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

of XXX

amending and correcting Implementing Regulation (EU) 2021/1165 authorising certain products and substances for use in organic production and establishing their lists

(Text with EEA relevance)

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

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

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007¹, and in particular Article 24(9) thereof,

Whereas:

- (1) Article 45(2) of Regulation (EU) 2018/848 empowers the Commission to grant specific authorisations for the use of products and substances in organic products originating from third countries and the outermost regions of the Union that are to be placed on the market in the Union. Article 10 of Commission Implementing Regulation (EU) 2021/1165², sets out the procedure for granting such authorisations, but only in relation to third countries. It is therefore necessary to provide for the procedure for granting specific authorisations for the use of products and substances in organic products originating from the outermost regions of the Union. For reasons of clarity, the list of products and substances authorised in the outermost regions of the Union, once available, should be added in Annex VI to Implementing Regulation (EU) 2021/1165.
- (2) Commission Implementing Regulation (EU) 540/2011³ has been amended following the re-assessment of the active substances lavandulyl senecioate⁴, potassium hydrogen carbonate⁵, straight chain lepidopteran pheromones (acetates)⁶, sheep fat⁷ and quartz

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¹ OJ L 150, 14.6.2018, p. 1, ELI: <http://data.europa.eu/eli/reg/2018/848/oj>.

² Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists (OJ L 253, 16.7.2021, p. 13, ELI: http://data.europa.eu/eli/reg_impl/2021/1165/oj).

³ 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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

⁴ Commission Implementing Regulation (EU) 2020/646 of 13 May 2020 approving the active substance Lavandulyl senecioate as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 151, 14.5.2020, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2020/646/oj).

⁵ Commission Implementing Regulation (EU) 2021/1452 of 3 September 2021 renewing the approval of the active substance potassium hydrogen carbonate as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing

sand⁸. In order to reflect these amendments, the entries for potassium hydrogen carbonate, sheep fat and quartz sand should be removed from point 4 of Annex I to Implementing Regulation (EU) 2021/1165 and the entries for lavandulyl senecioate, potassium hydrogen carbonate, straight chain lepidopteran pheromones (acetates), sheep fat and quartz sand should be included in point 2 of that Annex, which lists low-risk active substances.

- (3) In accordance with the procedure provided for in Article 24(7) of Regulation (EU) 2018/848, Member States have submitted dossiers on certain substances to the other Member States and the Commission, in view of their authorisation and inclusion in Annexes I, II, III and V to Implementing Regulation (EU) 2021/1165. Those dossiers have been examined by the Expert Group for Technical Advice on Organic Production ('EGTOP') and the Commission.
- (4) Based on the recent assessment of straight chain lepidopteran pheromones in Commission Implementing Regulation (EU) 2022/1251⁹ and the guidance document on semio-chemicals¹⁰, pheromones and other semio-chemicals are applied via traps or dispensers, whether active or passive. Moreover, Article 24(3), point (c)(ii), of Regulation (EU) 2018/848 sets restrictions on the nature of the products that may be applied directly on the edible parts of the crops, and in the case of semio-chemicals, traps and dispensers are to prevent contact with the crop pursuant to Part I, point 1.10.3, of Annex II to that Regulation. It is therefore appropriate to remove the condition that pheromones and other semio-chemicals are to be used only in traps and dispensers in the table entry for 'pheromones and other semio-chemicals' in point 4 of Annex I to Implementing Regulation (EU) 2021/1165.
- (5) In accordance with Annex II to Implementing Regulation (EU) 2021/1165, products and by-products of plant origin may be used as fertilisers in organic production, but

Regulation (EU) No 540/2011 (OJ L 313, 6.9.2021, p. 30, ELI: http://data.europa.eu/eli/reg_impl/2021/1452/oj).

⁶ Commission Implementing Regulation (EU) 2022/1251 of 19 July 2022 renewing the approval of the active substances Straight Chain Lepidopteran Pheromones (acetates) as low-risk active substances, and Straight Chain Lepidopteran Pheromones (aldehydes and alcohols) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 191, 20.7.2022, p. 35, ELI: http://data.europa.eu/eli/reg_impl/2022/1251/oj).

