

EUROPEAN COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

authorising certain products and substances for use in organic production and establishing their lists

(Text with EEA relevance)

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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 $834/2007^1$, and in particular Article 24(9) and point (a) of Article 39(2) thereof,

Whereas:

- (1) Pursuant to Article 9(3) of Regulation (EU) 2018/848, only products and substances authorised under Article 24 of that Regulation may be used in organic production provided that their use in non-organic production has also been authorised in accordance with relevant provisions of Union law. The Commission has already evaluated the use of certain products and substances in organic production on the basis of the objectives and principles laid down in Council Regulation (EC) No 834/2007². The selected products and substances were consequently authorised under specific conditions by Commission Regulation (EC) No 889/2008³ and listed in certain Annexes to that Regulation. The objectives and principles laid down in Regulation (EU) 2018/848 are similar to those in Regulation (EC) No 834/2007. As it is necessary to ensure the continuity of organic production, those products and substances should be included in the restrictive lists to be established on the basis of Regulation (EU) 2018/848.
- (2) In addition, in accordance with Article 24(7) of Regulation (EU) 2018/848, Member States have submitted dossiers on certain products and substances to the Commission and to the other Member States, in view of their authorisation and inclusion in the lists to be established under that Regulation.
- (3) Under certain circumstances and conditions set out, in particular, in point 1.10.2. of Part I of Annex II to Regulation (EU) 2018/848, certain authorised products and substances may be used to protect plants. For that purpose, the Commission should authorise active substances to be used in plant protection products as referred to in

¹ OJ L 150, 14.6.2018, p. 1.

² Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

³ 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).

point (a) of Article 24(1) of Regulation (EU) 2018/848 and establish the list of those active substances.

- (4) Under certain circumstances and conditions set out, in particular, in point 1.9.3 of Part I, points 1.9.1.2(b), 1.9.2.2(d), 1.9.3.2(b) and 1.9.5.2(a) of Part II and points 2.2.2(c) and 2.3.2 and the second indent of the fourth paragraph of point 3.1.5.3 of Part III of Annex II to Regulation (EU) 2018/848, certain fertilisers, soil conditioners and nutrients may be used for plant nutrition, litter improvement and enrichment, algae cultivation or husbandry environment of aquaculture animals. For that purpose, the Commission should authorise fertilisers, soil conditioners and nutrients as referred to in point (b) of Article 24(1) of Regulation (EU) 2018/848 and establish their list.
- (5) Under certain circumstances and conditions set out, in particular, in points 1.4.1(i) and 1.5.2.3 of Part II, point 3.1.3.1(d) of Part III and point 2.3 of Part V of Annex II to Regulation (EU) 2018/848, certain non-organic feed materials of plant, algal, animal or yeast origin, feed materials of microbial or mineral origin, feed additives and processing aids may be used for animal nutrition. For that purpose, the Commission should authorise non-organic feed materials of plant, algal, animal or yeast origin, feed materials of microbial or generation (EU) 2018/848 and referred to in points (c) and (d) of Article 24(1) of Regulation (EU) 2018/848 and establish their lists.
- (6) In addition, some non-organic feed materials are directly authorised in accordance with Regulation (EU) 2018/848. For the sake of clarity, those feed materials should also be listed together with the feed materials authorised by this Regulation, with a reference to the specific provisions of Regulation (EU) 2018/848.
- (7) Under certain circumstances and conditions set out, in particular, in points 1.11 of Part I, points 1.5.1.6, 1.5.1.7 and 1.9.4.4(c) of Part II, point 3.1.4.1(f) of Part III, point 2.2.3 of Part IV, point 2.4 of Part V and point 1.4 of Part VII of Annex II and points 4.2 and 7.5 of Annex III to Regulation (EU) 2018/848, only certain products and substances may be used for cleaning and disinfection. For that purpose, the Commission should authorise products for cleaning and disinfection as referred to in points (e), (f) and (g) of Article 24(1) of Regulation (EU) 2018/848 and establish their lists.
- (8) Certain products for cleaning and disinfection of buildings and installations for livestock, aquaculture animals and seaweed production have been evaluated and listed in Annex VII to Regulation (EC) No 889/2008. However, products for cleaning and disinfection of buildings and installations used for plant production and of processing and storage facilities are so far evaluated and authorised only by Member States. Before authorising those products in organic production, an evaluation should be done at Union level by the Commission assisted by the Expert Group for Technical Advice on Organic Production. That evaluation should include a revision of all existing authorised products and substances for cleaning and disinfection.
- (9) For the sake of ensuring the continuity of organic production, the products listed in Annex VII to Regulation (EC) No 889/2008 and those authorised at Member States' level should continue to be authorised until 31 December 2023 to allow the establishment of the lists of products for cleaning and disinfection in accordance with the provisions laid down in points (e), (f) and (g) of Article 24(1) of Regulation (EU) 2018/848. Nevertheless, those products must comply with the relevant requirements of Union law, in particular Regulation (EC) No 648/2004 of the European Parliament and

of the Council⁴ and Regulation (EU) No 528/2012 of the European Parliament and of the Council⁵ and with the organic criteria laid down in Chapter II and points (a) and (b) of Article 24(3) of Regulation (EU) 2018/848.

- (10) Under certain circumstances and conditions set out, in particular, in points 2.2.1 and 2.2.2(a) of Part IV of Annex II to Regulation (EU) 2018/848, certain food additives, including food enzymes to be used as food additives, and processing aids may be used in the production of processed organic food. For that purpose, the Commission should authorise food additives and processing aids as referred to in point (a) of Article 24(2) of Regulation (EU) 2018/848 and establish their list.
- (11) Food additives and food processing aids used in the production of processed organic food were listed respectively in sections A, B and C of Annex VIII to Regulation (EC) No 889/2008. However, according to their uses and functions in the final product, certain of those products might be classified as additives and not as processing aids. This classification needs a specific and exhaustive analysis of those products in the production of processed organic food. Such analysis should be conducted on all products listed as processing aids in Regulation (EC) No 889/2008. That process will take time and cannot be completed before the date of application of Regulation (EU) 2018/848. Consequently, the products currently listed as processing aids in Regulation (EC) No 889/2008 will be listed as processing aids in this Regulation until a specific and exhaustive analysis has been carried out.
- (12) Under certain circumstances and conditions set out, in particular, in point 2.2.1 of Part IV of Annex II to Regulation (EU) 2018/848, certain non-organic agricultural ingredients may be used for the production of processed organic food. For that purpose, the Commission should authorise such non-organic agricultural ingredients as referred to in point (b) of Article 24(2) of Regulation (EU) 2018/848 and establish their list. The dossiers on non-organic agricultural ingredients to be used for the production of processed organic food that have been submitted by Member States in accordance with Article 24(7) of Regulation (EU) 2018/848 were evaluated within the Committee on Organic Production. The selected products and substances that comply with the objectives and principles laid down in Regulation (EU) 2018/848 should be included in the restrictive list to be established by this Regulation, where necessary under specific conditions.
- (13) However, in order to give enough time to operators to adapt to the new restrictive list of authorised non-organic agricultural ingredients and, in particular, to find a source of agricultural ingredients that have been produced in accordance with Regulation (EU) 2018/848, it is appropriate that the list of non-organic agricultural ingredients authorised for use in processing of organic food by this Regulation applies from 1 January 2024.
- (14) Given the composition of certain non-organic agricultural ingredients, some of their uses in processed organic food may correspond to uses as food additives, food processing aids or products and substances referred to in point 2.2.2 of Part IV of Annex II to Regulation (EU) 2018/848. Those uses require a specific authorisation in accordance with point 2.2 of Part IV of Annex II to Regulation (EU) 2018/848 and

⁴ Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1).

⁵ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 26.6.2012, p. 1).

such uses should not be allowed via the authorisation of non-organic agricultural ingredients.

