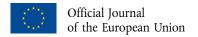
26.5.2025



2025/973

### **COMMISSION IMPLEMENTING REGULATION (EU) 2025/973**

### of 23 May 2025

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)

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) thereof,

### Whereas:

- 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) 2021/1165 (2) 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.
- Commission Implementing Regulation (EU) 540/2011 (3) has been amended following the re-assessment of the active substances lavandulyl senecioate (4), potassium hydrogen carbonate (5), straight chain lepidopteran pheromones (acetates) (6), sheep fat (7) and quartz sand (8). In order to reflect these amendments, the entries for potassium

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

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).

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).

Commission Implementing Regulation (EU) 2020/646 of 13 May 2020 approving the active substance Lavandulyl senecioate as a lowrisk 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 Regulation (EU) No 540/2011 (OJ L 313, 6.9.2021, p. 30, ELI: http://data.europa.eu/eli/reg\_impl/2021/1452/oj). 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).

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).

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).

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 Implementing Regulation (EU) 2022/1251 and the guidance document on semio-chemicals (\*), 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 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 greenhouses (10) and fertilisers (11), 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 fertilisers (12), 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 production (13). It is therefore appropriate to add an entry for carbon dioxide in Annex II to Implementing Regulation (EU) 2021/1165.

<sup>(°)</sup> 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.

<sup>(10)</sup> 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.

<sup>(11)</sup> 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.

<sup>(</sup>¹²) 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.

<sup>(13)</sup> 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.

(8) Based on recommendations from EGTOP regarding fertilisers (14), 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 Council (15). Annex II to Implementing Regulation (EU) 2021/1165 should therefore be amended accordingly.

- (9) Based on recommendations from EGTOP regarding fertilisers (16), 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 fertilisers (17), 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 Council (18) and to the particular nutritional purpose of those substances under Commission Regulation (EU) 2020/354 (19).
- (12) Based on recommendations from EGTOP regarding feed (20) (21), single cell proteins from *Trichoderma viride* and Aspergillus oryyzae 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.

<sup>(14)</sup> 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.

<sup>(15)</sup> 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).

<sup>(16)</sup> 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.

<sup>(17)</sup> 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.

<sup>(18)</sup> 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).

<sup>(19)</sup> 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).

<sup>(20)</sup> 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.

<sup>(21)</sup> 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.

(13) Commission Regulation (EC) No 2277/2003 (<sup>22</sup>) had authorised calcium stearate to be used as a feed additive in organic production. However, Commission Regulation (EU) No 892/2010 (<sup>23</sup>) 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 889/2008 (<sup>24</sup>) by Commission Implementing Regulation (EU) No 505/2012 (<sup>25</sup>). 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 68/2013 (<sup>26</sup>). 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 Council (<sup>27</sup>), 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 purposes<sup>20</sup>, 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) 2022/415 (<sup>28</sup>), 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.

<sup>(22)</sup> 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).

<sup>(23)</sup> 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).

<sup>(24)</sup> Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/889/oj).

<sup>(25)</sup> 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).

<sup>(26)</sup> 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).

<sup>(27)</sup> 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).

<sup>(28)</sup> 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 certain 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 purposes (29), 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 Council (30). 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 food (31), 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 Authority (32). 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 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.

<sup>(2°)</sup> 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.

<sup>(30)</sup> 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).

<sup>(31)</sup> 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.

<sup>(32)</sup> 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.

(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 Council (33). 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 nutrients (34), 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 products (35), the use of ethylene for flower induction in pineapple and the use in organic crops of 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,

<sup>(3)</sup> 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).

<sup>(34)</sup> 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.

<sup>(35)</sup> 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.

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, 23 May 2025.

For the Commission The President Ursula VON DER LEYEN

# ANNEX I

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

- (1) in point 2, the table is amended as follows:
  - (a) the following entry is inserted between the entries '16D' and '20D':

'19D	23960-07-8	Lavandulyl senecioate'	
1,2		24,411441)130110013410	i

(b) the following entries are added after the entry for other low risk substances from plant or animal origin \*:

'32D	298-14-6	Potassium hydrogen carbonate	
38D		Straight chain lepidopteran pheromones (acetates)	
39D	98999-15-6	Sheep fat	use as repellent by smell'
44D	14808-60-7 and 7631-86-9	Quartz sand Silicon dioxide	

- (2) in point 4, the table is amended as follows:
  - (a) the entries '244A', '247A', '249A' and '255A and others' are deleted;
  - (b) the following entry is inserted between the entries '47B' and '10E':