⁷ Commission Implementing Regulation (EU) 2022/1474 of 6 September 2022 renewing the approval of the low-risk active substance sheep fat in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 232, 7.9.2022, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2022/1474/oj).

⁸ Commission Implementing Regulation (EU) 2023/1488 of 6 July 2023 renewing the approval of the low-risk active substance quartz sand in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 183, 20.7.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/1488/oj).

⁹ Commission Implementing Regulation (EU) 2022/1251 of 19 July 2022 renewing the approval of the active substances Straight Chain Lepidopteran Pheromones (acetates) as low-risk active substances, and Straight Chain Lepidopteran Pheromones (aldehydes and alcohols) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 191, 20.7.2022, p. 35, ELI: http://data.europa.eu/eli/reg_impl/2022/1251/oj).

¹⁰ European Commission: Directorate-General for Health and Food Safety, 'Guidance document on semiochemical active substances and plant protection products', SANTE/12815/2014 rev. 11, January 2024, https://food.ec.europa.eu/document/download/ae787d28-356b-4e42-8c15-89ed8c91faf2_en?filename=pesticides_ppp_app-proc_guide_doss_semiochemicals_202401.pdf.

also as soil conditioners and nutrients under that Annex. The entry ‘products and by-products of plant origin for fertilisers’ should therefore be clarified and adapted accordingly.

- (6) Based on recommendations from EGTOP regarding greenhouses¹¹ and fertilisers¹², the entry concerning stone meal, clays and clay minerals in Annex II to Implementing Regulation (EU) 2021/1165 should be amended by adding further products. In addition, since stone meal, clays and clay minerals may be used as an inert medium in sprouted seeds production, such use should be included in that entry in accordance with the specific conditions set out in Part I, point 1.3(a), of Annex II to Regulation (EU) 2018/848.
- (7) Based on recommendations from EGTOP regarding greenhouses and fertilisers¹³, the use of carbon dioxide should be allowed as a nutrient for the enrichment of water for algae production in closed systems on land, and the substance should be of food grade to avoid any contamination of water. Moreover, EGTOP has assessed and concluded positively on the use of carbon dioxide in organic greenhouse production¹⁴. It is therefore appropriate to add an entry for carbon dioxide in Annex II to Implementing Regulation (EU) 2021/1165.
- (8) Based on recommendations from EGTOP regarding fertilisers¹⁵, the use of calcium acetate should be authorised but only for foliar application on vegetables in greenhouses and on apple trees to prevent deficiency in calcium. Based on those recommendations, also the use of calcium phosphate should be authorised in organic production but only when derived from sewage sludge ash and only when contained in products complying with the requirements of Regulation (EU) 2019/1009 of the European Parliament and of the Council¹⁶. Annex II to Implementing Regulation (EU) 2021/1165 should therefore be amended accordingly.

¹¹ EGTOP, ‘Final report on Greenhouses’, 19 June 2016, https://agriculture.ec.europa.eu/document/download/7ae7f682-cf88-4c1e-8686-afd5617ec7ae_en?filename=final-report-etop-greenhouse-production.pdf.

¹² EGTOP, ‘Final report on Plant Protection (X) and Fertilisers (VII)’, 3 May 2024, https://agriculture.ec.europa.eu/document/download/57c18571-67ba-4e28-b9df-139f2ac36b91_en?filename=egtop-report-ppp-10_and_fertilisers-7_en.pdf.

¹³ EGTOP, ‘Final report on Greenhouses’, 19 June 2016, https://agriculture.ec.europa.eu/document/download/7ae7f682-cf88-4c1e-8686-afd5617ec7ae_en?filename=final-report-etop-greenhouse-production.pdf; EGTOP, ‘Final report on Fertilisers (VI) and Plant Protection Products (VIII)’, 28 August 2023, https://agriculture.ec.europa.eu/document/download/a4561074-266c-40dd-881b-c27f150e3d8a_en?filename=egtop-report-fertilisers-vi-and-ppp-viii_en.pdf.

¹⁴ EGTOP, ‘Final report on Greenhouses’, 19 June 2016, https://agriculture.ec.europa.eu/document/download/7ae7f682-cf88-4c1e-8686-afd5617ec7ae_en?filename=final-report-etop-greenhouse-production.pdf.