- (15) Under certain circumstances and conditions set out, in particular, in point 1.3(a) of Part VII of Annex II to Regulation (EU) 2018/848, certain processing aids may be used for the production of yeast and yeast products. For that purpose, the Commission should authorise processing aids for the production of yeast and yeast products as referred to in point (c) of Article 24(2) of Regulation (EU) 2018/848 and establish their list.
- (16) In accordance with point 2.2 of Part VI of Annex II to Regulation (EU) 2018/848, only products and substances authorised pursuant to Article 24 of that Regulation for use in organic production may be used for the making of products of the wine sector as referred to point (l) of Article 1(2) of Regulation (EU) No 1308/2013 of the European Parliament and of the Council⁶. For that purpose, the Commission should authorise such products and substances and establish their list.
- (17) Article 45(2) of Regulation (EU) 2018/848 empowers the Commission to grant specific authorisations for the use of products and substances in third countries and in the outermost regions of the Union. How to initiate the procedure to be followed by Member States in respect of the outermost regions of the Union is set out in Article 24(7) of that Regulation. However, the procedure to be followed for such authorisations in respect of third countries is not detailed in Regulation (EU) 2018/848. Therefore, it is appropriate to establish that procedure in this Regulation, in line with the procedure to be followed to authorise products and substances for use in organic production in the Union, as set out in Article 24 of Regulation (EU) 2018/848. As those authorisations may be granted for a renewable period of 2 years, it is appropriate, in order to avoid confusion with products and substances in a dedicated Annex.
- (18) In the interest of clarity and legal certainty, Regulation (EC) No 889/2008 should be repealed. However, as the list of products for cleaning and disinfection will not be established before 1 January 2024, Annex VII to Regulation (EC) No 889/2008 should continue to apply until 31 December 2023. In that context, it is appropriate to specify that products listed in that Annex which are not authorised pursuant to Regulation (EU) No 528/2012, cannot be used as biocidal products. Furthermore, the list of non-organic agricultural ingredients to be used for the production of processed organic food established by this Regulation will only apply from 1 January 2024. Therefore, it is appropriate to provide that processed organic food that has been produced before 1 January 2024 with non-organic agricultural ingredients listed in that Annex may be placed on the market after that date until the stocks are exhausted.
- (19) The certificate to be issued to operators by the competent authorities, or, where appropriate, the control authorities or control bodies in accordance with Article 35(1) of Regulation (EU) 2018/848 can be issued from 1 January 2022. However, it will not be provided to all operators concerned on that day. For the sake of ensuring the continuity of organic production and by way of derogation from Article 35(2) of Regulation (EU) 2018/848, the documentary evidence issued to operators by the

⁶ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

control authorities or control bodies in accordance with Article 68 of Regulation (EC) No 889/2008 before 1 January 2022 should remain valid until the end of the validity period. However, as pursuant to Article 38(3) of Regulation (EU) 2018/848 operators are to be subject to a verification of compliance at least once a year and, in accordance with Article 38(5) of that Regulation, the delivery of the certificate is to be based on the results of that verification, the validity should not go beyond 31 December 2022.

- (20) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848. However, for the reasons set out in recital 18 of this Regulation, the provisions referring to the lists of products for cleaning and disinfection and to the list of non-organic agricultural ingredients to be used for the production of processed organic food should apply from 1 January 2024.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Organic Production,

HAS ADOPTED THIS REGULATION:

Article 1

Active substances in plant protection products

For the purposes of point (a) of Article 24(1) of Regulation (EU) 2018/848, only the active substances listed in Annex I to this Regulation may be contained in plant protection products used in organic production as set out in that Annex, provided that those plant protection products:

- (a) have been authorised pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁷;
- (b) are used in accordance with the conditions for use as specified in the authorisations of the products containing them, granted by the Member States; and
- (c) are used in compliance with the conditions set out in the Annex to Commission Implementing Regulation (EU) No $540/2011^8$.

Article 2

Fertilisers, soil conditioners and nutrients

For the purposes of point (b) of Article 24(1) of Regulation (EU) 2018/848, only the products and substances listed in Annex II to this Regulation may be used in organic production as fertilisers, soil conditioners and nutrients for plant nutrition, litter improvement and enrichment or algae cultivation or husbandry environment of aquaculture animals, provided that they are compliant with the relevant provisions of Union law, in particular with Regulation (EC) No 2003/2003 of the European Parliament and of the Council⁹, the relevant applicable Articles of Regulation (EU) 2019/1009 of the European Parliament and of the

⁷ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).

⁸ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁹ Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1).

Council¹⁰, Regulation (EC) No 1069/2009 of the European Parliament and of the Council¹¹ and Commission Regulation (EU) No 142/2011¹² and, where applicable, in accordance with national provisions based on Union law.

Article 3

Non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin

For the purposes of point (c) of Article 24(1) of Regulation (EU) 2018/848, only the products and substances listed in Part A of Annex III to this Regulation may be used in organic production as non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 767/2009 of the European Parliament and of the Council¹³ and, where applicable, in accordance with national provisions based on Union law.

Article 4

Feed additives and processing aids

For the purposes of point (d) of Article 24(1) of Regulation (EU) 2018/848, only the products and substances listed in Part B of Annex III to this Regulation may be used in organic production as feed additives and processing aids used in animal nutrition, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 1831/2003 of the European Parliament and of the Council¹⁴ and, where applicable, in accordance with national provisions based on Union law.

Article 5

Products for cleaning and disinfection

1. For the purposes of point (e) of Article 24(1) of Regulation (EU) 2018/848, only the products listed in Part A of Annex IV to this Regulation may be used for the cleaning

Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L170 25.6.2019, p. 1).

¹¹ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1).

¹² Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

¹³ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

¹⁴ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production, provided that those products comply with the provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012 and, where applicable, in accordance with national provisions based on Union law.

- 2. For the purposes of point (f) of Article 24(1) of Regulation (EU) 2018/848, only the products listed in Part B of Annex IV to this Regulation may be used for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding, provided that those products comply with the provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012 and, where applicable, in accordance with national provisions based on Union law.
- 3. For the purposes of point (g) of Article 24(1) of Regulation (EU) 2018/848, only the products listed in Part C of Annex IV to this Regulation may be used for cleaning and disinfection in processing and storage facilities, provided that those products comply with the provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012 and, where applicable, in accordance with national provisions based on Union law.
- 4. Pending their inclusion in Part A, B or C of Annex IV to this Regulation, products for cleaning and disinfection referred to in points (e), (f) and (g) of Article 24(1) of Regulation (EU) 2018/848 that were authorised for use in organic production under Regulation (EC) No 834/2007 or under national law prior to the date of application of Regulation (EU) 2018/848 may continue to be used if they comply with the relevant provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012 and, where applicable, in accordance with national provisions based on Union law.

Article 6

Food additives and processing aids

For the purposes of point (a) of Article 24(2) of Regulation (EU) 2018/848, only the products and substances listed in Part A of Annex V to this Regulation may be used as food additives, including food enzymes to be used as food additives, and processing aids in the production of processed organic food, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 1333/2008 of the European Parliament and of the Council¹⁵ and, where applicable, in accordance with national provisions based on Union law.

Article 7

Non-organic agricultural ingredients to be used for the production of processed organic food

For the purposes of point (b) of Article 24(2) of Regulation (EU) 2018/848, only the nonorganic agricultural ingredients listed in Part B of Annex V to this Regulation may be used for the production of processed organic food, provided that their use is in accordance with the

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Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law.

The first paragraph is without prejudice to the detailed requirements for organic production of processed food provided in Section 2 of Part IV of Annex II to Regulation (EU) 2018/848. In particular, the first paragraph shall not apply to non-organic agricultural ingredients that are used as food additives, processing aids or products and substances referred to in point 2.2.2 of Part IV of Annex II to Regulation (EU) 2018/848.

Article 8

Processing aids for the production of yeast and yeast products

For the purposes of point (c) of Article 24(2) of Regulation (EU) 2018/848, only the products and substances listed in Part C of Annex V to this Regulation may be used as processing aids for the production of yeast and yeast products for food and feed, provided that their use is in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law.

Article 9

Products and substances for use in organic production of wine

For the purposes of point 2.2 of Part VI of Annex II to Regulation (EU) 2018/848, only the products and substances listed in Part D of Annex V to this Regulation may be used for the production and conservation of organic grapevine products as referred to in Part II of Annex VII to Regulation (EU) No 1308/2013, provided that their use is in accordance with the relevant provisions of Union law, in particular within the limits and conditions set out in Regulation (EU) No 1308/2013 and Commission Delegated Regulation (EU) 2019/934¹⁶ and, where applicable, in accordance with national provisions based on Union law.

Article 10

Procedure to grant specific authorisations for the use of products and substances in certain areas of third countries

1. Where a control authority or control body recognised under Article 46(1) of Regulation (EU) 2018/848 considers that a product or substance should be granted a specific authorisation for use in a certain area outside the Union due to the specific conditions set out in Article 45(2) of that Regulation, it may request the Commission to carry out an assessment. For that purpose, it shall notify the Commission of a dossier describing the product or substance concerned, giving the reasons for such specific authorisation and explaining why the products and substances authorised under this Regulation are not adequate to be used due to the specific conditions in the relevant area. It shall ensure that the dossier is fit to be made publicly available subject to Union and national legislation of the Member States on data protection.

