicant to exploit its marketing rights under the name of Taminco BV it is necessary to change the terms of the authorisation.
- (5) Implementing Regulation (EU) No 371/2011 should therefore be amended accordingly.
- (6) Since safety reasons do not require the immediate application of the amendment made by this Regulation to Implementing Regulation (EU) No 371/2011, it is appropriate to provide for a transitional period during which existing stocks may be used up.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1***Amendments to Implementing Regulation (EU) No 371/2011**

Implementing Regulation (EU) No 371/2011 is amended as follows:

- (1) in the title, the words 'holder of the authorisation Taminco N.V.' are replaced by the words 'holder of the authorisation Taminco BV';

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Implementing Regulation (EU) No 371/2011 of 15 April 2011 concerning the authorisation of dimethylglycine sodium salt as feed additive for chickens for fattening (holder of the authorisation Taminco N.V.) (OJ L 102, 16.4.2011, p. 6).

- (2) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Taminco BVBA' are replaced by 'Taminco BV'.

*Article 2*

**Transitional measures**

Existing stocks of the additive which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until they are exhausted.

*Article 3*

**Entry into force**

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

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

Done at Brussels, 30 April 2021.

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

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**COMMISSION IMPLEMENTING REGULATION (EU) 2021/719****of 30 April 2021****concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358 as a feed additive for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-valine. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 September 2020 <sup>(2)</sup> that, under the proposed conditions of use, L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358, when supplemented to diets in appropriate amounts, does not have an adverse effect on animal health, consumer health or the environment. With respect to the safety of the user of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358, the Authority could neither exclude a risk by inhalation, nor that the substance it is irritant to skin or eyes, or a dermal sensitiser. Therefore, appropriate protective measures should be taken for this additive to prevent adverse effects on human health, in particular as regards the users of the additive. Furthermore, the Authority concluded that the substance is considered an efficacious source of the essential amino acid L-valine for animal nutrition and that, in order to be efficacious in ruminants, it should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as a feed additive, subject to the conditions laid down in that Annex.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> EFSA Journal 2020; 18(11):6286.

*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*.

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

Done at Brussels, 30 April 2021.

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

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## ANNEX

| Identification number of the additive | Name of the holder of authorisation | Additive | Composition, chemical formula, description, analytical method. | Species or category of animal | Maximum age | Minimum content                                                 | Maximum content | Other provisions | End of period of authorisation |
|---------------------------------------|-------------------------------------|----------|----------------------------------------------------------------|-------------------------------|-------------|-----------------------------------------------------------------|-----------------|------------------|--------------------------------|
|                                       |                                     |          |                                                                |                               |             | mg additive/kg of complete feed with a moisture content of 12 % |                 |                  |                                |

## Category of nutritional additives. Functional group: amino acids, their salts and analogues.

|        |   |          |                                                                                                                                                                                                                                                        |             |   |   |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |           |
|--------|---|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---|---|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 3c371i | - | L-valine | <b>Additive composition:</b><br>Powder with a minimum content of L-valine of 98 % (on a dry matter basis) and a maximum content of 1,5 % water                                                                                                         | All species | - | - | - | <ol style="list-style-type: none"> <li>1. L-valine may be placed on the market and used as an additive consisting of a preparation.</li> <li>2. The additive may be used via water for drinking.</li> <li>3. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated.</li> <li>4. The label of the additive and premixture shall indicate the following: 'The supplementation with L-valine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.'</li> <li>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the</li> </ol> | 23.5.2031 |
|        |   |          | <b>Characterisation of the active substance:</b><br>L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by <i>Corynebacterium glutamicum</i> CGMCC 7.358<br>Chemical formula: C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub><br>CAS number: 72-18-4 |             |   |   |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |           |
|        |   |          | <b>Analytical method <sup>(1)</sup>:</b><br>For the identification of L-valine in the feed additive:<br>— Food Chemical Codex "L-valine monograph"                                                                                                     |             |   |   |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |           |

|  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |  |  |  |                                                                                                                                                                                                                                                                                                                    |  |
|--|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  |  | <p>For the quantification of valine in the feed additive:</p> <ul style="list-style-type: none"> <li>— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)</li> </ul> <p>For the quantification of valine in premixtures, feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F)</li> </ul> <p>For the quantification of valine in water:</p> <ul style="list-style-type: none"> <li>— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FD)</li> </ul> |  |  |  |  | <p>potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection, safety glasses and gloves.</p> |  |
|--|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

(<sup>1</sup>) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>



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