¹⁵ EGTOP, ‘Final report on Plant Protection (X) and Fertilisers (VII)’, 3 May 2024, https://agriculture.ec.europa.eu/document/download/57c18571-67ba-4e28-b9df-139f2ac36b91_en?filename=egtop-report-ppp-10_and_fertilisers-7_en.pdf.

¹⁶ 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 L 170, 25.6.2019, p. 1, ELI: <http://data.europa.eu/eli/reg/2019/1009/oj>).

- (9) Based on recommendations from EGTOP regarding fertilisers¹⁷, the use of plant fibre mats without any added fertilisers, soil conditioners or other nutrients should be allowed as an inert medium in the production of sprouted seeds in accordance with Part I, point 1.3(a), of Annex II to Regulation (EU) 2018/848. Moreover, on the basis of the dossier submitted, it is appropriate to require that such plant fibre mats be only mechanically manufactured with no use of additives or binders, and that the plant fibre used be of organic origin. Annex II to Implementing Regulation (EU) 2021/1165 should therefore be amended accordingly.
- (10) Based on recommendations from EGTOP regarding fertilisers¹⁸, the use of calcium and magnesium gluconate should be authorised, provided that it is obtained only from microbial fermentation and under strict limits. Annex II to Implementing Regulation (EU) 2021/1165 should therefore be amended accordingly.
- (11) Annex III to Implementing Regulation (EU) 2021/1165 allows the use of ‘calcium chloride’ and ‘propylene glycol’ (feed materials) as well as ‘iron dextran 10 %’ (nutritional additive) as feed intended for particular nutritional purposes. The specific conditions and limits for that use should be clarified to ensure a correct understanding of the relevant entries. In particular, reference should be made to the definition of ‘feed intended for particular nutritional purposes’ in Regulation (EC) No 767/2009 of the European Parliament and of the Council¹⁹ and to the particular nutritional purpose of those substances under Commission Regulation (EU) 2020/354²⁰.
- (12) Based on recommendations from EGTOP regarding feed^{21 22}, single cell proteins from *Trichoderma viride* and *Aspergillus oryzae* and products from *Bacillus subtilis* rich in protein used as feed materials, lecithins used as a feed additives in feed for all animals, and ethanol and papain used as processing aids should be authorised. Annex III to Implementing Regulation (EU) 2021/1165 should therefore be amended accordingly.
- (13) Commission Regulation (EC) No 2277/2003²³ had authorised calcium stearate to be used as a feed additive in organic production. However, Commission Regulation (EU)

¹⁷ EGTOP, ‘Final report on Fertilisers (VI) and Plant Protection Products (VIII)’, 28 August 2023, https://agriculture.ec.europa.eu/document/download/a4561074-266c-40dd-881b-c27f150e3d8a_en?filename=egtop-report-fertilisers-vi-and-ppp-viii_en.pdf.

¹⁸ EGTOP, ‘Final report on Plant Protection (X) and Fertilisers (VII)’, 3 May 2024, https://agriculture.ec.europa.eu/document/download/57c18571-67ba-4e28-b9df-139f2ac36b91_en?filename=egtop-report-ppp-10_and_fertilisers-7_en.pdf.

¹⁹ 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, ELI: <http://data.europa.eu/eli/reg/2009/767/oj>).

²⁰ Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC (OJ L 67, 5.3.2020, p. 1, ELI: <http://data.europa.eu/eli/reg/2020/354/oj>).

²¹ EGTOP, ‘Final report on Feed (VII) and Pet Food (II)’, 16 March 2023, https://agriculture.ec.europa.eu/document/download/46e56928-5332-4ae5-919e-c5c108422537_en?filename=egtop-report-feed-vii-and-petfood-ii_en.pdf.

²² EGTOP, ‘Final report on Feed (VIII) and Food (IX)’, 1 July 2024, https://agriculture.ec.europa.eu/document/download/88317fd1-c9d2-4dca-bbc3-64521f806d09_en?filename=egtop-report-feed-viii_and_food-ix_en.pdf.