¹⁶ Commission Delegated Regulation (EU) 2019/934 of 12 March 2019 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards wine-growing areas where the alcoholic strength may be increased, authorised oenological practices and restrictions applicable to the production and conservation of grapevine products, the minimum percentage of alcohol for by-products and their disposal, and publication of OIV files (OJ L 149, 7.6.2019, p. 1).

- 2. The Commission shall forward the request referred to in paragraph 1 to the Member States and shall publish any such requests.
- 3. The Commission shall analyse the dossier referred to in paragraph 1. The Commission shall authorise the product or substance in the light of the specific conditions referred to in the dossier only if its analysis concludes, as a whole that:
 - (a) such specific authorisation is justified in the area concerned;
 - (b) the product or substance described in the dossier complies with the principles laid down in Chapter II, the criteria set out in Article 24(3) and the condition set out in Article 24(5) of Regulation (EU) 2018/848; and
 - (c) the use of the product or substance is in accordance with the relevant provisions of Union law, in particular for active substances contained in plant protection products with Regulation (EC) No 396/2005 of the European Parliament and of the Council¹⁷.

The authorised product or substance shall be included in Annex VI to this Regulation.

4. When the 2-year period referred to in Article 45(2) of Regulation (EU) 2018/848 expires, the authorisation shall be automatically renewed for another period of 2 years, provided that no new elements are available and no Member State or control authority or control body recognised under Article 46(1) of Regulation (EU) 2018/848 has objected, justifying that the conclusion by the Commission referred to in paragraph 3 need to be reassessed.

Article 11

Repeal

Regulation (EC) No 889/2008 is repealed.

However, Annexes VII and IX shall continue to apply until 31 December 2023.

Article 12

Transitional provisions

- 1. For the purposes of Article 5(4) of this Regulation, the products for cleaning and disinfection listed in Annex VII to Regulation (EC) No 889/2008 may continue to be used until 31 December 2023 for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production, subject to Part D of Annex IV to this Regulation.
- 2. For the purposes of point (b) of Article 24(2) of Regulation (EU) 2018/848, the nonorganic agricultural ingredients listed in Annex IX to Regulation (EC) No 889/2008 may continue to be used for the production of processed organic food until 31 December 2023. Processed organic food that has been produced before 1 January

¹⁷ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

2024 with those non-organic agricultural ingredients may be placed on the market after that date until the stocks are exhausted.

3. Documentary evidence issued in accordance with Article 68 of Regulation (EC) No 889/2008 prior to 1 January 2022 shall remain valid until the end of its validity period but not beyond 31 December 2022.

Article 13

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.

However, Article 5(1), (2) and (3) and Article 7 shall apply from 1 January 2024.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

> For the Commission The President Ursula VON DER LEYEN

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Annex I

ACTIVE SUBSTANCES CONTAINED IN PLANT PROTECTION PRODUCTS AUTHORISED FOR USE IN ORGANIC PRODUCTION AS REFERRED TO IN POINT (a) OF ARTICLE 24(1) OF REGULATION (EU) 2018/848

The active substances listed in this Annex may be contained in plant protection products used in organic production as set out in this Annex, provided that these plant protection products are authorised pursuant to Regulation (EC) No 1107/2009. These plant protection products shall be used in compliance with the conditions set out in the Annex to Implementing Regulation (EU) No 540/2011 and in accordance with the conditions specified in the authorisations granted by the Member States where they are used. More restrictive conditions for use in organic production are specified in the last column of each table below.

In accordance with Article 9(3) of Regulation (EU) 2018/848, safeners, synergists and coformulants as components of plant protection products, and adjuvants that are to be mixed with plant protection products shall be allowed for use in organic production, provided that they are authorised pursuant to Regulation (EC) No 1107/2009. The substances in this Annex may only be used for the control of pests as defined in Article 3(24) of Regulation (EU) 2018/848.

In accordance with point 1.10.2 of Part II of Annex II to Regulation (EU) 2018/848, these substances may only be used where plants cannot be adequately protected from pests by measures provided for in point 1.10.1 of that Part II, in particular by the use of biological control agents, such as beneficial insects, mites and nematodes complying with the provisions of Regulation (EU) No 1143/2014 of the European Parliament and of the Council¹.

For the purposes of this Annex, active substances are divided into following subcategories:

1. Basic substances

Basic substances listed in Part C of the Annex to Implementing Regulation (EU) No 540/2011 and based on food and from plant or animal origin as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council² may be used for plant protection in organic production. Such basic substances are marked with an asterisk in the table below. They shall be used in accordance with the uses, conditions and restrictions set in the relevant

¹ Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species (OJ L 317, 4.11.2014, p. 35).

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).

review reports³ and taking into account the additional restrictions, if any, in the last column of the table below.

Other basic substances listed in Part C of the Annex to Implementing Regulation (EU) No 540/2011 and not based on food from plant or animal origin may be used for plant protection in organic production only when they are listed in the table below. Such basic substances shall be used in accordance with the uses, conditions and restrictions set in the relevant review reports³ and taking into account the additional restrictions, if any, in the right column of the table below.

Basic substances shall not be used as herbicides.

Number and Part of Annex ⁴	CAS	Name	Specific conditions and limits
1C		Equisetum arvense L.*	
2C	9012-76-4	Chitosan hydrochloride*	obtained from <i>Aspergillus</i> or organic aquaculture or from sustainable fisheries, as defined in Article 2 of Regulation (EU) No 1380/2013 of the European Parliament and of the Council ⁵
3C	57-50-1	Sucrose*	
4C	1305-62-0	Calcium Hydroxide	
5C	90132-02-8	Vinegar*	
6C	8002-43-5	Lecithins*	
7C	-	Salix spp. Cortex*	
8C	57-48-7	Fructose*	
9C	144-55-8	Sodium hydrogen carbonate	
10C	92129-90-3	Whey*	

³ Available in the Pesticides Database: https://ec.europa.eu/food/plant/pesticides/eu-pesticidesdatabase/active-substances/?event=search.as

⁴ Listing according to Implementing Regulation (EU) No 540/2011, numbers and which category: Part A active substances deemed to have been approved under Regulation (EC) No 1107/2009, B, active substances approved under Regulation (EC) No 1107/2009, C basic substances, D low-risk active substances and E candidates for substitution.

⁵ Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354 28.12.2013, p. 22).

11C	7783-28-0	Diammonium phosphate	only in traps
12C	8001-21-6	Sunflower oil*	
14C	84012-40-8 90131-83-2	Urtica spp. (Urtica dioica extract) (Urtica urens extract)*	
15C	7722-84-1	Hydrogen peroxide	
16C	7647-14-5	Sodium chloride	
17C	8029-31-0	Beer*	
18C	-	Mustard seeds powder*	
20C	8002-72-0	Onion oil*	
21C	52-89-1	L-cysteine (E 920)	
22C	8049-98-7	Cow milk*	
23C	-	Allium cepa* L. bulb extract	
		Quassia* extracted from <i>Quassia amara</i> L.	only as insecticide, repellent only if authorised by Member States under Article 53 of Regulation (EC) No 1107/2009
		Other basic substances based on food and from plant or animal origin*	

2. Low risk active substances

Low risk active substances, other than micro-organisms, listed in Part D of the Annex to Implementing Regulation (EU) No 540/2011 may be used for plant protection in organic production when they are listed in the table below or elsewhere in this Annex. Such low risk active substances shall be used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) No 1107/2009 and taking into account the additional restrictions, if any, in the last column of the table below.

Number and Part of Annex ⁶	CAS	Name	Specific conditions and limits
2D		COS-OGA	
3D		Cerevisane and other products based on fragments of cells of micro-	Not from GMO origin

⁶ Listing according to Implementing Regulation (EU) No 540/2011, numbers and which category: Part A active substances deemed to have been approved under Regulation (EC) No 1107/2009, B, active substances approved under Regulation (EC) No 1107/2009, C basic substances, D low-risk active substances and E candidates for substitution.

		organisms	
5D	10045-86-6	Ferric phosphate (iron (III) orthophosphate)	
12D	9008-22-4	Laminarin	Kelp shall be obtained from organic aquaculture or from sustainable fisheries, as defined in Article 2 of Regulation (EU) No 1380/2013

3. Micro-organisms

All micro-organisms listed in Parts A, B and D of the Annex to Implementing Regulation (EU) No 540/2011 may be used in organic production, provided that they are not from GMO origin and only when used in accordance with the uses, conditions and restrictions set in the relevant review reports³. Micro-organisms including viruses are biological control agents that are considered as active substances by Regulation (EC) No 1107/2009.

