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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.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2021/418

of 9 March 2021

amending Directive 2002/46/EC of the European Parliament and of the Council as regards nicotinamide riboside chloride and magnesium citrate malate used in the manufacture of food supplements and as regards the units of measurement used for copper

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements ⁽¹⁾, and in particular Article 4(5) thereof,

Whereas:

- (1) Annexes I and II to Directive 2002/46/EC list the vitamins and minerals and their forms, which may be used in the manufacture of food supplements.
- (2) Pursuant to Article 14 of Directive 2002/46/EC, provisions on vitamin and mineral substances in food supplements that may have an effect upon public health are to be adopted after consultation with the European Food Safety Authority ('the Authority').
- (3) Pursuant to Article 14(1) and 14(3)(a) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽²⁾ food shall not be placed on the market if it is unsafe with regard to the normal conditions of use of the food by the consumer.
- (4) Following a request from the European Commission to deliver an opinion on nicotinamide riboside chloride as a novel food including the safety of its use in food supplements as a source of niacin and the bioavailability of nicotinamide, a form of niacin, from this source, in the context of Directive 2002/46/EC, on 4 July 2019 the Authority adopted a scientific opinion on the safety of nicotinamide riboside chloride as a novel food ingredient for use as a source of niacin in food supplements ⁽³⁾.
- (5) It follows from that opinion that the use of nicotinamide riboside chloride in food supplements is not of safety concern provided that certain limitations are respected which are set out in the approval of this substance by Commission Regulation (EU) 2020/16 ⁽⁴⁾.

⁽¹⁾ OJ L 183, 12.7.2002, p. 51.

⁽²⁾ 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).

⁽³⁾ EFSA Journal 2019;17(8):5775.

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/16 of 10 January 2020 authorising the placing on the market of nicotinamide riboside chloride as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 7, 13.1.2020, p. 6).

- (6) Based on the Authority's favourable opinion and on the authorisation as a novel food ingredient as set out in Regulation (EU) 2020/16, nicotinamide riboside chloride should be included in the list set out in Annex II to Directive 2002/46/EC.
- (7) Pursuant to Article 8 of Regulation (EU) 2015/2283 of the European Parliament and of the Council ⁽⁵⁾, magnesium citrate malate was included in the Union list of authorised novel foods provided for in the Annex to Commission Implementing Regulation (EU) 2017/2470 ⁽⁶⁾. This listing provides that magnesium citrate malate is authorised exclusively as a novel food ingredient for the use in food supplements as defined in Directive 2002/46/EC. This listing does not include a maximum daily limit for its use in food supplements.
- (8) Following a request from the European Commission to deliver an opinion on the nutrient source, magnesium citrate malate, the Authority adopted a scientific opinion on the bioavailability of magnesium from magnesium citrate malate when added for nutritional purposes to food supplements ⁽⁷⁾. The Authority concluded that magnesium citrate malate is a source from which magnesium is bioavailable. The assessment of the bioavailability of a nutrient source is of relevance to its safety assessment as explained by the Authority in its guidance document 'Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources' ⁽⁸⁾. The Authority explains that its approach to evaluating the bioavailability of a nutrient source is by using comparative studies that consider the bioavailability of the chemical forms of the nutrient that are already on the positive lists in the relevant legislation. The Authority further explains that the classification of the bioavailability of a nutrient source as being equivalent, higher or lower than a reference source has implications for the safety of the source at the proposed uses and use levels and with respect to relevant health-based guidance values, such as the tolerable upper intake level (UL) for the nutrient itself.
- (9) The Authority in its above-mentioned guidance document, explains that the evaluation of the safety of a nutrient source does not include an assessment of the nutritional, physiological function or safety of the nutrient *per se*, in line with the relevant legal basis for this evaluation. The Authority, however explained that if the proposed uses and use levels of the source were likely to reach the UL for that nutrient, it would consider this in its safety assessment. The Authority, in its scientific opinion on the bioavailability of magnesium citrate malate, noted that at the proposed maximum use levels for magnesium citrate malate, the existing UL for magnesium in food supplements, water, or added to food and beverages (250 mg per day) was exceeded. Directive 2002/46/EC recognises that excessive intake of vitamins and minerals may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those maximum levels should be set taking into account the UL of the vitamin or mineral, as established by scientific risk assessment based on generally acceptable scientific data, and on intakes of the nutrient from the normal diet. It is to be noted that in 2001, the Scientific Committee on Food ⁽⁹⁾ set the UL for magnesium based on a mild, transient laxative effect which is easily reversible and to which the body can easily adapt within days. On the basis of generally acceptable scientific data, the reported adverse effects from the intake of magnesium when used in the manufacture of food supplements are not considered to be of a severe nature that would necessitate the setting of a maximum safe level for the use of magnesium citrate malate at the proposed use levels in food supplements. However, this situation could be revised as scientific information becomes available that would demonstrate the need to establish a harmonised maximum safe level for magnesium. Furthermore, until such limits are set at EU level, national rules governing the use of magnesium in the manufacture of food supplements may be applied on the basis of the criteria laid down in Article 5 of Directive 2002/46/EC.
- (10) Based on the Authority's favourable opinion on the bioavailability of magnesium from magnesium citrate malate, and on its authorisation as a novel food ingredient as set out in Implementing Regulation (EU) 2017/2470, magnesium citrate malate should be included in the list set out in Annex II to Directive 2002/46/EC.