²³ Commission Regulation (EC) No 2277/2003 of 22 December 2003 amending Annexes I and II to Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 336, 23.12.2003, p. 68, ELI: <http://data.europa.eu/eli/reg/2003/2277/oj>).

No 892/2010²⁴ listed calcium stearate among the products that are not feed additives. Consequently, in 2012, it was removed from the list of authorised feed additives in Commission Regulation (EC) No 889/2008²⁵ by Commission Implementing Regulation (EU) No 505/2012²⁶. Currently, calcium stearate is covered by the feed materials listed in the table in Part C, point 13, number 13.6.4, of the Annex to Commission Regulation (EU) No 68/2013²⁷. Calcium stearate should therefore be authorised as a feed material for organic production. Annex III to Implementing Regulation (EU) 2021/1165 should be amended accordingly.

(14) In Part B, point 1(a), of Annex III to Implementing Regulation (EU) 2021/1165, feed additives are identified by the European food additive number (E number). In accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council²⁸, feed additives are to be identified by their functional group. For reasons of consistency, feed additives should also be identified by their functional group code in Implementing Regulation (EU) 2021/1165. Annex III to Implementing Regulation (EU) 2021/1165 should therefore be amended accordingly.

(15) In its recommendations on the use of calcium propionate as a preservative and as feed intended for particular nutritional purposes²⁰, EGTOP did not recommend its inclusion as a feed additive, with the justification that calcium chloride can be used for particular nutritional purposes and that calcium propionate is not to be used as a preservative. However, calcium propionate is absorbed more slowly than calcium chloride and will prevent the irritating effects when only using calcium chloride. In the table in Part B, entry '60' of the Annex to Regulation (EU) 2020/354, calcium propionate is listed as feed intended for particular nutritional purposes. Pursuant to Commission Implementing Regulation (EU) 2022/415²⁹, calcium propionate is a feed additive. Calcium propionate should therefore be listed as an authorised feed additive in Annex III to Implementing Regulation (EU) 2021/1165, provided that it is used only as feed intended for particular nutritional purposes.

²⁴ Commission Regulation (EU) No 892/2010 of 8 October 2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council (OJ L 266, 9.10.2010, p. 6, ELI: <http://data.europa.eu/eli/reg/2010/892/oj>).

²⁵ 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, ELI: <http://data.europa.eu/eli/reg/2008/889/oj>).

²⁶ Commission Implementing Regulation (EU) No 505/2012 of 14 June 2012 amending and correcting Regulation (EC) No 889/2008 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 154, 15.6.2012, p. 12, ELI: http://data.europa.eu/eli/reg_impl/2012/505/oj).

²⁷ Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1, ELI: <http://data.europa.eu/eli/reg/2013/68/oj>).

²⁸ 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, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>).

²⁹ Commission Implementing Regulation (EU) 2022/415 of 11 March 2022 concerning the authorisation of malic acid, citric acid produced by *Aspergillus niger* DSM 25794 or CGMCC 4513/CGMCC 5751 or CICC 40347/CGMCC 5343, sorbic acid and potassium sorbate, acetic acid, sodium diacetate and calcium acetate, propionic acid, sodium propionate, calcium propionate and ammonium propionate, formic acid, sodium formate, calcium formate and ammonium formate, and lactic acid produced by *Bacillus coagulans* (LMG S-26145 or DSM 23965), or *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate as feed additives for all animal species (OJ L 85, 14.3.2022, p. 6, ELI: http://data.europa.eu/eli/reg_impl/2022/415/oj).