4. Active substances not included in any of the above categories

The active substances as approved pursuant to Regulation (EC) No 1107/2009 and listed in the table below may be used as plant protection products in organic production only when they are used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) No 1107/2009 and taking into account the additional restrictions, if any, in the right column of the table below.

Number and part of Annex ⁷	CAS	Name	Specific conditions and limits
139A	131929-60-7 131929-63-0	Spinosad	
225A	124-38-9	Carbon dioxide	
227A	74-85-1	Ethylene	only on bananas and potatoes; however, it may also be used on citrus as part of a strategy for the prevention of fruit fly

⁷ Listing according to Implementing Regulation (EU) No 540/2011, numbers and which category: Part A active substances deemed to have been approved under Regulation (EC) No 1107/2009, B, active substances approved under Regulation (EC) No 1107/2009, C basic substances, D low-risk active substances and E candidates for substitution.

			damage
230A	i.a. 67701-09-1	Fatty acids	all uses authorised, except herbicide
231A	8008-99-9	Garlic extract (Allium sativum)	
234A	CAS No not allocated	Hydrolysed proteins excluding gelatine	
	CIPAC No 901		
244A	298-14-6	Potassium hydrogen carbonate	
249A	98999-15-6	Repellents by smell of animal or plant origin/sheep fat	
255A and others		Pheromones and other semiochemicals	only in traps and dispensers
220A	1332-58-7	Aluminium silicate (kaolin)	
236A	61790-53-2	Kieselgur (diatomaceous earth)	
247A	14808-60-7 7637-86-9	Quartz sand	
343A	11141-17-6	Azadirachtin (Margosa extract)	extracted from Neem tree
	84696-25-3		seeds (Azadirachta indica)
240A	8000-29-1	Citronella oil	all uses authorised, except herbicide
241A	84961-50-2	Clove oil	all uses authorised, except herbicide
242A	8002-13-9	Rape seed oil	all uses authorised, except herbicide
243A	8008-79-5	Spearmint oil	all uses authorised, except herbicide
56A	8028-48-6 5989-27-5	Orange oil	all uses authorised, except herbicide
228A	68647-73-4	Tea tree oil	all uses authorised, except herbicide
246A	8003-34-7	Pyrethrins extracted from plants	
292A	7704-34-9	Sulphur	
294A 295A	64742-46-7 72623-86-0 97862-82-3 8042-47-5	Paraffin oils	

345A	1344-81-6	Lime sulphur (calcium polysulphide)	
44B	9050-36-6	Maltodextrin	
45B	97-53-0	Eugenol	
46B	106-24-1	Geraniol	
47B	89-83-8	Thymol	
10E	20427-59-2	Copper hydroxide	in accordance with
10E	1332-65-6 1332-40-7	Copper oxychloride	Implementing Regulation (EU) No 540/2011 only uses
10E	1317-39-1	Copper oxide	- resulting in a total application of maximum 28
10E	8011-63-0	Bordeaux mixture	kg of copper per hectare
10E	12527-76-3	Tribasic copper sulphate	over a period of 7 years may be authorised
40A 5E	52918-63-5 91465-08-6	Pyrethroids (only deltamethrin or lambda-cyhalothrin)	only in traps with specific attractants against <i>Bactrocera oleae</i> and <i>Ceratitis capitata</i>

<u>Annex II</u>

<u>AUTHORISED FERTILISERS, SOIL CONDITIONERS AND NUTRIENTS</u> <u>REFERRED TO IN POINT (b) OF ARTICLE 24(1) OF REGULATION (EU) 2018/848</u>

Fertilisers, soil conditioners and nutrients⁸ listed in this Annex may be used in organic production, provided that they are compliant with

- the relevant Union and national legislations on fertilising products, in particular, where applicable, Regulation (EC) No 2003/2003 and Regulation (EU) 2019/1009; and
- Union legislation on animal by-products, in particular Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011, in particular Annexes V and XI.

In accordance with point 1.9.6 of Part I of Annex II to Regulation (EU) 2018/848, preparations of micro-organisms may be used to improve the overall condition of the soil or to improve the availability of nutrients in the soil or in the crops.

They may only be used according to the specifications and restrictions of use of those respective Union and national legislations. More restrictive conditions for use in organic production are specified in the right column of the tables.

⁸ Covering in particular all the product function categories listed in Part I of Annex I to Regulation (EU) 2019/1009.

Name	
Compound products or products containing only materials listed hereunder	Description, specific conditions and limits
Farmyard manure	product comprising a mixture of animal excrements and vegetable matter (animal bedding and feed material)
	factory farming origin forbidden
Dried farmyard manure and dehydrated poultry manure	factory farming origin forbidden
Composted animal excrements, including poultry manure and composted farmyard manure included	factory farming origin forbidden
Liquid animal excrements	use after controlled fermentation and/or appropriate dilution
	factory farming origin forbidden
Composted or fermented mixture of household waste	product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production
	only vegetable and animal household waste
	only when produced in a closed and monitored collection system, accepted by the Member State
	maximum concentrations in mg/kg of dry matter: cadmium: 0.7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0.4; chromium (total): 70; chromium (VI): not detectable
Peat	use limited to horticulture (market gardening, floriculture, arboriculture, nursery)
Mushroom culture wastes	the initial composition of the substrate shall be limited to products of this Annex
Dejectaofworms(vermicompost) and insect frass- substrate mixture	where relevant in accordance with Regulation (EC) No 1069/2009
Guano	
Composted or fermented mixture of vegetable matter	product obtained from mixtures of vegetable matter, which have been submitted to composting or to anaerobic fermentation for biogas production
Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex	animal by-products (including by-products of wild animals) of category 3 and digestive tract content of category 2 (categories as defined in Regulation (EC) No 1069/2009)

	factory farming origin forbidden
	the processes have to be in accordance with Regulation (EU) No 142/2011
	not to be applied to edible parts of the crop
Products or by-products of animal origin as below: Blood meal Hoof meal Horn meal Bone meal or degelatinised bone meal Fish meal	
Meat meal Feather, hair and skin meal ('chiquette') Wool Fur (1)	(1) Maximum concentration in mg/kg of dry matter of chromium (VI): not detectable
Hair Dairy products Hydrolysed proteins (2)	(2) Not to be applied to edible parts of the crop
Products and by-products of plant origin for fertilisers	e.g.: oilseed cake meal, cocoa husks, malt culms
Hydrolysed proteins of plant origin	
Algae and algae products	 as far as directly obtained by: (i) physical processes including dehydration, freezing and grinding (ii) extraction with water or aqueous acid and/or alkaline solution (iii) fermentation only from organic or sustainable algae production, in accordance with Article 2 of Pagulation (EU) No.
	accordance with Article 2 of Regulation (EU) No 1380/2013 or collection
Sawdust and wood chips	wood not chemically treated after felling
Composted bark	wood not chemically treated after felling
Wood ash	from wood not chemically treated after felling