⁽⁵⁾ Regulation (EU) 2015/2283 of the Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

⁽⁶⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽⁷⁾ EFSA Journal 2018;16(12):5484.

⁽⁸⁾ EFSA Journal 2018;16(6):5294.

⁽⁹⁾ http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf

- (11) Pursuant to Article 8(1) and (3) of Directive 2002/46/EC, the amount of copper present in a food supplement is to be declared on the labelling in numerical form using the units of measurement specified in Annex I to Directive 2002/46/EC. Pursuant to Article 8(3) of Directive 2002/46/EC, the information on this substance is also to be expressed as a percentage of the reference values set out in Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council⁽¹⁰⁾. Pursuant to Annex I to Directive 2002/46/EC, the units of measurement for copper required for labelling purposes for food supplements are 'µg', whereas those required for copper pursuant to Regulation (EU) No 1169/2011 are 'mg'. For reasons of consistency and clarity, the units of measurement for copper in Annex I to Directive 2002/46/EC should also be 'mg'. Since the modification of the units of measurement for copper is not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.
- (12) The Advisory Group on the Food Chain and Animal and Plant Health was consulted and its comments were taken into consideration.
- (13) In order to avoid disruptions in trade, sufficient time should be given to allow producers to comply with the new units of measurement for copper. Moreover, in the absence of safety concerns, the marketing of existing stocks of copper-containing food supplements should be allowed after the date of application of Article 1 of this Regulation, until those stocks are exhausted.
- (14) Directive 2002/46/EC should therefore be amended accordingly.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Directive 2002/46/EC is amended in accordance with the Annex to this Regulation.

Article 2

Annex II to Directive 2002/46/EC is amended in accordance with the Annex to this Regulation.

Article 3

Products placed on the market or labelled prior to 30 September 2022 and that do not comply with point 1 of the Annex to this Regulation may be marketed after that date until the existing stocks run out.

Article 4

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

Article 1 shall apply from 30 September 2022.

⁽¹⁰⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

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

Done at Brussels, 9 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Directive 2002/46/EC is amended as follows:

(1) in point 2 of Annex I to Directive 2002/46/EC the entry 'Copper (µg)' is replaced by the following:

'Copper (mg)';

(2) Annex II is amended as follows:

(a) in point A.7. NIACIN the following entry is added after the entry for 'inositol hexanicotinate (inositol hexaniacinate)':

'(d) nicotinamide riboside chloride';

(b) in point B the following entry is added after the entry 'magnesium chloride':

'magnesium citrate malate'.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/419**of 9 March 2021**

amending Implementing Regulation (EU) 2018/2019 as regards certain plants for planting of *Jasminum polyanthum* Franchet originating in Israel and adapting Combined Nomenclature codes for *Ullucus tuberosus* and amending Implementing Regulation (EU) 2020/1213 as regards the phytosanitary measures for the introduction of those plants for planting into the Union territory

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ⁽¹⁾, and in particular Article 42(3) and the first and the third subparagraphs of Article 42(4) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2018/2019 ⁽²⁾ establishes a list of high risk plants, plant products and other objects within the meaning of Article 42 of Regulation (EU) 2016/2031.
- (2) Commission Implementing Regulation (EU) 2018/2018 ⁽³⁾ lays down specific rules concerning the procedure to be followed in order to carry out the risk assessment referred to in Article 42(4) of Regulation (EU) 2016/2031 for those high risk plants, plant products and other objects.
- (3) Following a preliminary assessment, 35 plants for planting originating from all third countries were included in the Annex to Implementing Regulation (EU) 2018/2019 as high risk plants, amongst which is the genus *Jasminum* L.
- (4) In accordance with Regulation (EU) 2016/2031, if it is concluded, on the basis of a risk assessment, that a plant, plant product or other object originating in a third country, group of third countries or a specific area of the third country concerned poses an unacceptable pest risk, but that that risk can be reduced to an acceptable level by applying certain measures, the Commission is to remove that plant, plant product or other object from the list established by Implementing Regulation (EU) 2018/2019 and add it to the list referred to in Article 41(2) of Regulation (EU) 2016/2031.
- (5) In addition, Commission Implementing Regulation (EU) 2020/1213 ⁽⁴⁾ sets out the phytosanitary measures for the introduction into the Union territory of certain plants, plant products and other objects, which have been removed from the Annex to Implementing Regulation (EU) 2018/2019.
- (6) On 25 September 2019, Israel submitted to the Commission a request for export to the Union of unrooted cuttings of plants for planting of *Jasminum polyanthum* Franchet ('the specified plants'). That request was supported by the respective technical dossier.

⁽¹⁾ OJ L 317, 23.11.2016, p. 4.