# ANNEX II

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

(1) in the table, the entry 'products and by-products of plant origin for fertilisers' is replaced by the following:

Products and by-products of plant origin	e.g., oilseed cake meal, cocoa husks, malt culms'	
in the table, the entry 'stone meal, clays and clay minerals' is replaced by the following:		
Stone meal, sand of natural origin, clays and	e.g., perlite, sand and vermiculite, including when heat treated,	

'Stone meal, sand of natural origin, clays and clay minerals

e.g., perlite, sand and vermiculite, including when heat treated, perlite, sand and vermiculite, including when heat treated, may also be used for sprouted seeds production as an inert medium as referred to in Part I, point 1.3(a), of Annex II to Regulation (EU) 2018/848'

(3) in the table, the following entries are added after the entry 'selenium salts':

'Carbon dioxide	use for enrichment of water for algae production on land in closed systems; in this case, carbon dioxide shall be of food grade	
	when available, carbon dioxide shall be obtained as a by-product of other processes or from renewable sources pursuant to Directive (EU) 2018/2001 of the European Parliament and of the Council (*)	
	may also be used in greenhouse production	
Calcium acetate	only for foliar application on vegetables in greenhouses and on apple trees to prevent deficiency in calcium	
	obtained from calcium carbonate of natural origin	
Calcium phosphate	only when derived from sewage sludge ash	
	only products complying with the requirements of Regulation (EU) 2019/1009	
Plant fibre mats	plant-based fibres, such as hemp fibre, flax fibre, coconut fibre	
	with no addition of any fertiliser, soil conditioner or nutrient nor additives or binders, only mechanically manufactured	
	only for sprouted seeds production as an inert medium referred to in Part I, point 1.3(a), of Annex II to Regulation (EU) 2018/848	
	when available, materials from organic production shall be used	
Calcium and magnesium gluconate	derived from microbial fermentation	

<sup>(\*)</sup> Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (OJ L 328, 21.12.2018, p. 82, ELI: http://data.europa.eu/eli/dir/2018/2001/oj).'.

(2)

# ANNEX III

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

- (1) Part A is amended as follows:
  - (a) in point (1), in the table, the entry '11.1.6' is replaced by the following:

'11.1.6	Calcium chloride	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (0), of Regulation (EC) No 767/2009 for the reduction of the risk of milk fever and subclinical hypocalcaemia in accordance with Part B, table entry "60", of the Annex to Commission Regulation (EU) 2020/354 (*), including bolus formulation calcium chloride when purified from naturally occurring brine, if available only for dairy cows in need and for a limited period
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- (\*) 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).'.
- (b) in point (2), the table is amended as follows:
  - (i) the following entries are inserted between the entries '12.1.5' and '12.1.12':

'ex 12.1.9	Single cell proteins from Trichoderma viride and Aspergillus oryzae	only from non-GM strain and culture media not obtained from substrates with synthetic nitrogen sources obtained from substrates coming from organic production when used for ruminants and other herbivores when used, antifoaming agents shall be authorised for organic production
12.1.10	Products from Bacillus subtilis rich in protein	only from non-GM strain and culture media not obtained from substrates with synthetic nitrogen sources obtained from substrates coming from organic production when used for ruminants and other herbivores when used, antifoaming agents shall be authorised for organic production'

(ii) the following entry is inserted between the entries '12.1.12' and '13.11.1':

'ex 13.6.4	Calcium stearate'	
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(iii) the entry '13.11.1' is replaced by the following:

ʻ13.11.1	Propylene glycol; [1,2-propanediol]; [propane-1,2-diol]	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (o), of Regulation (EC) No 767/2009 for the reduction of the risk of ketosis in accordance with Part B, table entry "61", of the Annex to Regulation (EU) 2020/354, including bolus formulation only for dairy cows, ewes and goats in need and for a limited period'
		limited period'

# (2) Part B is amended as follows:

(a) in point (1)(a), the table is replaced by the following:

'ID number or functional group	Name	Specific conditions and limits
1a200	Sorbic acid	
1k236	Formic acid	
1k237i	Sodium formate	
1a260	Acetic acid	
1a270 1a270i	Lactic acids	
1k280	Propionic acid	
1a282	Calcium propionate	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (0), of Regulation (EC) No 767/2009 for the reduction of the risk of milk fever and subclinical hypocalcaemia in accordance with Part B, table entry "60", of the Annex to Regulation (EU) 2020/354, including bolus formulation  only for dairy cows in need and for a limited period'
1a330	Citric acid	

(b) in point (1)(c), in the table, the entry '1c322, 1c322i' is replaced by the following:

'1c322, 1c322i	Lecithins	derived from organic raw material from 1 January 2027, only from organic production'

- (c) in point (3)(b), the table is amended as follows:
  - (i) the following entry is inserted between the entries '3b104' and '3b107':

'3b105	Iron(II) fumarate	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (0), of Regulation (EC) No 767/2009 for compensation of insufficient iron availability after birth in accordance with Part B, table entry "64", of the Annex to Regulation (EU) 2020/354
		only for suckling piglets in need and for a limited period'

(ii) the entry '3b110' is replaced by the following:

'3b110	Iron dextran 10 %	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (0), of Regulation (EC) No 767/2009 for compensation of insufficient iron availability after birth in accordance with Part B, table entry "64", of the Annex to Regulation (EU) 2020/354
		growing medium for the fermentation process for dextran shall be of non-GMO origin
		only for suckling piglets in need and for a limited period'

- (d) the following point is added:
  - '(5) PROCESSING AIDS

For processing aids as defined in Article 2(2), point (h), of Regulation (EC) No 1831/2003, the specific conditions and limits set out in the following table shall apply.

Name	Specific conditions and limits
Ethanol	to be used only as extraction solvent for the production of protein meals and only when protein meals from mechanical extraction are not available in sufficient quantities
	only from fermentation if available
	only from organic production if available
Papain	only for the production of flavouring innards for the manufacture of pet food that are defined in point 18 of Annex I to Regulation (EU) No 142/2011
	provided that the enzyme is inactivated during the process and therefore is not present as such in the resulting flavouring innards and does not have any technological effect on the product
	from 1 January 2027, only from organic raw material'

### ANNEX IV

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

(1) Part A is replaced by the following:

### 'PART A

Authorised food additives and processing aids referred to in Article 24(2), point (a), of Regulation (EU) 2018/848, including carriers and other substances used in the same way and with the same purpose as processing aids

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 limits set out in the table below shall apply in addition to the conditions of the authorisations under Regulation (EC) No 1333/2008.

The use as food additives or as processing aids shall be attributed on a case-by-case basis in accordance with Regulation (EC) No 1333/2008 and national legislation on processing aids.

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 "E-number or Einecs, or both" shall be calculated as ingredients of agricultural origin.

E-number or Einecs (+), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
or both		Use as an additive	Use as a processing aid
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 norbixin	Red Leicester cheese	
		Double Gloucester cheese	
		Cheddar	
		Mimolette cheese	
E 170/207-439-9 and 215-279-6	Calcium carbonate	products of plant and animal origin	products of plant origin
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 <sub>2</sub> in mg/l)	
E 223	Sodium metabisulphite	crustaceans	

E-number or Einecs (†), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits		
		Use as an additive	Use as a processing aid	
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 <sub>2</sub> in mg/l)		
E 250	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 amount that may be added during the manufacturing expressed as NO <sub>2</sub> ion: 50 mg/kg		
		maximum residual amount from all sources for the product ready for marketing throughout the shelf life of the product expressed as NO <sub>2</sub> ion: 30 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 amount that may be added		
		during the manufacturing expressed as NO <sub>3</sub> ion: 55 mg/kg maximum residual amount from all sources for the product ready for marketing throughout the shelf life of the product expressed as NO <sub>3</sub> ion: 35 mg/kg		
E 267*	Buffered vinegar	products of plant and animal origin only from organic production		
E 270/200-018-0	Lactic acid	products of plant and animal origin	cheese for the regulation of pF of the brine bath in cheese production	

E-number or Einecs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits		
		Use as an additive	Use as a processing aid	
E 290/204-696-9	Carbon dioxide	products of plant and animal origin	products of plant and animal origin	
E 296	Malic acid	products of plant origin		
E 300	Ascorbic acid	products of plant origin meat products (category 08,3 (**)) and meat preparations (category 08,2 (**)) to which other ingredients than additives or salt have been added		
E 301	Sodium ascorbate	meat products may only be used in connection with nitrates and nitrites		
E 306*	Tocopherol-rich extract	products of plant and animal origin only as antioxidant		
E 322*	Lecithins	products of plant and animal origin only from organic production		
E 325	Sodium lactate	products of plant origin		
		milk-based products		
		meat products		
E 330/201-069-1	Citric acid	products of plant and animal origin	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 (L(+)-)	products of plant origin mead		
E 335*	Sodium tartrates	products of plant origin from 1 January 2027, only from organic production		
E 336*	Potassium tartrates	products of plant origin from 1 January 2027, only from organic production		
E 337*	Potassium sodium tartrate	products of plant origin from 1 January 2027, only from organic production		

E-number or Einecs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits		
or both		Use as an additive	Use as a processing aid	
E 341(i)	Monocalcium phosphate	self-raising flour		
		only as raising agent		
E 392*	Extracts of	products of plant and animal origin		
	rosemary	only from organic production		
E 400	Alginic acid	products of plant origin		
		milk products		
E 401	Sodium alginate	products of plant origin		
		milk products		
		sausages based on meat		
E 402	Potassium alginate	products of plant origin		
		milk-based products		
E 406	Agar	products of plant origin		
		milk-based products		
		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 only from organic production only as thickener		

E-number or Einecs (†), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits		
or both		Use as an additive	Use as a processing aid	
E 418*	Gellan gum	products of plant and animal origin from organic production, if available only high-acyl form		
E 422*	Glycerol	plant extracts and flavourings only from plant origin only from organic production as solvent and carrier as humectant in gel capsules as surface coating of tablets		
E 440(i)*	Pectin	products of plant origin		
		milk-based products		
E 460/232-674-9	Cellulose	gelatine	gelatine	
			products of plant origin	
E 464	Hydroxypropyl methyl cellulose	products of plant and animal origin only as encapsulation material for capsules		
E 500/207-838-8, 205-633-8, 208-580-9	Sodium carbonates	products of plant and animal origin	products of plant and animal origin	
E 501/209-529-3, 206-059-0	Potassium carbonates	products of plant origin	grapes only as drying agent to produce dried grapes	
E 503	Ammonium carbonates	products of plant origin		
E 504	Magnesium carbonates	products of plant origin		
E 509/233-140-8	Calcium chloride	products of plant origin only to induce coagulation	products of plant origing only as clarifying/flocculating agent	
		milk-based products only as stabiliser		
		sausages based on meat only to induce coagulation to form casing		

E-number or Einecs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits		
or both		Use as an additive	Use as a processing aid	
E 511/232-094-6	Magnesium chloride	products of plant origin only to induce coagulation	products of plant origin only as clarifying/ flocculating agent	
E 516/231-900-3	Calcium sulphate	products of plant origin only as carrier or to induce coagulation	products of plant origin only as clarifying/ flocculating agent	
		surface-treated Laugengebäck only as surface treatment	sugar(s)	
E 524/215-185-5	Sodium hydroxide	flavourings only as acidity regulator	oil from plant origin excluding olive oil	
			plant protein extracts	
E 551/231-545-4	Silicon dioxide	cocoa only as anticaking agent for use in automated dispensing machines	products of plant origin	
		herbs and spices in dried powdered form		
		flavourings		
		propolis		
E 553b	Talc	products of plant origin	products of plant origin	
		sausages based on meat only as surface treatment		
E 901*/232-383-7	Beeswax	confectionery only from organic production only as glazing agent	products of plant origin only from organic production only as releasing agent	

E-number or Einecs (†), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits		
		Use as an additive	Use as a processing aid	
E 903*/232-399-4	Carnauba wax	confectionery only from organic production only as glazing agent  citrus fruit only from organic production only as mitigating method for mandatory extreme cold treatment of fruit against harmful organisms in accordance with Commission Implementing Regulation (EU) 2019/2072 (***)	products of plant origin only from organic production only as releasing agent	
E 938	Argon	products of plant and animal origin		
E 939	Helium	products of plant and animal origin		
E 941/231-783-9	Nitrogen	products of plant and animal origin	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		
-/200-578-6	Ethanol		products of plant and animal origin only as solvent on crystallization primers for the production of sugar and/or extraction solvent	
-/200-580-7	Acetic acid		products of plant origin from organic production, if available	
			fish from organic production, if available	
-/215-108-5	Bentonite		products of plant origin	
			mead only as sticking agent	

E-number or Einecs (†),	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits		
or both		Use as an additive	Use as a processing aid	
-/215-137-3	Calcium hydroxide		products of plant origin	
-/231-595-7	Hydrochloric acid		gelatine	
			Gouda, Edam and Maasdammer cheeses, Boerenkaas, Friese and Leidse Nagelkaas	
			only as regulation of the pH of the brine bath in the processing of cheeses	
-/231-639-5	Sulphuric acid		gelatine	
			sugar(s)	
-/231-765-0	Hydrogen peroxide		gelatine	
-/232-554-6	Gelatine		products of plant origin	
-/232-555-1	Casein		products of plant origin	
-/293-292-6	Isinglass		products of plant origin	
-/931-328-0	Activated carbon		products of plant and animal origin	
	Ammonium hydroxide		gelatine	
	Diammonium phosphate		fruit wines, cider, perry and mead	
	L(+)lactic acid from fermentation		plant protein extracts	
	Thiamin hydrochloride		fruit wines, cider, perry and mead	
	Diatomaceous earth		products of plant origin	
			gelatine	
	Egg white albumin		products of plant origin	
	Hop extract		products of plant origin from organic production, if available	
			only for antimicrobial purposes	

E-number or Einecs (*),	Name	Organic foodstuffs in which the additive o specific conditions	r processing aid may be used and and limits
or both		Use as an additive	Use as a processing aid
	Hazelnut shells		products of plant origin
	Perlite		products of plant origin
			gelatine
	Pine rosin extract		products of plant origin from organic production, if available only for antimicrobial purposes
	Rice meal		products of plant origin
	Tannic acid		products of plant origin only as filtration aid
	Vegetable oils		products of plant and animal origin only from organic production only as greasing, releasing or antifoaming agent
	Vinegar		products of plant origin only from organic production
			only from organic production
	Water		products of plant and animal origin water intended for human consumption within the meaning of Directive (EU) 2020/2184 of the European Parliament and of the Council (****)

E-number or Einecs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
	Wood fibre		products of plant and animal origin
			the source of timber shall be restricted to certified, sustainably harvested wood
			wood used shall not contain toxic components (post- harvest treatment, naturally occurring toxins or toxins from microorganisms)

<sup>(\*)</sup> European Inventory of Existing Commercial Chemical Substances (OJ C 146, 15.6.1990, p. 4).

(\*\*) Food categories in Part D of Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OI L 354, 31.12.2008, p. 16. ELI: http://data.europa.eu/eli/reg/2008/1333/oi).

(\*\*\*\*) Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1, ELI: http://data.europa.eu/eli/dir/2020/2184/oj).';

(2) in Part C, in the table, the following entry is added after the entry 'vegetable oils':

'Fermentation activators	X	nutrients from yeast extract or autolysate
		up to 5 % of the substrate calculated in weight of dry matter'

- (3) in Part D, the table is amended as follows:
  - (a) the entry 'yeasts for wine production' is replaced by the following:

Yeasts for wine	Part A, Table 2, point 1.11	for the individual yeast
production	Part A, Table 2, point 9.1	strains, organic if available'

(b) the entry 'lactic acid bacteria' is replaced by the following:

'Lactic acid bacteria Part A, Table 2, point 1.12 Part A, Table 2, point 9.2'	
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<sup>16</sup> December 2008 on food additives (OJ L 354, 31.12.2008, p. 16, ELI: http://data.europa.eu/eli/reg/2008/1333/oj).

(\*\*\*) Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1, ELI: http://data.europa.eu/eli/reg\_impl/2019/2072/oj).

### ANNEX V

### 'ANNEX VI

Products and substances authorised for use in organic production in third countries and in the outermost regions of the Union pursuant to Article 45(2) of Regulation (EU) 2018/848

#### PART A

### PRODUCTS AND SUBSTANCES AUTHORISED FOR USE IN ORGANIC PRODUCTION IN THIRD COUNTRIES

# Active substances to be used in plant protection products

Active substances listed in the table below may be used in organic production in third countries, provided that they comply with the relevant third country legislation, are exempted from maximum residue levels in accordance with Codex Alimentarius guidelines CXG 97-2022 (\*), are included in Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council (\*\*), or specific maximum residue levels have been set in that Regulation. They are subject to the corresponding specific conditions and limits set out in that table.

CAS number	Name of the active substance	Specific conditions and limits
	Microorganisms including viruses,	not from GMO origin
when used as biological control agents	not produced by using growing media of GMO origin	
74-85-1	Ethylene	for flower induction in pineapple

### PART B

# PRODUCTS AND SUBSTANCES AUTHORISED FOR USE IN ORGANIC PRODUCTION IN THE OUTERMOST REGIONS OF THE UNION

### Active substances to be used in plant protection products

Active substances listed in the table below may be used in organic production in the outermost regions of the Union, provided that they comply with the relevant provisions of Union law and, where applicable, with national provisions based on Union law.

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<sup>(\*)</sup> https://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en.

<sup>(\*\*)</sup> 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, ELI: http://data.europa.eu/eli/reg/2005/396/oj).'.