Soft ground rock phosphate	product obtained by grinding soft mineral phosphates and containing tricalcium phosphate and calcium carbonate as essential ingredients
	minimum content of nutrients (percentage by weight): 25 % P2O5
	 phosphorus expressed as P2O5 soluble in mineral acids, at least 55 % of the declared content of P2O5 being soluble in 2 % formic acid particle size: at least 90 % by weight able to pass through a sieve with a mesh of 0,063 mm
	 at least 99 % by weight able to pass through a sieve with a mesh of 0,125 mm
	until 15 July 2022, cadmium content less than or equal to 90 mg/kg of $P_{2}0_{5}$;
	from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply
Aluminium-calcium phosphate	product obtained in amorphous form by heat treatment and grinding, containing aluminium and calcium phosphates as essential ingredients
	minimum content of nutrients (percentage by weight):
	 30 % P₂O₅ phosphorus expressed as P₂O₅ soluble in mineral acids, at least 75 % of the declared content of P₂O₅ being soluble in alkaline ammonium citrate (Joulie) particle size: at least 90 % by weight able to pass through a sieve with a mesh of 0,160 mm at least 98 % by weight able to pass through a
	sieve with a mesh of 0,630 mm
	until 15 July 2022, cadmium content less than or equal to 90 mg/kg of P_2O_5 ;
	from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply
	use limited to basic soils $(pH > 7,5)$
Basic slag (Thomas phosphates or Thomas slag)	product obtained in iron-smelting by treatment of the phosphorus melts and containing calcium silicophosphates as its essential ingredients
	minimum content of nutrients (percentage by weight): $12 \% P_2O_5$ phosphorus expressed as phosphorus pentoxide soluble in mineral acids, at least 75 % of the declared content of phosphorus pentoxide being soluble in 2 % citric acid or P_2O_5

	 phosphorus expressed as phosphorus pentoxide soluble in 2% citric acid particle size: at least 75 % able to pass through a sieve with a mesh of 0,160 mm at least 96 % able to pass through a sieve with a mesh of 0,630 mm
	from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply
Crude potassium salt	product obtained from crude potassium salts
	minimum content of nutrients (percentage by weight): 9 % K ₂ O potassium expressed as water- soluble K ₂ O 2 % MgO magnesium in the form of water- soluble salts, expressed as magnesium oxide
	from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply
Potassium sulphate, possibly containing magnesium salt	product obtained from crude potassium salt by a physical extraction process, containing possibly also magnesium salts
Stillage and stillage extract	ammonium stillage excluded
Calcium carbonate, for instance: chalk, maerl, ground limestone, Breton ameliorant, (maerl), phosphate chalk	only of natural origin
Mollusc waste	only from organic aquaculture or from sustainable fisheries, in accordance with Article 2 of Regulation (EU) No 1380/2013
Egg shells	factory farming origin forbidden
Magnesium and calcium	only of natural origin
carbonate	e.g. magnesian chalk, ground magnesium, limestone
Magnesium sulphate (kieserite)	only of natural origin
Calcium chloride solution	only for foliar treatment of apple trees, to prevent deficit of calcium
Calcium sulphate (gypsum)	product of natural origin containing calcium sulphate at various degrees of hydration
	minimum content of nutrients (percentage per weight): 25 % CaO 35 % SO ₃ calcium and sulphur expressed as total CaO + SO ₃ fineness of grind:

	at least 80 % to page through a give with a 2
	 at least 80 % to pass through a sieve with a 2 mm mesh width, at least 99 % to pass through a sieve with a 10 mm mesh width
	from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply
Industrial lime from sugar production	by-product of sugar production from sugar beet and sugar cane
Industrial lime from vacuum salt production	by-product of the vacuum salt production from brine found in mountains
Elemental sulphur	until 15 July 2022: as listed in accordance with Part D of Annex I to Regulation (EC) No 2003/2003
	from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply
Inorganic Micronutrient Fertilisers	until 15 July 2022: as listed in accordance with Part E of Annex I to Regulation (EC) No 2003/2003;
	from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply
Sodium chloride	
Stone meal, clays and clay minerals	
Leonardite (Raw organic sediment rich in humic acids)	only if obtained as a by-product of mining activities
Humic and fulvic acids	only if obtained by inorganic salts/solutions excluding ammonium salts; or obtained from drinking water purification
Xylite	only if obtained as a by-product of mining activities (e.g. by-product of brown coal mining)
Chitin (Polysaccharide obtained from the shell of crustaceans)	obtained from organic aquaculture or from sustainable fisheries, in accordance with Article 2 of Regulation (EU) No 1380/2013
Organic ⁹ rich sediment from fresh water bodies formed under exclusion of oxygen	only organic sediments that are by-products of fresh water body management or extracted from former freshwater areas
(e.g. sapropel)	when applicable, extraction should be done in a way to cause minimal impact on the aquatic system
	only sediments derived from sources free from contaminations of pesticides, persistent organic pollutants and petrol like substances

⁹ Here 'organic' is used in the sense of organic chemistry, not organic farming

	until 15 July 2022: maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable
	from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply
Biochar - pyrolysis product made from a wide variety of	only from plant materials, when treated after harvest only with products included in Annex I
organic materials of plant origin and applied as a soil conditioner	until 15 July 2022: maximum value of 4 mg polycyclic aromatic hydro-carbons (PAHs) per kg dry matter (DM)
	from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply

Annex III

AUTHORISED PRODUCTS AND SUBSTANCES FOR USE AS FEED OR IN FEED PRODUCTION

Part A: Authorised non-organic feed material of plant, algal, animal or yeast origin or feed material of microbial or mineral origin referred to in point (c) of Article 24(1) of Regulation (EU) 2018/848

(1) FEED MATERIALS OF MINERAL ORIGIN

Number in feed catalogue ¹⁰	Name	Specific conditions and limits
11.1.1	Calcium carbonate	
11.1.2	Calcareous marine shells	
11.1.4	Maerl	
11.1.5	Lithotamnium	
11.1.13	Calcium gluconate	
11.2.1	Magnesium oxide	
11.2.4	Magnesium sulphate anhydrous	
11.2.6	Magnesium chloride	
11.2.7	Magnesium carbonate	
11.3.1	Dicalcium phosphate	
11.3.3	Monocalcium phosphate	
11.3.5	Calcium-magnesium phosphate	
11.3.8	Magnesium phosphate	
11.3.10	Monosodium phosphate	
11.3.16	Calcium sodium phosphate	
11.3.17	Monoammonium phosphate (Ammonium dihydrogen orthophosphate)	only for aquaculture
11.4.1	Sodium chloride	
11.4.2	Sodium bicarbonate	
11.4.4	Sodium carbonate	
11.4.6	Sodium sulphate	
11.5.1	Potassium chloride	

¹⁰ In accordance with Commission Regulation (EU) No 68/2013 of 16 January on the Catalogue of feed materials (OJ L29, 30.1.2013, p. 1).

(2) OTHER FEED MATERIALS

	Number In feed catalogue	Name	Specific conditions and limits	
1	0	Meal, oil and other feed materials of fish, mollusc or crustacean origin	provided that they are obtained from fisheries that have been certified as sustainable under a scheme recognised by the competent authority in line with the principles laid down in Regulation (EU) No 1380/2013 provided that they are produced or prepared without chemically synthesised solvents their use is authorised only to non-herbivores livestock the use of fish protein hydrolysate is authorised only for	
			young non-herbivores livestock	
1	0	Meal, oil and other feed materials of fish, mollusc or crustacean origin	for carnivorous aquaculture animals from fisheries that have been certified as sustainable under a scheme recognised by the competent authority in line with the principles laid down in Regulation (EU) No 1380/2013, in accordance with point 3.1.3.1(c) of Part III of Annex II to Regulation (EU) 2018/848 derived from trimmings of fish, crustaceans or molluscs already caught for human consumption in accordance with point 3.1.3.3(c) of Part III of Annex II to Regulation (EU) 2018/848, or derived from whole fish, crustaceans or molluscs caught and not used for human consumption in accordance with point 3.1.3.3(d) of Part III of Annex II to Regulation (EU) 2018/848	
1	0	Fishmeal and fish oil	in the grow-out phase, for fish in inland waters, penaeid shrimps and freshwater prawns and tropical freshwater fish from fisheries that have been certified as sustainable under a scheme recognised by the competent authority in line with the principles laid down in Regulation (EU) No 1380/2013, in accordance with point 3.1.3.1(c) of Part III of Annex II to Regulation (EU) 2018/848 only where natural feed in ponds and lake is not available in sufficient quantities, maximum 25 % of fishmeal and 10 % of fish oil in the feed ration of penaeid shrimps and freshwater prawns (<i>Macrobrachium</i> spp.) and maximum 10 % of fishmeal or fish oil in the feed ration of simsa catfish (<i>Pangasius</i> spp.), in accordance with point 3.1.3.4 (c)(i) and (ii) of Part III of Annex II to Regulation (EU) 2018/848	

¹¹ In accordance with Regulation (EU) No 68/2013.

ex 12.1.5	Yeasts	yeast obtained from <i>Saccharomyces cerevisiae or</i> <i>Saccharomyces carlsbergensis,</i> inactivated resulting in absence of live micro-organisms when not available from organic production	
ex 12.1.12	Yeast products	fermentation product obtained from <i>Saccharomyces</i> <i>cerevisiae</i> , <i>Saccharomyces carlsbergensis</i> , inactivated resulting in absence of live micro-organisms containing yeast parts	
		when not available from organic production product obtained from wool grease (lanolin) by saponification, separations and crystallisation, from shellfish or other sources	
	Cholesterol	to secure the quantitative dietary needs of penaeid shrimps and freshwater prawns (<i>Macrobrachium</i> spp.) in the grow- out stage and in earlier life stages in nurseries and hatcheries when not available from organic production	
	Herbs	in accordance with point (e)(iv) of Article 24(3) of Regulation (EU) 2018/848, in particular: - when not available in organic form - produced/prepared without chemical solvents - maximum 1 % in the feed ration	
	Molasses	 in accordance with point (e)(iv) of Article 24(3) of Regulation (EU) 2018/848, in particular: when not available in organic form produced/prepared without chemical solvents maximum 1 % in the feed ration 	
	Phytoplankt on and zooplankton	only in the larval rearing of organic juveniles	
	specific protein compounds	 In accordance with point 1.9.3.1 (c) and 1.9.4.2 (c) of Regulation (EU) 2018/848, in particular: until 31 December 2026, when not available in organic form, produced/prepared without chemical solvents, for feeding piglets of up to 35 kg or young poultry, maximum 5 % of the dry matter of feed from agricultural origin per period of 12 months 	
	Spices	 in accordance with point (e)(iv) of Article 24(3) of Regulation (EU) 2018/848, in particular: when not available in organic form produced/prepared without chemical solvents maximum 1 % in the feed ration 	

Part B: Authorised feed additives and processing aids used in animal nutrition referred to in point (d) of Article 24(1) of Regulation (EU) 2018/848

Feed additives listed in this Part must be authorised under Regulation (EC) No 1831/2003.

The specific conditions set out here are to be applied in addition to the conditions of the authorisations under Regulation (EC) No 1831/2003.

(1) TECHNOLOGICAL ADDITIVES

ID number or functional group	Name	Specific conditions and limits
E 200	Sorbic acid	
E 236	Formic acid	
E 237	Sodium formate	
E 260	Acetic acid	
E 270	Lactic acid	
E 280	Propionic acid	
E 330	Citric acid	

(a) Preservatives

(b) Antioxidants

ID number or functional group	Name	Specific conditions and limits
1b306(i)	Tocopherol extracts from vegetable oils	
1b306(ii)	Tocopherol-rich extracts from vegetable oils (delta rich)	

ID number or functional group	Name	Specific conditions and limits
1c322, 1c322i	Lecithins	only when derived from organic raw material use restricted to aquaculture animal feed

(c) Emulsifiers, stabilisers, thickeners and gelling agents

(d) Binders and anti-caking agents

ID number or functional group	Name	Specific conditions and limits
E 412	Guar gum	
E 535	Sodium ferrocyanide	maximum content: 20 mg/kg NaCl calculated as ferrocyanide anion
E 551b	Colloidal silica	
E 551c	Kieselgur (diatomaceous earth, purified)	
1m558i	Bentonite	
E 559	Kaolinitic clays, free of asbestos	
E 560	Natural mixtures of steatites and chlorite	
E 561	Vermiculite	
E 562	Sepiolite	
E 566	Natrolite-Phonolite	
1g568	Clinoptilolite of sedimentary origin	
E 599	Perlite	

(e) Silage additives

ID number or functional group	Name	Specific conditions and limits
1k	Enzymes, micro-organisms	
1k236	Formic acid	only authorised to ensure adequate
1k237	Sodium formate	fermentation
1k280	Propionic acid	
1k281	Sodium propionate	

(2) SENSORY ADDITIVES

ID number or functional group	Name	Specific conditions and limits
ex2a	Astaxanthin	only when derived from organic sources, such as organic crustacean shells
		only in the feed ration for salmon and trout within the limit of their physiological needs
		if no astaxanthin derived from organic sources are available, astaxanthin from natural sources may be used such as Astaxanthin-rich <i>Phaffia rhodozyma</i>
ex2b	Flavouring compounds	only extracts from agricultural products, including Chestnut extract (<i>Castanea</i> <i>sativa</i> Mill.)

(3) NUTRITIONAL ADDITIVES

(a) Vitamins, pro-vitamins and chemically well-defined substances having similar effect

ID number or functional group	Name		Specific conditions and limits
ex3a	Vitamins Provitamins	and	derived from agricultural products if not available from agricultural products:

		 derived synthetically, only those identical to vitamins derived from agricultural products may be used for monogastric animals and aquaculture animals derived synthetically, only vitamins A, D and E identical to vitamins derived from agricultural products may be used for ruminants; the use is subject to prior authorisation of the Member States based on the assessment of the possibility for organic ruminants to obtain the necessary quantities of the said vitamins through their feed rations
3a920	Betaine anhydrous	only for monogastric animals from organic production; if not available, from natural origin

(b) Compounds of trace elements

ID number or functional group	Name	Specific conditions and limits
3b101	Iron(II) carbonate (siderite)	
3b103	Iron(II) sulphate monohydrate	
3b104	Iron(II) sulphate heptahydrate	
3b201	Potassium iodide	
3b202	Calcium iodate, anhydrous	
3b203	Coated granulated calcium iodate anhydrous	
3b301	Cobalt(II) acetate tetrahydrate	
3b302	Cobalt(II) carbonate	
3b303	Cobalt(II) carbonate hydroxide (2:3) monohydrate	
3b304	Coated granulated cobalt(II) carbonate	
3b305	Cobalt(II) sulphate heptahydrate	
3b402	Copper(II) carbonate dihydroxy monohydrate	
3b404	Copper (II) oxide	
3b405	Copper(II) sulphate pentahydrate	
3b409	Dicopper chloride trihydroxide	
3b502	Manganese (II) oxide	

3b503	Manganous sulfate, monohydrate	
3b603	Zinc oxide	
3b604	Zinc sulphate heptahydrate	
3b605	Zinc sulphate monohydrate	
3b609	Zinc chloride hydroxide monohydrate	
3b701	Sodium molybdate dihydrate	
3b801	Sodium selenite	
3b802	Coated granulated sodium selenite	
3b803	Sodium selenate	
3b810, 3b811, 3b8.12, 3b813 and 3b817	Selenised yeast inactivated a.o.	

(c) Amino acids, their salts and analogues

ID number or functional group	Name	Specific conditions and limits
3c3.5.1 and 3c352	L-histidine monohydrochloride monohydrate	produced through fermentation may be used in the feed ration for salmonids when the feed sources listed in point 3.1.3.3 of Part II of Annex II to Regulation (EU) 2018/848, do not provide a sufficient amount of histidine to meet the dietary needs of the fish

(4) ZOOTECHNICAL ADDITIVES

ID number or functional group	Name	Specific conditions and limits
4a, 4b, 4c and 4d	Enzymes and microorganism	

Annex IV

AUTHORISED PRODUCTS FOR CLEANING AND DISINFECTION REFERRED TO IN POINTS (e), (f) AND (g) OF ARTICLE 24(1) OF REGULATION (EU) 2018/848

Part A

Products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production

Part B

Products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding

Part C

Products for cleaning and disinfection in processing and storage facilities

Part D

Products referred to in Article 12(1) of Regulation (EU) 2018/848

The following products or products containing the following active substances as listed in Annex VII to Regulation (EC) No 889/2008 cannot be used as biocidal products:

- caustic soda;
- caustic potash;
- oxalic acid;
- natural essences of plants;
- nitric acid;
- phosporic acid;
- nitric acid;
- phosporic acid;
- sodium carbonate;
- copper sulphate;
- potassium permanganate;
- tea seed cake made of natural camelia seed;
- humic acid;
- peroxyacetic acids.

EN

Annex V

<u>AUTHORISED PRODUCTS AND SUBSTANCES FOR USE IN THE PRODUCTION</u> <u>OF PROCESSED ORGANIC FOOD AND OF YEAST USED AS FOOD OR FEED</u>

Part A: Authorised food additives and processing aids referred to in point (a) of Article 24(2) of Regulation (EU) 2018/848

SECTION A1 — FOOD ADDITIVES, INCLUDING CARRIERS

The organic foodstuffs to which food additives may be added are within the limit of authorisations given in accordance with Regulation (EC) No 1333/2008.

The specific conditions and restrictions set out here are to be applied in addition to the conditions of the authorisations under Regulation (EC) No 1333/2008.

For the purpose of the calculation of the percentages referred to in Article 30(5) of Regulation (EU) 2018/848, food additives marked with an asterisk in the column of the code number shall be calculated as ingredients of agricultural origin.