⁽²⁾ Commission Implementing Regulation (EU) 2018/2019 of 18 December 2018 establishing a provisional list of high risk plants, plant products or other objects, within the meaning of Article 42 of Regulation (EU) 2016/2031 and a list of plants for which phytosanitary certificates are not required for introduction into the Union, within the meaning of Article 73 of that Regulation (OJ L 323, 19.12.2018, p. 10).

⁽³⁾ Commission Implementing Regulation (EU) 2018/2018 of 18 December 2018 laying down specific rules concerning the procedure to be followed in order to carry out the risk assessment of high risk plants, plant products and other objects within the meaning of Article 42(1) of Regulation (EU) 2016/2031 of the European Parliament and of the Council (OJ L 323, 19.12.2018, p. 7).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/1213 of 21 August 2020 concerning the phytosanitary measures for the introduction into the Union of certain plants, plant products and other objects which have been removed from the Annex to Implementing Regulation (EU) 2018/2019 (OJ L 275, 24.8.2020, p. 5).

- (7) On 12 August 2020, the European Food Safety Authority ('the Authority') published a scientific opinion regarding the commodity risk assessment of *Jasminum polyanthum* plants for planting from Israel ⁽⁵⁾. The Authority identified *Scirtothrips dorsalis*, *Aonidiella orientalis*, *Milviscutulus mangiferae*, *Paracoccus marginatus*, *Pulvinaria psidii* and *Colletotrichum siamense* ('the specified pests') as pests relevant for those plants for planting, evaluated the risk mitigation measures described in the dossier for those pests and estimated their likelihood of pest freedom.
- (8) On the basis of that opinion, the phytosanitary risk from introduction into the Union territory of unrooted cutting of plants for planting of *Jasminum polyanthum* Franchet, originating in Israel is considered to be reduced to an acceptable level, provided that appropriate mitigation measures are applied to address the risk of pests related to those plants for planting.
- (9) Those measures, adopted as phytosanitary import requirements, ensure the phytosanitary protection of the Union territory from introduction of the specified plants into it. Therefore, the unrooted cuttings of plants for planting of *Jasminum polyanthum* originating in Israel should no longer be considered high risk plants, and should be removed from the Annex to Implementing Regulation (EU) 2018/2019.
- (10) The measures described by Israel in the dossier are considered sufficient to reduce the risk from introduction into the Union territory of the specified plants to an acceptable level. Therefore, the measures adopted by this Regulation should be based on those described by Israel in the dossier.
- (11) *Scirtothrips dorsalis* is listed as a Union quarantine pest in Annex II to Commission Implementing Regulation (EU) 2019/2072 ⁽⁶⁾. *Aonidiella orientalis*, *Milviscutulus mangiferae*, *Paracoccus marginatus*, *Pulvinaria psidii* and *Colletotrichum siamense* are not yet included in the list of Union quarantine pests of Implementing Regulation (EU) 2019/2072, but they may fulfil the conditions to be included following a further complete risk assessment. For this reason, phytosanitary measures are necessary concerning those pests, until a full risk assessment is carried out.
- (12) The Annex to Implementing Regulation (EU) 2020/1213 should therefore be replaced by a new one, in order to include those phytosanitary measures.
- (13) It should also include the relisting of the respective plants, plant products and other objects in alphabetical order, in order to facilitate the readability of that list.
- (14) Experience gained from import controls after the application date of Regulation (EU) 2018/2019 has shown that some additional Combined Nomenclature (CN) codes laid down in Annex I to Council Regulation (EEC) No 2658/87 ⁽⁷⁾ need to be included in point 2 of the Annex to that Regulation in order to cover all the commodities traded as plants of *Ullucus tuberosus*. Therefore, the Annex to Implementing Regulation (EU) 2018/2019 should be amended accordingly.
- (15) In order to comply with the Union obligations deriving from the World Trade Organization Agreement on the application of sanitary and phytosanitary measures, the import of those commodities should resume within the shortest possible delay.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Plants, Animals, Food and Feed,

⁽⁵⁾ EFSA PLH Panel (EFSA Panel on Plant Health), Scientific Opinion on the commodity risk assessment of *Jasminum polyanthum* plants from Israel. EFSA Journal 2020;18(8):6225, 78 pp. <https://doi.org/10.2903/j.efsa.2020.6225>.

⁽⁶⁾ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

⁽⁷⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Amendment of Implementing Regulation (EU) 2018/2019

The Annex to Implementing Regulation (EU) 2018/2019 is amended in accordance with Annex I to this Regulation.

Article 2

Amendment of Implementing Regulation (EU) 2020/1213

The Annex to Implementing Regulation (EU) 2020/1213 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

This Regulation shall enter into force on the third 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, 9 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

The Annex to Implementing Regulation (EU) 2018/2019 is amended as follows:

- (a) in point 1, in the second column 'Description', the word '*Jasminum* L.' is replaced by '*Jasminum* L., other than unrooted cuttings of plants for planting of *Jasminum polyanthum* Franchet originating in Israel;'
- (b) in point 2, the table is replaced by the following:

'CN code	Description
ex 0601 10 90	<i>Ullucus tuberosus</i> Loz.'
ex 0601 20 90	
ex 0604 20 90	
ex 0714 90 20	
ex 1209 91 80	
ex 1404 90 00	