- (16) In its recommendations on the use of iron(II) fumarate as a feed intended for particular nutritional purposes³⁰, EGTOP did not recommend the inclusion of iron(II) fumarate in Implementing Regulation (EU) 2021/1165 as it considered that the iron dextran authorised in that Implementing Regulation was the most effective product for iron deficiency. However, iron dextran and iron(II) fumarate are not alternatives but are both needed due to their different states, with iron dextran being liquid and iron(II) fumarate being solid. Iron(II) fumarate should therefore be listed as a feed additive in Annex III to Implementing Regulation (EU) 2021/1165.
- (17) Food additives and food processing aids used in the production of processed organic food are listed in two separate sections in Part A of Annex V to Implementing Regulation (EU) 2021/1165. The use of a product as a food additive or as a processing aid is to be determined in accordance with the definitions of food additive and processing aid in Article 3(2) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council³¹. Depending on their technological function in the final product, certain products classified as processing aids should instead be classified as food additives and certain other products should be classified as food additives and as food processing aids according to their uses. For the sake of clarity, the lists of food additives and food processing aids in Part A, Sections A1 and A2, of Annex V to Implementing Regulation (EU) 2021/1165 should therefore be merged into a single list, and further specific conditions should be set for processing aids that can also be used as food additives.
- (18) In that merged list, the specific condition that the additive ‘calcium carbonate’ is not to be used for colouring or calcium enrichment should be deleted as the rules provided for in Part IV, points 2.2.2(c), (d) and (f), of Annex II to Regulation (EU) 2018/848 already contain that condition.
- (19) Based on recommendations from EGTOP regarding food³², buffered vinegar should be included as a food additive in the list of authorised food additives and processing aids in Part A of Annex V to Implementing Regulation (EU) 2021/1165.
- (20) In the list of authorised food additives and processing aids in Part A of Annex V to Implementing Regulation (EU) 2021/1165, the maximum levels for sodium nitrite and potassium nitrate should be expressed as nitrite ion and nitrate ion, in line with the Acceptable Daily Intakes (ADIs) established by the European Food Safety Authority³³. For that purpose, a conversion factor between sodium nitrite and nitrite ion of 0.67 and a conversion factor between sodium nitrate and nitrate ion of 0.73 should be applied.
- (21) In Part A, section A1, of Annex V to Implementing Regulation (EU) 2021/1165, gellan gum is listed as an authorised food additive that is to be produced in accordance

³⁰ EGTOP, ‘Final report on Feed (VII) and Pet Food (II)’, 16 March 2023, https://agriculture.ec.europa.eu/document/download/46e56928-5332-4ae5-919e-c5c108422537_en?filename=egtop-report-feed-vii-and-petfood-ii_en.pdf.

³¹ 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, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>).

³² EGTOP, ‘Final report on Feed (VIII) and Food (IX)’, 1 July 2024, https://agriculture.ec.europa.eu/document/download/88317fd1-c9d2-4dca-bbc3-64521f806d09_en?filename=egtop-report-feed-viii-and-food-ix_en.pdf.

³³ EFSA, *Re-evaluation of potassium nitrite (E 249) and sodium nitrite (E 250) as food additives*, EFSA Journal 2017;15(6):4786, <https://doi.org/10.2903/j.efsa.2017.4786>.

with organic production rules from 1 January 2026. Gellan gum production depends on maintaining specific and consistent raw material qualities for the microorganism. So far, attempts to manufacture gellan gum using organic agricultural raw materials have been unsuccessful. Gellan gum is used as an additive in organic processed food. To avoid disruption of the production of organic processed food, the use of non-organic gellan gum should continue to be authorised in organic production. This should be reflected in the entry for gellan gum in the merged list of authorised food additives and processing aids in Part A of Annex V to Implementing Regulation (EU) 2021/1165.

- (22) In Part A, section A1, of Annex V to Implementing Regulation (EU) 2021/1165, the use of hydrochloric acid, hydrogen peroxide and ammonium hydroxide is authorised for gelatine production under the condition that gelatine production complies with the rules for production of gelatine laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council³⁴. It is not necessary to repeat that specific condition in the merged list of authorised food additives and processing aids in Part A of Annex V to Implementing Regulation (EU) 2021/1165.
- (23) In its recommendations on yeast-based nutrients³⁵, EGTOP confirmed that nutrients corresponding to minerals, vitamins and amino acids were essential fermentation activators to assist yeast production. However, EGTOP concluded that the use of synthetic nutrients was not in line with the principles of organic production. EGTOP therefore recommended authorising the use of nutrients that derive exclusively from yeast extract or from autolysate to assist yeast production in a limited quantity of up to 5 % of the substrate concerned calculated in weight of dry matter. Fermentation activators consisting of nutrients from yeast extract or autolysate should therefore be listed in Part C of Annex V to Implementing Regulation (EU) 2021/1165 as authorised products, within the limit of 5 % of the substrate.
- (24) In accordance with Part VI, point 3.4, of Annex II to Regulation (EU) 2018/848, a Member State has submitted a dossier for an authorisation to use yeasts and lactic acid bacteria as acidity regulators in organic wine production. In accordance with Part D of Annex V to Implementing Regulation (EU) 2021/1165, yeasts for wine production and lactic acid bacteria are authorised as fermentation agents. These fermentation agents also exhibit acidity regulation properties. Since these fermentation agents are suitable alternatives to other acidity regulators already authorised for organic wine production, their use as acidity regulators should be authorised, and Part D of Annex V to Implementing Regulation (EU) 2021/1165 should be changed accordingly.
- (25) Based on recommendations from EGTOP regarding plant protection products³⁶, the use of ethylene for flower induction in pineapple and the use in organic crops of