Code	Name	Organic foodstuffs to which it may be added	Specific conditions and limits
E 153	Vegetable carbon	edible cheese rind of ashy goat cheese	
		Morbier cheese	
E 160b(i)*	Annatto bixin	Red Leicester cheese	
		Double Gloucester cheese	
		Cheddar	
		Mimolette cheese	
E 160b(ii)*	Annatto	Red Leicester cheese	
	norbixin	Double Gloucester cheese	
		Cheddar	
		Mimolette cheese	
E 170	Calcium carbonate	products of plant and animal origin	shall not be used for colouring or calcium enrichment of products
E 220	Sulphur dioxide	fruit wines (wine made from fruits other than grapes, including cider and perry) and mead with and without added sugar	100 mg/l (maximum levels available from all sources, expressed as SO ₂ in mg/l)
E 223	Sodium	crustaceans	

	metabisulphite		
E 224	Potassium metabisulphite	fruit wines (wine made from fruits other than grapes, including cider and perry) and mead with and without added sugar	100 mg/l (maximum levels available from all sources, expressed as SO ₂ in mg/l)
E250	Sodium nitrite	meat products	may only be used, if it has been demonstrated to the satisfaction of the competent authority that no technological alternative, giving the same guarantees and/or allowing to maintain the specific features of the product, is available
			not in combination with E252
			maximum ingoing amount expressed as NaNO ₂ : 80 mg/kg, maximum residual amount expressed as NaNO ₂ : 50 mg/kg
E252	Potassium nitrate	meat products	may only be used, if it has been demonstrated to the satisfaction of the competent authority that no technological alternative, giving the same guarantees and/or allowing to maintain the specific features of the product, is available
			not in combination with E250
			maximum ingoing amount expressed as NaNO ₃ : 80 mg/kg, maximum residual amount expressed as NaNO ₃ : 50 mg/kg
E 270	Lactic acid	products of plant and animal origin	
E 290	Carbon dioxide	products of plant and animal origin	
E 296	Malic acid	products of plant origin	
E 300	Ascorbic acid	products of plant origin meat products	
E 301	Sodium ascorbate	meat products	may only be used in connection with nitrates and nitrites

E 306*	Tocopherol- rich	products of plant and animal origin	antioxidant
E 222*	extract		
E 322*	Lecithins	products of plant origin milk products	only from organic production
E 325	Sodium lactate	products of plant origin milk-based and meat products	
E 330	Citric acid	products of plant and animal origin	
E 331	Sodium citrates	products of plant and animal origin	
E 333	Calcium citrates	products of plant origin	
E 334	Tartaric acid	products of plant origin	
	(L(+)-)	mead	
E 335	Sodium tartrates	products of plant origin	
E 336	Potassium tartrates	products of plant origin	
E 341(i)	Monocalcium phosphate	self-raising flour	raising agent
E 392*	Extracts of Rosemary	products of plant and animal origin	only from organic production
E 400	Alginic acid	products of plant origin	
		milk products	
E 401	Sodium	products of plant origin	
	alginate	milk products	
		sausages based on meat	
E 402	Potassium	products of plant origin	
	alginate	milk-based products	
E 406	Agar	products of plant origin	
		milk-based products and meat products	
E 407	Carrageenan	products of plant origin	

		milk-based products	
E 410*	Locust bean gum	products of plant and animal origin	only from organic production
E 412*	Guar gum	products of plant and animal origin	only from organic production
E 414*	Arabic gum	products of plant and animal origin	only from organic production
E 415	Xanthan gum	products of plant and animal origin	
E 417	Tara gum	products of plant and animal origin	thickener only from organic production
E 418	Gellan gum	products of plant and	high-acyl form only
		animal origin	only from organic production
E 422	Glycerol	plant extracts	only from plant origin
		flavourings	solvent and carrier in plant extracts and flavourings
			humectant in gel capsules
			surface coating of tablets
			only from organic production
E 440(i)*	Pectin	products of plant origin	
		milk-based products	
E 460	Cellulose	gelatine	
E 464	Hydroxypropyl methyl cellulose	products of plant and animal origin	encapsulation material for capsules
E 500	Sodium carbonates	products of plant and animal origin	
E 501	Potassium carbonates	products of plant origin	
E 503	Ammonium carbonates	products of plant origin	
E 504	Magnesium carbonates	products of plant origin	
E 509	Calcium chloride	Milk-based products	coagulation agent

E 516	Calcium sulphate	products of plant origin	carrier
E 524	Sodium	'Laugengebäck'	surface treatment
	hydroxide	flavourings	acidity regulator
E 551	Silicon dioxide	herbs and spices in dried powdered form,	
		flavourings	
		propolis	
E 553b	Talc	sausages based on meat	surface treatment
E 901	Beeswax	confectionery	glazing agent
			only from organic production
E 903	Carnauba wax	confectionery	glazing agent
		citrus fruit	mitigating method for mandatory extreme cold treatment of fruit as a mandatory quarantine measure against harmful organisms in accordance with Commission Implementing Directive (EU) 2017/1279 ¹²
			only from organic production
E 938	Argon	products of plant and animal origin	
E 939	Helium	products of plant and animal origin	
E 941	Nitrogen	products of plant and animal origin	
E 948	Oxygen	products of plant and animal origin	
E 968	Erythritol	products of plant and animal origin	only from organic production without using ion exchange technology

¹² Commission Implementing Directive (EU) 2017/1279 of 14 July 2017 amending Annexes I to V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 184, 15.7.2017, p. 33).

SECTION A2 — PROCESSING AIDS AND OTHER PRODUCTS, WHICH MAY BE USED FOR PROCESSING OF INGREDIENTS OF AGRICULTURAL ORIGIN FROM ORGANIC PRODUCTION

The specific conditions and restrictions set out here are to be applied in addition to the conditions of the authorisations under Regulation (EC) No 1333/2008.

Name	Only authorised for the processing of the following organic foodstuffs	Specific conditions and limits
Water	products of plant and animal origin	drinking water within the meaning of Council Directive 98/83/EC ¹³
Calcium chloride	products of plant origin sausages based on meat	coagulation agent
Calcium carbonate	products of plant origin	
Calcium hydroxide	products of plant origin	
Calcium sulfate	products of plant origin	coagulation agent
Magnesium chloride (or nigari)	products of plant origin	coagulation agent
Potassium carbonate	Grapes	drying agent
Sodium carbonate	products of plant and animal origin	
Lactic acid	Cheese	for the regulation of the pH of the brine bath in cheese production
L(+)lactic acid from fermentation	plant protein extracts	
Citric acid	products of plant and animal origin	
Sodium hydroxide	Sugar(s)	
	oil from plant origin excluding olive oil	
	plant protein extracts	
Sulphuric acid	gelatine	
	sugar(s)	

¹³ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).

Hop extract	sugar	only for antimicrobial purposes
		from organic production, if available
Pine rosin extract	sugar	only for antimicrobial purposes
		from organic production, if available
Hydrochloric acid	gelatine Gouda-, Edam and Maasdammer cheeses,	gelatine production in compliance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ¹⁴
	Boerenkaas, Friese and Leidse Nagelkaas	for the regulation of the pH of the brine bath in the processing of cheeses
Ammonium hydroxide	Gelatine	gelatine production in compliance with Regulation (EC) No 853/2004
Hydrogen peroxide	Gelatine	gelatine production in compliance with Regulation (EC) No 853/2004
Carbon dioxide	products of plant and animal origin	
Nitrogen	products of plant and animal origin	
Ethanol	products of plant and animal origin	solvent
Tannic acid	products of plant origin	filtration aid
Egg white albumin	products of plant origin	
Casein	products of plant origin	
Gelatin	products of plant origin	
Isinglass	products of plant origin	
Vegetable oils	products of plant and animal origin	greasing, releasing or antifoaming agent only from organic production
Silicon dioxide gel or colloidal solution	products of plant origin	
Activated carbon	products of plant and	
(CAS-7440-44-0)	animal origin	
Talc	products of plant origin	in compliance with the specific purity criteria for food additive E 553b
Bentonite	products of plant origin	sticking agent for mead
	mead	
Cellulose	products of plant origin	

¹⁴ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)

	gelatine	
Diatomaceous earth	products of plant origin	
	gelatine	
Perlite	products of plant origin	
	gelatine	
Hazelnut shells	products of plant origin	
Rice meal	products of plant origin	
Beeswax	products of plant origin	releasing agent
		only from organic production
Carnauba wax	products of plant origin	releasing agent
		only from organic production
Acetic acid/vinegar	products of plant origin;	only from organic production
		from natural fermentation
	fish	
Thiamin hydrochloride	fruit wines, cider, perry and mead	
Diammonium phosphate	fruit wines, cider, perry and mead	
Wood fibre	products of plant and animal origin	the source of timber should be restricted to certified, sustainably harvested wood
		wood used must not contain toxic components (post-harvest treatment, naturally occurring toxins or toxins from micro-organisms)

Part B: Authorised non-organic agricultural ingredients to be used for the production of processed organic food referred to in point (b) of Article 24(2) of Regulation (EU) 2018/848

Name	Specific conditions and limits
Algae Arame (<i>Eisenia bicyclis</i>), unprocessed as well as products of first-stage processing directly related to these products.	
Algae Hijiki (<i>Hizikia fusiforme</i>), unprocessed as well as products of first-stage processing directly related to these products.	