ANNEX II

The Annex to Implementing Regulation (EU) 2020/1213 is replaced by the following:

'ANNEX

List of plants, plant products and other objects, originating from third countries, and the corresponding measures for their introduction into the Union territory, as referred to in Article 2

Plants, plant products or other objects	CN Code	Third countries of origin	Measures
<i>Acer japonicum</i> Thunberg, <i>Acer palmatum</i> Thunberg and <i>Acer shirasawanum</i> Koidzumi, bare rooted, dormant, free of leaves, grafted or budded, one- to three- year old plants for planting	ex 0602 90 41 ex 0602 90 45 ex 0602 90 46 ex 0602 90 48 ex 0602 90 50	New Zealand	(a) Official statement that: (i) the plants are free from <i>Eotetranychus sexmaculatus</i> ; (ii) the plants have been grown throughout their life in a place of production, which, together with the sites of production that form part of it, is registered and supervised by the national plant protection organisation of the country of origin; (iii) the site of production has been found free from <i>Eotetranychus sexmaculatus</i> during official inspections carried out at appropriate times, since the beginning of the production cycle of the plants; in case of suspicion of the presence of <i>Eotetranychus sexmaculatus</i> at the site of production, appropriate treatments have been carried out to ensure the absence of the pest; a surrounding zone of 100 m has been established, which is subject to specific surveys at appropriate times to detect <i>Eotetranychus sexmaculatus</i> and where the pest has been found on any host plants, those plants have been rogued out and destroyed immediately; (iv) a system has been put in place to ensure that tools and machinery have been cleaned to be free from soil and plant debris and disinfected to be free from the <i>Eotetranychus sexmaculatus</i> , before they have been introduced into the site of production; (v) at harvest, the plants have been cleaned and trimmed and the plants have undergone an official phytosanitary inspection, consisting at least of a detailed visual examination, in particular of stems and branches of the plants to confirm the absence of the <i>Eotetranychus sexmaculatus</i> ; (vi) immediately prior to export, consignments of the plants have been subjected to an official inspection for the presence of <i>Eotetranychus sexmaculatus</i> , in particular of stems and branches of the plants, and the size of the sample for inspection has been such as to enable at least the detection of 1 % level of infestation with a level of confidence of 99 %;

			(b) the phytosanitary certificates for those plants include under the heading "Additional Declaration": (i) the following statement: "The consignment complies with Commission Implementing Regulation (EU) 2020/1362"; (ii) the specification of the registered sites of production.
<i>Acer japonicum</i> Thunberg, <i>Acer palmatum</i> Thunberg and <i>Acer shirasawanum</i> Koidzumi, bare rooted, dormant, free of leaves, grafted or budded, one- to three- year old plants for planting	ex 0602 90 41 ex 0602 90 45 ex 0602 90 46 ex 0602 90 48 ex 0602 90 50	New Zealand	(a) Official statement that: (i) the plants are free from <i>Oemona hirta</i> and <i>Platypus apicalis</i>; (ii) the plants have been grown throughout their life in a place of production, which, together with the sites of production that form part of it is registered and supervised by the national plant protection organisation of the country of origin; (iii) the site of production has been found free from <i>Oemona hirta</i> and <i>Platypus apicalis</i> during official inspections carried out at appropriate times, since the beginning of the production cycle of the plants; in case of suspicion of the presence of <i>Oemona hirta</i> or <i>Platypus apicalis</i> at the site of production, appropriate treatments have been carried out to ensure the absence of the pests; (iv) at harvest, the plants have been cleaned and have undergone an official inspection to confirm the absence of <i>Oemona hirta</i> and <i>Platypus apicalis</i>; (v) immediately prior to export, consignments of the plants have been subjected to an official inspection for the presence of <i>Oemona hirta</i> and <i>Platypus apicalis</i> and the size of the sample for inspection has been such as to enable at least the detection of 1 % level of infestation with a level of confidence of 99 %; (b) the phytosanitary certificates for those plants include under the heading "Additional Declaration": (i) the following statement: "The consignment complies with Commission Implementing Regulation (EU) 2020/1362"; (ii) the specification of the registered sites of production.
<i>Albizia julibrissin</i> Durazzini, bare rooted, dormant grafted plants for planting with a maximum diameter of 2,5 cm	ex 0602 90 41 ex 0602 90 45 ex 0602 90 46 ex 0602 90 48	Israel	(a) Official statement that: (i) the plants are free from <i>Euwallacea fornicatus sensu lato</i> and <i>Fusarium euwallaceae</i>; (ii) the plants have been grown throughout their life in a place of production, which is registered and supervised by the national plant protection organisation of the country of origin. That registration has included the respective production sites within the place of production; (iii) the plants fulfil one of the following requirements: 1. the plants have a diameter of less than 2 cm at the base of the stem or

