



2023/2229

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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2229

of 25 October 2023

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:

- (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 all low-risk substances in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽⁴⁾ from plant or animal origin (not from GMO origin), may be used in organic production without an additional evaluation by EGTOP.
- (3) Sodium hydrogen carbonate is listed in point 1 of Annex I to Implementing Regulation (EU) 2021/1165 as a basic substance that may be used in organic production as a plant protection product. Sodium hydrogen carbonate is also listed in Regulation (EC) No 1107/2009 under low-risk substances in plant protection products. It should therefore also be authorised as a low-risk substance in organic production as a plant protection product.
- (4) Based on recommendations from EGTOP regarding fertilisers, soil conditioners and nutrients³, the entry 'Composted or fermented mixture of household waste' should be replaced by 'Composted or fermented bio-waste' to allow for other sources of bio-waste than household waste to be used for composting or fermenting in organic production.
- (5) In its recommendations with regard to fertilisers, soil conditioners and nutrients EGTOP also confirmed, that the use of selenium salts in case of deficiency of the soils employed for animal rearing and/or grazing is in line with the objectives and principles of organic production. The use of that substance should therefore be authorised.
- (6) Based on recommendations from EGTOP regarding feed and pet food ⁽⁵⁾, the use of the following substances should be authorised: (i) propylene glycol, algal oil and calcium chloride used as feed material; (ii) iron chelate, and iron dextran, copper chelate, manganese chelates, zinc chelates of proteins and selenised yeast as trace elements.

⁽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 (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

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

- (7) Based on recommendations from EGTOP regarding food⁵, the use of the following substances should be authorised:
(i) ascorbic acid on meat preparations to which other ingredients than additives or salt have been added; (ii) lecithins on animal products; and (iii) potassium sodium tartrate on products of plant origin.
- (8) EGTOP further recommended that sodium tartrates, potassium tartrates, and potassium sodium tartrate should be authorised from 1 January 2027 only if they are from organic production⁽⁶⁾, because EGTOP considered the timeframe of three years sufficient to ensure that tartrates from organic origin be available to all operators. The entries 'sodium tartrates' and 'potassium tartrates' should therefore be amended to introduce these specific conditions and limits, and a new entry 'potassium sodium tartrate' should be inserted in the list of 'Food additives, including carriers' of Part A of Annex V to Implementing Regulation (EU) 2021/1165.
- (9) EGTOP has started the evaluation of substances for cleaning and disinfection to be authorised in organic production. However, it appears that this will require more time than was anticipated in Implementing Regulation (EU) 2021/1165. As the lists of products for cleaning and disinfection will not be established before 1 January 2026, Annex VII to Commission Regulation (EC) No 889/2008⁽⁷⁾ should continue to apply until 31 December 2025. The provisions referring to the lists of products for cleaning and disinfection should therefore only apply from 1 January 2026.
- (10) The CAS number for chitosan has been erroneously attributed to chitosan hydrochloride in point 1 (Basic substances) of Annex I to Implementing Regulation (EU) 2021/1165 and the entry for chitosan is therefore missing. These errors need to be corrected.
- (11) Implementing Regulation (EU) 2021/1165 should therefore be amended and corrected accordingly.
- (12) 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) in Article 12(1), the date '31 December 2023' is replaced by '31 December 2025';
- (2) Article 13 is amended as follows:
 - (a) the third paragraph is replaced by the following:
'Article 5(1), (2) and (3) shall apply from 1 January 2026.';
 - (b) the following fourth paragraph is inserted after the third paragraph:
'Article 7 shall apply from 1 January 2024.';
- (3) Annex I is amended in accordance with Annex I to this Regulation;
- (4) Annex II is amended in accordance with Annex II to this Regulation;
- (5) Annex III is amended in accordance with Annex III to this Regulation;
- (6) Annex V is amended in accordance with Annex IV to this Regulation.

⁽⁶⁾ EGTOP final report on Food VIII: 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).

Article 2

Corrections to Implementing Regulation (EU) 2021/1165

Point 1 (Basic substances) of Annex I to Implementing Regulation (EU) 2021/1165 is corrected as follows:

(1) the entry 2C for 'Chitosan hydrochloride' is replaced by the following:

'2C	70694-72-3	Chitosan hydrochloride (*)	obtained from Aspergillus or organic aquaculture or from sustainable fisheries, as defined in Article 2 of Regulation (EU) No 1380/2013 of the European Parliament and of the Council (*)
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(*) Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).;

(2) the following entry is added:

'24C	9012-76-4	Chitosan*	obtained from Aspergillus or organic aquaculture or from sustainable fisheries, as defined in Article 2 of Regulation (EU) No 1380/2013'
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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*.

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

Done at Brussels, 25 October 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

In the table in point 2 (Low risk active substances) of Annex I to Implementing Regulation (EU) 2021/1165, the following entries are added:

(1) after the entry '20D Ferric pyrophosphate':

'24D	144-55-8	Sodium hydrogen carbonate'	
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(2) after the entry '28D Aqueous extract from the germinated seeds of sweet Lupinus albus':

		'Other low risk substances from plant or animal origin *'	Herbicidal uses not allowed'
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ANNEX II

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

(1) the entry for 'Composted or fermented mixture of household waste' is replaced by the following:

'Composted or fermented bio-waste (Directive 2008/98/EC of the European Parliament and of the Council (*)	product obtained from separate bio-waste collection at source, which has been submitted to composting or to anaerobic fermentation for biogas production only vegetable and animal bio-waste only when produced in a closed and monitored collection system, accepted by the Member State maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable
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(*) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).'

(2) the following entry is added after the entry "Potassium chloride (muriate of potash)":

'Selenium salts	only in case of deficiency in the soils used for animal rearing, and/or grazing or for the production of feed crops'
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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), 'FEED MATERIALS OF MINERAL ORIGIN', after the entry '11.1.5 Lithothamn', the following entry is inserted:

'11.1.6	Calcium chloride	<p>restricted to use in accordance with Commission Regulation (EU) 2020/354 (*) as feed intended for particular nutritional purposes: reduction of the risk of milk fever and subclinical hypocalcaemia on dairy cows</p> <p>use restricted as selective application(only for individual animals in need and for a limited period)</p> <p>calcium chloride when purified from naturally occurring brine, if available</p>
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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).;

(b) point (2), 'OTHER FEED MATERIALS' is amended as follows:

(i) before the entry '10 Meal, oil and other feed materials or fish or other aquatic animals' origin', the following entry is added:

'ex 7.1.4	Algal oil	<p>oil obtained by extraction from microalgae through fermentation</p> <p>growing medium for the fermentation process must not be of GMO origin and should be from organic raw materials, if available'</p>
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(ii) after the entry 'ex 12.1.12 yeast products', the following entry is inserted:

'13.11.1	Propylene glycol; [1,2-propanediol]; [propane-1,2-diol]	<p>restricted to use in accordance with Commission Regulation (EU) 2020/354 as feed intended for particular nutritional purposes: reduction of the risk of ketosis</p> <p>on dairy cows, ewes and goats</p> <p>use restricted to selective application (only to individual animals in need and for a limited period)'</p>
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(2) in Part B, point (3)(b) 'Compounds of trace elements' is amended as follows:

(i) after the entry '3b104 Iron (II) sulphate heptahydrate', the following entries are inserted:

'3b107	Iron (II) chelate of protein hydrolysates	from organic soy production, if available
3b110	Iron dextran 10 %	restricted to use in accordance with Commission Regulation (EU) 2020/354 as feed intended for particular nutritional purposes: compensation for insufficient iron availability after birth

		only for suckling piglets growing medium for the fermentation process for dextran must be of non-GMO origin use restricted to selective application (only for piglets in need and for a limited period)
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(ii) after the entry '3b405 Copper (II) sulphate pentahydrate', the following entry is inserted:

'3b407	Copper (II) chelate of protein hydrolysates	from organic soy production, if available'
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(iii) after the entry '3b503 Manganous sulphate, monohydrate', the following entry is inserted:

'3b505	Manganese chelates of protein hydrolysates	from organic soy production, if available'
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(iv) after the entry '3b609 Zinc chloride hydroxide monohydrate', the following entry is inserted:

'3b612	Zinc chelate of protein hydrolysates	from organic soy production, if available'
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(v) after the entry '3b810 Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated', the following entry is inserted:

'3b810i	Selenised yeast <i>Saccharomyces cerevisiae</i> CNCM I-3060, inactivated'	
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ANNEX IV

The table in Section A1 (Food additives, including carriers) of Part A of Annex V to Implementing Regulation (EU) 2021/1165 is amended as follows:

(1) the entry for 'E 300 Ascorbic acid' is replaced by the following:

'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	
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(*) 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 (OJ L 354, 31.12.2008, p. 16).;

(2) the entry for 'E 322 – Lecithins' is replaced by the following:

'E 322*	Lecithins	products of plant origin products of animal origin	only from organic production'
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(3) the entries for 'E 335– Sodium tartrates' and 'E 336 – potassium tartrates' are replaced by the following:

'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'

(4) the following entry is inserted after the entry 'E 336 – potassium tartrates':

'E 337	Potassium sodium tartrate	Products of plant origin	from 1 January 2027, only from organic production'
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