Bark of the Pau d'arco tree Handroanthus impetiginosus ('lapacho')	5	
Casings	from natural raw materials of animal or from plant origin material	
Gelatin	from other sources than porcine	
Milk mineral powder/liquid	only when used for its sensory function to replace wholly or partly sodium chloride	
Wild fishes and wild aquatic animals, unprocessed as well as products derived therefrom by processes.	only from fisheries that have been certified as sustainable under a scheme recognised by the competent authority in line with the principles laid down in Regulation (EU) No 1380/2013, in accordance with point 3.1.3.1(c) of Part III of Annex II to Regulation (EU) 2018/848 only when not available in organic aquaculture	

Part C: Authorised processing aids and other products for the production of yeast and yeast products referred to in point (c) of Article 24(2) of Regulation (EU) 2018/848

Name	Primary yeast	Yeast production/ confection/ formulation	Specific conditions and limits
Calcium chloride	X		
Carbon dioxide	X	Х	
Citric acid	X		for the regulation of the pH in yeast production
Lactic acid	X		for the regulation of the pH in yeast production
Nitrogen	X	Х	
Oxygen	X	Х	
Potato starch	X	X	for filtering only from organic production
Sodium carbonate	X	Х	for the regulation of the pH
Vegetable oils	X	X	greasing, releasing or anti- foaming agent only from organic production

Part D: Authorised products and substances for the production and conservation of organic grapevine products of the wine sector referred to in point 2.2. of Part VI of Annex II to Regulation (EU) 2018/848

Name	ID numbers	References in Annex I to Delegated Regulation (EU) 2019/934	Specific conditions and limits
Air		Part A, Table 1, points 1 and 8	
Gaseous oxygen	E 948	Part A, Table 1, point 1	
	CAS 17778- 80-2	Part A, Table 2, point 8.4	
Argon	E 938	Part A, Table 1, point 4	may not be used for
	CAS 7440- 37-1	Part A, Table 2, point 8.1	bubbling
Nitrogen	E 941	Part A, Table 1, points 4,	
	CAS 7727-	7 and 8	
	37-9	Part A, Table 2, point 8.2	
Carbon dioxide	E 290	Part A, Table 1, points 4 and 8	
	CAS 124-38- 9	Part A, Table 2, point 8.3	
Pieces of oak	-	Part A, Table 1, point 11	
wood			
Tartaric acid	E 334	Part A, Table 2, point 1.1	
(L(+)-)	CAS 87-69-4		
Lactic acid	E 270	Part A, Table 2, point 1.3	
Potassium L(+)-	E 336(ii)	Part A, Table 2, point 1.4	
tartrate	CAS 921- 53- 9		
Potassium bicarbonate	E 501(ii)	Part A, Table 2, point 1.5	
	CAS 298- 14- 6		
Calcium carbonate	E 170	Part A, Table 2, point 1.6	
	CAS 471-34- 1		
Calcium sulphate	E 516	Part A, Table 2, point 1.8	
Sulphur dioxide	E 220	Part A, Table 2, point 2.1	the maximum sulphur
	CAS 7446- 09-5		dioxide content shall not exceed 100 milligrams per

Potassium	E 228	Part A, Table 2, point 2.2	litre for red wines as
bisulphite	CAS 7773- 03-7		referred to in point A.1.(a) of Part B of Annex I to Delegated Regulation (FII)
Potassium metabisulphite	E 224 CAS 16731- 55-8	Part A, Table 2, point 2.3	Delegated Regulation (EU) 2019/934 and with a residual sugar level lower than 2 grams per litre the maximum sulphur dioxide content shall not exceed 150 milligrams per litre for white and rosé wines as referred to in point A.1.(b) of Part B of Annex I to Delegated Regulation (EU) 2019/934 and with a residual sugar level lower than 2 grams per litre for all other wines, the maximum sulphur dioxide content applied in accordance with Part B of Annex I to Delegated Regulation (EU) 2019/934 shall be reduced by 30
L ascorbic acid	E 300	Part A, Table 2, point 2.6	milligrams per litre
Charcoal for oenological use		Part A, Table 2, point 3.1	
Diammonium hydrogen phosphate	E 342/CAS 7783-28-0	Part A, Table 2, point 4.2	
Thiamine hydrochloride	CAS 67-03-8	Part A, Table 2, point 4.5	
Yeast autolysates		Part A, Table 2, point 4.6	
Yeast cell walls		Part A, Table 2, point 4.7	
Inactivated yeasts		Part A, Table 2, point 4.8	
		Part A, Table 2, point 10.5	
		Part A, Table 2, point 11.5	
Edible gelatine	CAS 9000- 70-8	Part A, Table 2, point 5.1	derived from organic raw material if available

Wheat protein		Part A, Table 2, point 5.2	derived from organic raw material if available
Peas protein		Part A, Table 2, point 5.3	derived from organic raw material if available
Potatoes protein		Part A, Table 2, point 5.4	derived from organic raw material if available
Isinglass		Part A, Table 2, point 5.5	derived from organic raw material if available
Casein	CAS 9005- 43-0	Part A, Table 2, point 5.6	derived from organic raw material if available
Potassium caseinates	CAS 68131- 54-4	Part A, Table 2, point 5.7	
Egg albumin	CAS 9006- 59-1	Part A, Table 2, point 5.8	derived from organic raw material if available
Bentonite	E 558	Part A, Table 2, point 5.9	
Silicon dioxide (gel or colloidal solution)	E 551	Part A, Table 2, point 5.10	
Tannins		Part A, Table 2, point 5.12	derived from organic raw material if available
		Part A, Table 2, point 6.4	
Chitosan derived from Aspergillus	CAS 9012- 76-4	Part A, Table 2, point 5.13	
niger		Part A, Table 2, point 10.3	
Yeast protein extracts		Part A, Table 2, point 5.15	derived from organic raw material if available
Potassium alginate	E 402/CAS 9005-36-1	Part A, Table 2, point 5.18	
Potassium hydrogen tartrate	E336(i)/CAS 868-14-4	Part A, Table 2, point 6.1	
Citric acid	E 330	Part A, Table 2, point 6.3	
Metatartaric acid	E 353	Part A, Table 2, point 6.7	
Gum arabic	E 414/CAS 9000-01-5	Part A, Table 2, point 6.8	derived from organic raw material if available
Yeast mannoproteins		Part A, Table 2, point 6.10	
Pectin lyases	EC 4.2.2.10	Part A, Table 2, point 7.2	only for oenological purposes in clarification

Pectin methylesterase	EC 3.1.1.11	Part A, Table 2, point 7.3	only for oenological purposes in clarification
Polygalacturonase	EC 3.2.1.15	Part A, Table 2, point 7.4	only for oenological purposes in clarification
Hemicellulase	EC 3.2.1.78	Part A, Table 2, point 7.5	only for oenological purposes in clarification
Cellulase	EC 3.2.1.4	Part A, Table 2, point 7.6	only for oenological purposes in clarification
Yeasts for wine production		Part A, Table 2, point 9.1	organic if available
Lactic acid bacteria		Part A, Table 2, point 9.2	
Copper citrate	CAS 866-82- 0	Part A, Table 2, point 10.2	
Aleppo pine resin		Part A, Table 2, point 11.1	
Fresh lees		Part A, Table 2, point 11.2	only from organic production

Annex VI

PRODUCTS AND SUBSTANCES AUTHORISED FOR USE IN ORGANIC PRODUCTION IN CERTAIN AREAS OF THIRD COUNTRIES PURSUANT TO ARTICLE 45(2) OF REGULATION (EU) 2018/848