			2. the plants have been grown in a site with complete physical protection against the introduction of <i>Euwallacea fornicatus sensu lato</i> at least during six months prior to export, which is subject to official inspections at appropriate times and has been found free from the pest, confirmed at least with traps which are checked at least every four weeks, including immediately prior to movement, or 3. the plants have been grown in a site of production which has been found free from <i>Euwallacea fornicatus sensu lato</i> and <i>Fusarium euwallaceae</i> since the beginning of the last complete cycle of vegetation, confirmed for <i>Euwallacea fornicatus sensu lato</i>, at least with traps, during official inspections carried out at least every four weeks; in case of suspicion of the presence of either of the two pests at the site of production, appropriate treatments against the pests have been carried out to ensure the absence of the pests; a surrounding zone of 1 km is established, which is monitored at appropriate times for <i>Euwallacea fornicatus sensu lato</i> and <i>Fusarium euwallaceae</i> and in case either of the two pests are found on any host plants, those plants should be immediately rogued out and destroyed; (iv) immediately prior to export, consignments of plants with a diameter of 2 cm or wider at the base of the stem have been subjected to an official inspection for the presence of the pest, in particular in stems and branches of the plants, including by destructive sampling. The size of the sample for inspection shall be such as to enable at least the detection of 1 % level of infestation with a level of confidence of 99 %; (b) the phytosanitary certificates for those plants include, under the heading "Additional Declaration": (i) the following statement: "The consignment complies with the provisions of Commission Implementing Regulation (EU) 2020/1213"; (ii) the specification of: — which requirement of point (a) (iii) in this entry has been fulfilled, and — the registered production site(s).
<i>Albizia julibrissin</i> Durazzini, bare rooted, dormant grafted plants for planting with a maximum diameter of 2,5 cm	ex 0602 90 41 ex 0602 90 45 ex 0602 90 46 ex 0602 90 48	Israel	(a) Official statement that: (i) the plants are free from <i>Aonidiella orientalis</i>; (ii) the plants have been grown throughout their life in a place of production, which is registered and supervised by the national plant protection organisation of the country of origin. That

			registration has included the respective productions sites within the place of production. That place of production has also fulfilled one of the following requirements: 1. the plants have been grown in a site with complete physical protection against the introduction of <i>Aonidiella orientalis</i> at least during six months prior to export, which is subject to official inspections every three weeks and found free from the pest, including immediately prior to movement, - or 2. the site of production has been found free from <i>Aonidiella orientalis</i> since the beginning of the last complete cycle of vegetation during official inspections carried out every three weeks; in case of suspicion of the presence of the pest at the site of production, appropriate treatments against the pest have been carried out to ensure the absence of the pest; a surrounding zone of 100m is established, which is monitored at appropriate times for <i>Aonidiella orientalis</i>, and where the pest is found on any plant, those plants should be immediately rogued out and destroyed; (iii) immediately prior to export, consignments of the plants have been subjected to an official inspection for the presence of <i>Aonidiella orientalis</i>, in particular in stems and branches of the plants. The size of the sample for inspection shall be such as to enable at least the detection of 1 % level of infestation with a level of confidence of 99 %; (b) the phytosanitary certificates for those plants include under the heading "Additional Declaration": (i) the following statement: "The consignment complies with the provisions of Commission Implementing Regulation (EU) 2020/1213"; (ii) the specification of: — which requirement of point (a) (ii) in this entry has been fulfilled, and — the registered production site(s).
<i>Jasminum polyanthum</i> Franchet, unrooted cuttings of plants for planting	ex 0602 10 90	Israel	(a) Official statement that: (i) the plants are free from <i>Scirtothrips dorsalis</i>, <i>Aonidiella orientalis</i>, <i>Milviscutulus mangiferae</i>, <i>Paracoccus marginatus</i>, <i>Pulvinaria psidii</i> and <i>Colletotrichum siamense</i>;

			(ii) the plants have been grown throughout their life in a place of production, which, together with the sites of production that form part of it, is registered and supervised by the national plant protection organisation of the country of origin; (iii) the plants have been grown in a site with physical protection against the introduction of <i>Scirtothrips dorsalis</i>, <i>Aonidiella orientalis</i>, <i>Milviscutulus mangiferae</i>, <i>Paracoccus marginatus</i>, <i>Pulvinaria psidii</i>; (iv) the production site has been subject to official inspections for the presence of <i>Scirtothrips dorsalis</i>, <i>Aonidiella orientalis</i>, <i>Milviscutulus mangiferae</i>, <i>Paracoccus marginatus</i>, <i>Pulvinaria psidii</i>, and <i>Colletotrichum siamense</i> every three weeks and found free from those pests; (v) immediately prior to export, consignments of the plants have been subjected to an official inspection for the presence of <i>Scirtothrips dorsalis</i>, <i>Aonidiella orientalis</i>, <i>Milviscutulus mangiferae</i>, <i>Paracoccus marginatus</i>, and <i>Pulvinaria psidii</i> with such a sample size as to enable at least the detection of 1 % level of infestation with a level of confidence of 99 %, and to an official inspection for the presence of <i>Colletotrichum siamense</i> including testing of symptomatic plants; (b) the phytosanitary certificates for those plants include under the heading "Additional Declaration": (i) the following statement: "The consignment complies with Commission Implementing Regulation (EU) 2021/419"; and (ii) the specification of the registered sites of production.
<i>Robinia pseudoacacia</i> , bare rooted, dormant grafted plants for planting with a maximum diameter of 2,5 cm	ex 0602 90 41 ex 0602 90 45 ex 0602 90 46 ex 0602 90 48	Israel	(a) Official statement that: (i) the plants are free from <i>Euwallacea fornicatus sensu lato</i> and <i>Fusarium euwallaceae</i>; (ii) the plants have been grown throughout their life in a place of production which is registered and supervised by the national plant protection organisation of the country of origin. That registration has included the respective productions sites within the place of production; (iii) the plants fulfil one of the following requirements: 1. the plants have a diameter of less than 2 cm at the base of the stem - or 2. the plants have been grown in a site with complete physical protection against the introduction of <i>Euwallacea fornicatus sensu lato</i> at least during six months prior to export, which is subject to official inspections at appropriate

			times and has been found free from the pest, confirmed at least with traps which are checked at least every four weeks, including immediately prior to movement, or 3. the plants have been grown in a site of production which has been found free from <i>Euwallacea fornicatus sensu lato</i> and <i>Fusarium euwallaceae</i> since the beginning of the last complete cycle of vegetation, confirmed for <i>Euwallacea fornicatus sensu lato</i>, at least with traps, during official inspections carried out at least every four weeks; in case of suspicion of the presence of either of the two pests at the site of production, appropriate treatments against the pests have been carried out to ensure the absence of the pests; a surrounding zone of 1 km is established, which is monitored at appropriate times for <i>Euwallacea fornicatus sensu lato</i> and <i>Fusarium euwallaceae</i> and where either of the two pests are found on any host plants, those plants should be immediately rogued out and destroyed; (iv) immediately prior to export, consignments of plants with a diameter of 2 cm or wider at the base of the stem have been subjected to an official inspection for the presence of the pest, in particular in stems and branches of the plants, including destructive sampling. The size of the sample for inspection shall be such as to enable at least the detection of 1 % level of infestation with a level of confidence of 99 %; (b) the phytosanitary certificates for those plants include, under the heading "Additional Declaration": (i) the following statement: "The consignment complies with the provisions of Commission Implementing Regulation (EU) 2020/1213"; (ii) the specification of: — which requirement of point (a) (iii) in this entry has been fulfilled, and — the registered production site(s).'
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COMMISSION IMPLEMENTING REGULATION (EU) 2021/420

of 9 March 2021

correcting Implementing Regulation (EU) 2020/1097 concerning the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying

(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 ⁽¹⁾, 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. Article 10(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾ and Article 4 for the authorisation of a new use of an additive.
- (2) Lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* were authorised by Commission Implementing Regulation (EU) 2020/1097 ⁽³⁾ concerning the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying.
- (3) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 April 2019 ⁽⁴⁾ that the maximum proposed use level of 80 mg total carotenoids/kg of complete feed for lutein-rich and lutein/zeaxanthin extracts is safe for poultry for fattening (except turkeys), minor poultry for fattening, poultry for laying (except turkeys) and minor poultry for laying. By mistake, the heading of the sixth and seventh columns of the Annex to Implementing Regulation (EU) 2020/1097 refers to 'mg of active substance of kg of complete feedingstuff with a moisture content of 12 %'. That reference is not correct as the EFSA opinion refers to the 'total carotenoids'. It is therefore appropriate to correct the heading of the sixth and seventh columns of the table in the Annex to that Implementing Regulation to reflect the wording appearing in the EFSA opinion of 3 April 2019.
- (4) The references to 'poultry for fattening (except turkeys)' and 'poultry for laying, (except turkeys)' have been modified to 'chickens for fattening' and 'laying hens'. This change does not affect or modify the categories of animals currently authorised, as the term 'poultry' covers turkeys for laying and fattening, chickens for fattening and laying hens. Therefore, it is more appropriate to refer directly to chickens for fattening and laying hens.
- (5) The EFSA opinion also indicated that the maximum use level of the lutein/zeaxanthin extract is 80 mg total carotenoids/kg of complete feed in poultry for fattening (except turkeys), minor poultry for fattening, poultry for laying (except turkeys) and minor poultry for laying. In addition, the EFSA opinion stated that in breeding minor poultry the maximum level should not exceed 50 mg total carotenoids/kg complete feed, considering the toxicological potential of zeaxanthin on reproduction. The EFSA opinion further stated that, since the breeding husbandry in minor poultry species does not differentiate between laying and breeding, it cannot be excluded that the additive contained in a layer diet would be given to minor breeding poultry. By mistake, the table in the Annex

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ Commission Implementing Regulation (EU) 2020/1097 of 24 July 2020 concerning the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying (OJ L 241, 27.7.2020, p. 23).⁽⁴⁾ EFSA Journal 2019; 17(5):5698.

to Implementing Regulation (EU) 2020/1097 set the maximum level of carotenoids of lutein/zeaxanthin extract for poultry for fattening (except turkeys), minor poultry for fattening, poultry for laying (except turkeys) and minor poultry for laying at 50 mg total carotenoids/kg feed, while this level should apply only to minor poultry for laying, to prevent any misuse on breeding animals. The rest of the poultry categories should have a maximum level of use of 80 mg total carotenoids/kg of complete feed.

- (6) Implementing Regulation (EU) 2020/1097 should therefore be corrected.
- (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

The Annex to Regulation (EU) 2020/1097 is replaced by the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 9 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	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 of total carotenoids/kg of complete feedingstuff with a moisture content of 12 %			

Category: Sensory additives. Functional group: Colourants. (ii) substances which, when fed to animals, add colours to food of animal origin

2a161b	Lutein-rich extract	<i>Additive composition</i> Lutein-rich extract of <i>Tagetes erecta</i> Benzene ≤ 2mg/kg	Chickens for fattening and minor poultry for fattening	-	-	80	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Lutein-rich extract must be placed on the market and used as an additive consisting of a preparation. 3. The mixture of lutein-rich extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xanthophylls content of 80 mg/kg of complete feed. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and skin protection	30.3.2031
		<i>Characterisation of the active substance</i> Lutein from a saponified extract of <i>Tagetes erecta</i> (dried flowers petals) obtained via extraction and saponification: — Total carotenoids (TC): ≥ 60g/kg — Lutein ≥ 75 % of total carotenoids (TC) — Zeaxanthin ≥ 4 % of total carotenoids (TC) Chemical formula: C ₄₀ H ₅₆ O ₂ CAS number 127-40-2 (lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Liquid form		-	-	80		
		<i>Analytical method</i> ⁽¹⁾ — For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xanthophylls in the feed additive: high Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Regulation (EU) No 231/2012 referring to FAO JECFA monograph “lutein from <i>Tagetes erecta</i> ” monograph No 3 (2006), Combined Compendium for Food Additive Specifications	Laying hens and minor poultry for laying.	-	-	80		

		— For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: high Performance Liquid Chromatography with visible detection (HPLC-Vis) — For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64						
2a161bi	Lutein/zeaxanthin extract	<i>Additive composition</i> Lutein/zeaxanthin extract of <i>Tagetes erecta</i> . Benzene ≤ 2mg/kg	Chickens for fattening and minor poultry for fattening	-	-	80	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Lutein/zeaxanthin extract must be placed on the market and used as an additive consisting of a preparation. 3. The mixture of lutein/zeaxanthin extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xanthophylls content of: a. 80 mg/kg of complete feed for chickens for fattening, minor poultry for fattening and laying hens. b. 50 mg/kg of complete feed for minor poultry for laying. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and skin protection.	30.3.2031
		<i>Characterisation of the active substance</i> Lutein/zeaxanthin saponified/isomerised extract of <i>Tagetes erecta</i> (dried flowers petals) obtained via extraction, saponification and isomerisation: — Total carotenoids (TC): ≥ 60g/kg — Lutein ≥ 37 % of TC; — Zeaxanthin ≥ 36 % of TC. <i>Liquid form</i> CAS number 127-40-2(lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Chemical formula: C ₄₀ H ₅₆ O ₂	Laying hens			80		
			Minor poultry for laying.			50		
		<i>Analytical method ⁽¹⁾</i> For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xanthophylls in the feed additive: — High Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Directive 2008/128/EC referring to FAO JECFA monograph “lutein from <i>Tagetes erecta</i> ” monograph No 3 (2006), Combined Compendium for Food Additive Specifications		-	-			

		For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: — High Performance Liquid Chromatography with visible detection (HPLC-Vis) For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: — Liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64							
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(¹) 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>

COMMISSION IMPLEMENTING REGULATION (EU) 2021/421**of 9 March 2021****concerning the authorisation of tincture derived from *Artemisia vulgaris* L. (mugwort tincture) 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 ⁽¹⁾, 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 a tincture derived from *Artemisia vulgaris* L. (mugwort tincture) as a feed additive for all animal species. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a tincture derived from *Artemisia vulgaris* L. (mugwort tincture) as a feed additive for all animal species. The applicant requested this additive to be classified in the additive category 'sensory additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 4 October 2019 ⁽²⁾ and 1 July 2020 ⁽³⁾ that, under the proposed conditions of use the tincture derived from *Artemisia vulgaris* L. (mugwort tincture) does not have adverse effects on animal health, consumer health or the environment. The Authority indicated that no conclusions can be drawn on the additive's potential to be a dermal/eye irritant or a skin sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (5) The Authority also concluded, that *Artemisia vulgaris* L. and its extracts are universally recognised to flavour food and their function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of tincture derived from *Artemisia vulgaris* L. (mugwort tincture) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised.
- (7) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (8) The fact that tincture derived from *Artemisia vulgaris* L. (mugwort tincture) is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed which is administered via water.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2019;17(11):5879

⁽³⁾ EFSA Journal 2020;18(7):6206

HAS ADOPTED THIS REGULATION:

Article 1

The tincture derived from *Artemisia vulgaris* L. (mugwort tincture) specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

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, 9 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

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 active substance/kg of complete feed with a moisture content of 12 %			

