

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/1040

of 16 April 2021

amending Delegated Regulation (EU) 2016/128 as regards the requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 ⁽¹⁾, and in particular Article 11(2) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2016/128 ⁽²⁾ lays down, among other issues, specific requirements on pesticides and the residues thereof, in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children.
- (2) Delegated Regulation (EU) 2016/128 defines residue of pesticides by using the terminology of Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽³⁾.
- (3) However, Article 3(2)(c) of Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁴⁾ provides for a more precise definition of pesticide residues.
- (4) For reasons of legal certainty and clarity, it is necessary to align the definition of a pesticide residue contained in Delegated Regulation (EU) 2016/128 with the definition contained in Article 3(2)(c) of Regulation (EC) No 396/2005.
- (5) Taking into account that the residue definitions for active substances should apply as defined in Regulation (EC) No 396/2005, it is appropriate to include only the parent compounds of the active substances in the lists set out in Annexes II and III to Delegated Regulation (EU) 2016/128, in view of future amendments to Regulation (EC) No 396/2005.

⁽¹⁾ OJ L 181, 29.6.2013, p. 35.

⁽²⁾ Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes (OJ L 25, 2.2.2016, p. 30).

⁽³⁾ 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).

⁽⁴⁾ 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).

(6) Delegated Regulation (EU) 2016/128 should therefore be amended accordingly.

HAS ADOPTED THIS REGULATION:

Article 1

Article 3, paragraph 1, of Delegated Regulation (EU) 2016/128 is replaced by the following:

‘1. For the purposes of this Article, ‘residue’ means pesticide residue as referred to in point (c) of Article 3(2) of Regulation (EC) No 396/2005.’.

Article 2

Annexes II and III to Delegated Regulation (EU) 2016/128 are amended in accordance with the Annex to this Regulation.

Article 3

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, 16 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes II and III to Delegated Regulation (EU) 2016/128 are amended as follows:

(1) Annex II is replaced by the following:

'ANNEX II

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 3(3)

Chemical name of the parent compound of the substance ¹	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl Demeton-S-methyl sulfone	0,006
Oxydemeton-methyl	
Ethoprophos	0,008
Fipronil	0,004
Propineb	0,006'

(2) Annex III is replaced by the following:

'ANNEX III

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 3(4)

Chemical name of the parent compound of the substance ⁽¹⁾
Aldrin
Dieldrin
Disulfoton
Endrin
Fensulfothion
Fentin
Haloxypop
Heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos'

(¹) The most updated residue definition applies as set out in the relevant Annexes II, III, IV or V to Regulation (EC) No 396/2005 (the residue definition is mentioned in brackets behind the parent compound of the substance).