



Brussels, **XXX**
SANTE/12694/2020
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[...] (2021) **XXX** draft

COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

amending Delegated Regulation (EU) No 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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 11(2) of 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 control¹ empowers the European Commission to adopt delegated acts in order to update the delegated acts adopted pursuant to Article 11(1) of that Regulation, namely, amongst other acts, Commission Delegated Regulation (EU) No 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 purposes².

This delegated Regulation aims to amend Delegated Regulation (EU) No 2016/128 by aligning the definition of a pesticide residue laid down in that Regulation with the more detailed definition provided for in 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.³

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States' experts were consulted within the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control⁴, which met on the subject on 25 September 2019⁵. Member States' experts were also consulted within the Expert Working Group on Pesticides Residues Monitoring, which met on the subject on 14 October 2019. Member States strongly supported the proposed alignment of the definition of a pesticide residue laid down in Delegated Regulation (EU) 2016/128 with the definition provided for in Article 3(2)(c) of Regulation (EC) No 396/2005.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis of this delegated Regulation is Article 11(2) of Regulation (EU) No 609/2013. Pursuant to that provision, the Commission is empowered to adopt delegated acts in order to update the Delegated acts adopted pursuant to Article 11(1) of that Regulation, such as Delegated Regulation (EU) No 2016/128, subject to the general requirements set out in Articles 6 and 9 of the same Regulation, to the additional requirements of Article 10, and taking into account relevant technical and scientific progress.

¹ 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 (OJ L 181, 29.6.2013, p. 35).

² OJ L 25, 2.2.2016, p. 30.

³ 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).

⁴ Reference E02893 in the Register of Commission Expert Groups and other similar entities.

⁵ https://ec.europa.eu/food/sites/food/files/safety/docs/labelling-nutrition_expert-group_20190925_sum.pdf

The proposed amendments to Delegated Regulation (EU) No 2016/128 relate to the fact that Article 3(2)(c) of Regulation (EC) No 396/2005 provides for a more precise definition of pesticide residues, specifying in addition that they may result from active substances currently or formerly used in plant protection products and that they may arise as a result of use in plant protection, veterinary medicine and as biocides.

For reasons of legal certainty and clarity, it is necessary to bring the definition laid down in Delegated Regulation (EU) No 2016/128 in line with the more precise definition provided for in Regulation (EC) No 396/2005. Furthermore, in view of future Implementing Regulations amending the Annexes to Regulation (EC) No 396/2005, and 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) No 2016/128.

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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 953/2009⁶, and in particular Article 11(2) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2016/128⁷ 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 Council⁸.
- (3) However, Article 3(2)(c) of Regulation (EC) No 396/2005 of the European Parliament and of the Council⁹ 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

⁶ OJ L 181, 29.6.2013, p. 35.

⁷ 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).

⁸ 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).

⁹ 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).

Delegated Regulation (EU) No 2016/128, in view of future amendments to Regulation (EC) No 396/2005.

(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) No 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) No 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,

For the Commission

The President

Ursula VON DER LEYEN



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ANNEX 1

ANNEX

to the

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ANNEX [...]

Annexes II and III to Delegated Regulation (EU) No 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 substance¹	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl Demeton-S-methyl sulfone Oxydemeton-methyl	0,006
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 substance¹
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).