Category: Sensory additives**Functional group: Flavouring compounds**

2b72-t	-	Mugwort tincture	<i>Additive composition</i> Tincture produced from the fragmented aerial parts of <i>Artemisia vulgaris</i> L. <i>Characterisation of the active substance</i> Tincture produced from the fragmented aerial parts of <i>Artemisia vulgaris</i> L by extended extraction with a water/ethanol mixture as defined by the Council of Europe ⁽¹⁾. The specifications of the active substance are: Dry matter: 1,4-1,9 % Ash: 0,2-0,5 % Organic fraction: 1,13-1,65 %, of which — Total polyphenols: 0,05-0,2 % — Phenolic acids 0,02-0,11 % — Chlorogenic acid: 0,0028-0,0136 % — α- and β-thujone: < 0,005 % — 1,8-cineole: 0,005 % — Solvent (ethanol): 98,1-98,6 %	All animal species	-	-		- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. - On the label of the additive and premixtures the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 400 mg/kg' - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.	30.3.2031
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			Liquid form CoE No 72 <i>Analytical method</i> ⁽²⁾ For the characterisation of the feed additive (Mugwort tincture): — gravimetric method for the determination of loss on drying and the ash content — spectrophotometric method for the determination of total polyphenols content — high performance thin layer chromatography (HPTLC) method for the determination of total phenolic acids, chlorogenic acid, alpha- and beta- thujones and eucalyptol					5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes 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 personal protective equipment, including breathing protection, safety glasses and gloves.	
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⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).
⁽²⁾ 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>

COMMISSION IMPLEMENTING REGULATION (EU) 2021/422**of 9 March 2021****concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for laying hens (holder of authorisation: Lactosan GmbH & Co KG)****(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 ⁽¹⁾, 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 a preparation of *Enterococcus faecium* DSM 7134. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of the preparation of *Enterococcus faecium* DSM 7134 as a feed additive for laying hens, to be classified in the category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 September 2020 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Enterococcus faecium* DSM 7134 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that this preparation is not a dermal or ocular irritant but a potential dermal and respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the preparation has the potential to be efficacious as zootechnical additive in feedingstuffs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods 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 the preparation of *Enterococcus faecium* DSM 7134 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the product 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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2020;18(11):6277.

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, 9 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			

Category of zootechnical additives. Functional group: gut flora stabilisers

4b1840	Lactosan GmbH & Co.KG.	<i>Enterococcus faecium</i> DSM 7134	<i>Additive composition</i> Preparation of <i>Enterococcus faecium</i> DSM 7134 containing a minimum of: Powder: 1×10^{10} CFU/g of additive Granules (microencapsulated): 1×10^{10} CFU/g of additive	Laying hens	-	1×10^9	-	5×10^8	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For use of the additive in water for drinking the homogenous dispersion of the additive shall be ensured. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, glasses and gloves.	30.3.2031
			<i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> DSM 7134								
			<i>Analytical method</i> ⁽¹⁾ For enumeration: Spread plate method using bile esculin azid agar (EN 15788). For identification: Pulsed Field Gel Electrophoresis (PFGE).								

⁽¹⁾ 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>

DECISIONS

COUNCIL DECISION (EU) 2021/423

of 4 March 2021

appointing an alternate member, proposed by the Kingdom of Denmark, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Danish Government,

Whereas:

- (1) On 10 December 2019, 20 January 2020, 3 February 2020 and 26 March 2020 the Council adopted, respectively, Decisions (EU) 2019/2157 ⁽¹⁾, (EU) 2020/102 ⁽²⁾, (EU) 2020/144 ⁽³⁾ and (EU) 2020/511 ⁽⁴⁾, appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025. On 8 June 2020, the Council adopted Decision (EU) 2020/766 ⁽⁵⁾ appointing the members and alternate members of the Committee of the Regions for the period from 1 February 2020 to 25 January 2025. On 30 July 2020, the Council adopted Decision (EU) 2020/1153 ⁽⁶⁾ appointing members and alternate members of the Committee of the Regions.
- (2) An alternate member's seat on the Committee of the Regions has become vacant following the end of the term of office of Ms EVA Borchorst MEJNERTZ,

HAS ADOPTED THIS DECISION:

Article 1

The following is hereby appointed as alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025:

— Ms Line KROGH LAY, Member of a Local Assembly: *Stevns kommunalbestyrelse*.

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- ⁽¹⁾ Council Decision (EU) 2019/2157 of 10 December 2019 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 327, 17.12.2019, p. 78).
- ⁽²⁾ Council Decision (EU) 2020/102 of 20 January 2020 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 20, 24.1.2020, p. 2).
- ⁽³⁾ Council Decision (EU) 2020/144 of 3 February 2020 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 32, 4.2.2020, p. 16).
- ⁽⁴⁾ Council Decision (EU) 2020/511 of 26 March 2020 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 113, 8.4.2020, p. 18).
- ⁽⁵⁾ Council Decision (EU) 2020/766 of 8 June 2020 appointing the members and alternate members of the Committee of the Regions for the period from 1 February 2020 to 25 January 2025 (OJ L 187, 12.6.2020, p. 3).
- ⁽⁶⁾ Council Decision (EU) 2020/1153 of 30 July 2020 appointing members and alternate members of the Committee of the Regions (OJ L 256, 5.8.2020, p. 12).

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 4 March 2021.

For the Council
The President
A. P. ZACARIAS

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