³⁴ 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, ELI: <http://data.europa.eu/eli/reg/2004/853/oj>).

³⁵ EGTOP, 'Final report on Food (X)', 31 January 2025, https://agriculture.ec.europa.eu/document/download/c4cef8da-34a4-48f7-9f5d-2c97f86f2a15_en?filename=egtop-report-food-x_en.pdf

³⁶ EGTOP, 'Final report on Fertilisers (VI) and Plant Protection Products (VIII)', 28 August 2023, https://agriculture.ec.europa.eu/document/download/a4561074-266c-40dd-881b-c27f150e3d8a_en?filename=egtop-report-fertilisers-vi-and-ppp-viii_en.pdf; EGTOP, 'Final report on Plant Protection (IX)', 14 December 2023, https://agriculture.ec.europa.eu/document/download/5a183a99-2e86-4add-a0ae-27fc519e5c11_en?filename=egtop-report-ppp-ix_en.pdf.

microorganisms that do not originate from genetically modified organisms, should be allowed for use in organic production in third countries as active substances contained in plant protection products. It is therefore appropriate to include those substances and the specific conditions and limits for their use in Annex VI to Implementing Regulation (EU) 2021/1165.

- (26) The basic substance ‘magnesium hydrogen metasilicate silicate mineral (Talc E 553b)’ is listed in the table in point 1 of Annex I to Implementing Regulation (EU) 2021/1165. However, the specific condition indicated in the column ‘specific conditions and limits’ is not an additional restriction on the use of that basic substance. This error should therefore be corrected.
- (27) Implementing Regulation (EU) 2021/1165 should therefore be amended and corrected accordingly.
- (28) The measures provided for in this Regulation are in accordance with the opinion of the Organic Production Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2021/1165

Implementing Regulation (EU) 2021/1165 is amended as follows:

- (1) The following Article 10a is inserted:

‘Article 10a

Procedure to grant specific authorisation for the use of products and substances in the outermost regions of the Union

1. Where a Member State considers that a product or substance should be granted a specific authorisation for use in an outermost region of the Union due to the specific conditions set out in Article 45(2) of Regulation (EU) 2018/848, 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 due to the specific conditions set out in Article 45(2) of Regulation (EU) 2018/848 and explaining why the products and substances authorised under this Regulation are not adequate to be used due to the specific conditions in the outermost region concerned. 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.

2. The Commission shall publish any requests referred to in paragraph 1.

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 outermost region 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.

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 needs to be reassessed.’;

- (2) Annex I is amended in accordance with Annex I to this Regulation;
- (3) Annex II is amended in accordance with Annex II to this Regulation;
- (4) Annex III is amended in accordance with Annex III to this Regulation;
- (5) Annex V is amended in accordance with Annex IV to this Regulation;
- (6) Annex VI is replaced by the text set out in Annex V to this Regulation.

Article 2

Correction of Implementing Regulation (EU) 2021/1165

In the table in point 1 of Annex I to Implementing Regulation (EU) 2021/1165, the entry ‘19C’ is replaced by the following:

‘19C	14807-96-6	Magnesium hydrogen metasilicate silicate mineral (Talc E 553b)’	
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Article 3

Entry into force

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN