

COMMISSION IMPLEMENTING REGULATION (EU) 2023/121**of 17 January 2023****amending and correcting Implementing Regulation (EU) 2021/1165 authorising certain products and substances for use in organic production and establishing their lists**

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:

- (1) 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 Commission Implementing Regulation (EU) 2021/1165 ⁽²⁾. Those dossiers have been examined by the Expert Group for Technical Advice on Organic Production (EGTOP) and the Commission.
- (2) In its recommendations with regard to active substances contained in plant protection products ⁽³⁾, EGTOP recommended that the use of the substance Talc E553b be added to the basic substances allowed in organic production. EGTOP also recommended to add the following to the low risk active substances used in organic farming: (i) ABE-IT 56, provided that it is neither obtained from GMO strains nor by using growing media of GMO origin; (ii) 'ferric pyrophosphate' and (iii) 'aqueous extract from the germinated seeds of sweet *Lupinus albus*'. Therefore, the use of those substances should be authorised.
- (3) EGTOP further recommended that deltamethrin in traps with specific attractants should be allowed to be used against *Rhagoletis completa*. Therefore, this use of deltamethrin should be authorised under its specific conditions and limits.
- (4) Based on recommendations from EGTOP with regard to fertilisers, soil conditioners and nutrients ⁽³⁾, the use of the following substances should be authorised: (i) recovered struvite and precipitated phosphate salts, provided that they meet the requirements laid down in Regulation (EU) 2019/1009 of the European Parliament and of the Council ⁽⁴⁾ and that animal manure as source material is not of factory farming origin; (ii) potassium chloride (muriate of potash) of natural origin; and (iii) sodium nitrate used for algae production on land in closed systems.

⁽¹⁾ OJ L 150, 14.6.2018, p. 1.

⁽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).

⁽³⁾ EGTOP final report on Fertilisers IV and Plant Protection Products VI and EGTOP final report on Plant Protection Products VII and Fertilisers V: https://agriculture.ec.europa.eu/farming/organic-farming/co-operation-and-expert-advice/egtop-reports_en.

⁽⁴⁾ 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).

- (5) Based on recommendations from EGTOP with regard to feed ⁽⁵⁾, the use of the following substances should be authorised: (i) monocalcium phosphate used as feed material of mineral origin; (ii) in addition to the ones obtained from *Saccharomyces cerevisiae* or *Saccharomyces carlsbergensis*, all authorised yeast and yeast products used as feed materials; (iii) xanthan gum used as technological feed additive within the functional group ‘emulsifiers, stabilisers, thickeners and gelling agents’; (iv) illite-montmorillonite-kaolinite and sepiolitic clay used as technological feed additives within the functional group ‘binders and anti-caking agents’; and (v) bentonite used as technological feed additive within a new functional group ‘substances for reduction of the contamination of feed by mycotoxins’.
- (6) Based on further recommendation from EGTOP with regard to feed ⁽⁶⁾, betaine anhydrous is currently authorised only for monogastric animals in Implementing Regulation (EU) 2021/1165. However, the recommendation from EGTOP was based on a file for betaine anhydrous used as nutritional additive for poultry, pigs and fish. Therefore, the authorisation of betaine anhydrous should also be granted for feeding fish.
- (7) Based on recommendations from EGTOP with regard to pet food ⁽⁷⁾, the use of the following substances should be authorised: (i) pentasodium triphosphate (STPP) and disodium dihydrogen diphosphate (SAPP) used as feed material of mineral origin; (ii) carrageenan; (iii) locust bean gum (carob gum), provided that locust bean gum is obtained through a roasting process (iv) acacia (gum arabic), used as gelling agents and/or emulsifiers; (v) taurine used as nutritional additive for cats and dogs; and (vi) ammonium chloride used as zootechnical additive for cats.
- (8) Based on recommendations from EGTOP with regard to food ⁽⁸⁾, the use of the following substances should be authorised: (i) silicon dioxide used as anti-caking agent for cocoa powder in automated drinks dispensing machines; and (ii) pine rosin extract and hop extract as antimicrobials in the production of food of plant origin.
- (9) Regulation (EU) 2021/1165 provides that gellan gum is authorised from 1 January 2023 only if it is from organic production. However, there is no sufficient quantity of gellan gum from organic production available. In order to allow operators to continue their food production, the application of that requirement should be postponed.
- (10) Guar gum E 412 is listed in Part B of Annex III to Implementing Regulation (EU) 2021/1165 as a binder and anti-caking agent within technological additives. However, in the European Union Register of feed additives, it is listed under emulsifying and stabilising agents, thickeners and gelling agents. That error needs to be corrected.
- (11) Talc E 553b was authorised as a food additive in foodstuffs of plant origin by Commission Regulation (EC) No 889/2008 ⁽⁷⁾. This use was not included in Annex V to Implementing Regulation (EU) 2021/1165. That error needs to be corrected.
- (12) Implementing Regulation (EU) 2021/1165 should therefore be amended and corrected accordingly.
- (13) The inclusion of talc E 553b as a food additive was erroneously limited and some organic operators may have continued to use it as a food additive in foodstuffs of plant origin. That error should therefore be corrected retroactively from the date of entry into force of Implementing Regulation (EU) 2021/1165.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Organic Production Committee,

⁽⁵⁾ EGTOP final report on Food VII – Feed V and EGTOP final report on Feed VI and pet Food I: https://agriculture.ec.europa.eu/farming/organic-farming/co-operation-and-expert-advice/egtop-reports_en.

⁽⁶⁾ EGTOP final report on Feed III – Food V: https://agriculture.ec.europa.eu/farming/organic-farming/co-operation-and-expert-advice/egtop-reports_en.

⁽⁷⁾ 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).

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2021/1165

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

- (1) Annex I is amended in accordance with Annex I to this Regulation;
- (2) Annex II is amended in accordance with Annex II to this Regulation;
- (3) Annex III is amended in accordance with Annex III to this Regulation;
- (4) Annex V is amended in accordance with Annex IV to this Regulation.

Article 2

Corrections to Implementing Regulation (EU) 2021/1165

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

- (1) point (1) (Technological additives) of Part B of Annex III is corrected as follows:
 - (a) in point (c), the following entry is added:

‘E412	Guar gum’	
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- (b) in point (d), the entry for ‘E 412 Guar gum’ is deleted;
- (2) in Section A1 (Food additives, including carriers) of Part A in Annex V, the entry for ‘E 553b Talc’ is replaced by the following:

E 553b	Talc	products of plant origin sausages based on meat	For sausages based on meat, only surface treatment
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Article 3

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*.

Article 2(2) shall apply from 5 August 2021.

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

Done at Brussels, 17 January 2023.

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 1 (Basic substances) the following entry is inserted after the entry '18C mustard seeds powder *':

'19C	14807-96-6	Magnesium hydrogen metasilicate silicate mineral (Talc E553b)	food grade in conformity with Commission Regulation (EU) No 231/2012 (*)
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(*) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).;

(2) in point 2 (Low risk active substances) the following entries are added:

'16D	CAS not allocated	ABE-IT 56 (components of lysate of <i>Saccharomyces cerevisiae</i> strain DDSF623)	not from GMO origin not produced by using growing media of GMO origin'
20 D	10058-44-3	Ferric pyrophosphate	
28 D		Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i>	

(3) in point 4 (Active substances not included in any of the above categories) the entry for '40A Deltamethrin' is replaced by the following:

'40A	52918-63-5	Deltamethrin	only in traps with specific attractants against <i>Bactrocera oleae</i> , <i>Ceratitis capitata</i> and <i>Rhagoletis completa</i> '
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ANNEX II

In the table in Annex II to Implementing Regulation (EU) 2021/1165, the following entries are added:

Recovered struvite and precipitated phosphate salts	products must meet the requirements laid down in Regulation (EU) 2019/1009 animal manure as source material cannot have factory farming origin
Sodium nitrate	only for algae production on land in closed systems
Potassium chloride (muriate of potash)	only of natural origin'

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), after the entry '11.3.1 Dicalcium phosphate', the following entry is inserted:

'11.3.2	Monocalcium phosphate'	
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(b) in point (1), after the entry '11.3.17 Monoammonium phosphate', the following entries are inserted:

'11.3.19	Pentasodium triphosphate (STPP)	only for pet food
11.3.27	Disodium dihydrogen diphosphate (SAPP)	only for pet food'

(c) in point (2), the entries for 'ex 12.1.5 Yeasts' and 'ex 12.1.12 Yeast products' are replaced by the following:

'12.1.5	Yeasts	when not available from organic production
12.1.12	Yeast products	when not available from organic production'

(2) Part B is amended as follows:

(a) in point (1)(c) (Emulsifiers, stabilisers, thickeners and gelling agents), the following entries are added:

'E 407	Carrageenan	only for pet food
E 410	Locust bean gum (Carob gum)	only for pet food obtained only from a roasting process from organic production if available
E 414	Acacia (Gum arabic)	only for pet food from organic production if available'
E 415	Xanthan gum	

(b) in point (1)(d) (Binders and anti-caking agents) the following entries are inserted in the order of the numbers of the codes:

'E 563	Sepiolitic clay	
1g599	Illite-montmorillonite-kaolinite'	

(c) in point (1), a new point (f) and the following entry are added:

'(f) *substances for reduction of the contamination of feed by mycotoxins*

ID number or functional group	Name	Specific conditions and limits
1m558	Bentonite'	

(d) point (3)(a) (Vitamins, pro-vitamins and chemically well-defined substances having similar effect) is amended as follows:

(i) the following entry is inserted after the entry for 'ex3a Vitamins and Provitamins':

'3a370	Taurine	only for cats and dogs not from synthetic origin, if available'
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(ii) the entry for '3a920 Betaine anhydrous' is replaced by the following:

'3a920	Betaine anhydrous	only for monogastric animals and fish from organic production; if not available, from natural origin'
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(e) in point (4) (Zootechnical additives) the following entry is added:

'4d7 and 4d8	Ammonium chloride	only for cats'
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ANNEX IV

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

(1) Section A1 (Food additives, including carriers) is amended as follows:

(a) the entry for 'E 418 Gellan gum' is replaced by the following:

'E 418	Gellan gum	products of plant and animal origin	high-acyl form only only from organic production, applicable as of 1 January 2026'
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(b) the entry for 'E 551 – Silicon dioxide' is replaced by the following:

'E 551	Silicon dioxide	cocoa, herbs and spices in dried powdered form flavourings propolis	for cocoa, only for use in automated dispensing machines'
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(2) in Section A2 (Processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production), the entries for hop extract and pine rosin extract are replaced by the following:

'Hop extract	products of plant origin	only for antimicrobial purposes from organic production, if available'
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'Pine rosin extract	products of plant origin	only for antimicrobial purposes from organic production, if available'
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