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**[...]**(2025) **XXX** draft

ANNEXES 1 to 2

## **ANNEXES**

**to the**

**COMMISSION REGULATION (EU) .../...**

**amending Annexes II and III to Regulation (EC) No 1333/2008 of the European  
Parliament and of the Council as regards foods intended for particular nutritional uses**

## ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

1. in Part A, table 1, entry 12 is replaced by the following:

‘12	Dry pasta, excluding gluten-free pasta (as food specially produced to reduce the gluten content of gluten-containing ingredients or substitute the gluten-containing ingredients), and pasta intended for hypoproteic diets’
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2. in Part A, table 2, entry 30 is replaced by the following:

‘30	Milk-based drinks and similar products intended for young children* and foods for infants and young children as mentioned in Regulation (EU) No 609/2013, including foods for special medical purposes for infants and young children
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\* Category of products established for the sole purpose of regulating the use of additives in the concerned food.’;

3. in Part D, the following entry is inserted after the entry for category 01.9 (Edible caseinates):

‘01.10	Milk-based drinks and similar products intended for young children*
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\* Category of products established for the sole purpose of regulating the use of additives in the concerned food.’;

4. in Part D, the entries for category 13 (Foods intended for particular nutritional uses as defined by Directive 2009/39/ EC) and its subcategories are replaced by the following:

‘13.	<b>Foods intended for specific groups as defined by Regulation (EU) No 609/2013</b>
13.1	Foods for infants and young children
13.1.1	Infant formulae as defined by Regulation (EU) No 609/2013
13.1.2	Follow-on formulae as defined by Regulation (EU) No 609/2013
13.1.3	Processed cereal-based foods and baby foods as defined by Regulation (EU) No 609/2013
13.1.5	Foods for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for infants and young children
13.1.5.1	Foods for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for infants

13.1.5.2	Foods for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for young children
13.2	Foods for special medical purposes as defined by Regulation (EU) No 609/2013 (excluding products from food category 13.1.4)
13.3	Total diet replacement for weight control food as defined by Regulation (EU) No 609/2013'

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5. in Part D, the entry for category 18 (Processed foods not covered by categories 1 to 17, excluding foods for infants and young children) is replaced by the following:

<b>'18.</b>	<b>Processed foods not covered by categories 1 to 17</b>
18.1	Processed foods not covered by categories 18.2 and 18.3, excluding foods for infants and young children
18.2	Meal replacement for weight control as referred to in Commission Regulation (EU) No 432/2012*
18.3	Foods specially produced to reduce the gluten content of gluten-containing ingredients or substitute the gluten-containing ingredients

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\* OJ L 136, 25.5.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/432/oj>.';

6. in Part E, the following entry is inserted after the entry for category 01.9 (Edible caseinates):

<b>'01.10</b>	<b>Milk-based drinks and similar products intended for young children*</b>				
	The maximum levels of use indicated refer to foods ready for consumption prepared following manufacturers' instructions				
	Note: For the manufacture of acidified milks, non-pathogenic L(+)-lactic acid producing cultures may be used				
	E 270	Lactic acid	<i>quantum satis</i>		only L(+)-form
	E 304(i)	L-ascorbyl palmitate	100	(19)	
	E 306	Tocopherol-rich extract	100	(19)	
	E 307	Alpha-tocopherol	100	(19)	
	E 308	Gamma-	100	(19)	

		tocopherol			
	E 309	Delta-tocopherol	100	(19)	
	E 322	Lecithins	10 000	(14)	
	E 330	Citric acid	<i>quantum satis</i>		
	E 331	Sodium citrates	2 000		
	E 332	Potassium citrates	<i>quantum satis</i>		
	E 338	Phosphoric acid		(1) (4)	
	E 339	Sodium phosphates	1 000	(1) (4)	
	E 340	Potassium phosphates	1 000	(1) (4)	
	E 407	Carrageenan	300		
	E 410	Locust bean gum	10 000	(21)	
	E 412	Guar gum	10 000	(21)	
	E 414	Gum arabic (acacia gum)	10 000	(21)	
	E 415	Xanthan gum	10 000	(21)	
	E 440	Pectins	5 000	(21)	
	E 471	Mono- and diglycerides of fatty acids	4 000	(14)	
	E 472c	Citric acid esters of mono- and diglycerides of fatty acids	7 500	(14)	only when sold as powder
	E 472c	Citric acid esters of mono- and diglycerides of fatty acids	9 000	(14)	only when sold as liquid where the products contain partially hydrolysed proteins, peptides or

					amino acids
	E 473	Sucrose esters of fatty acids	120	(14)	only in products containing hydrolysed proteins, peptides or amino acids
	E 500	Sodium carbonates	<i>quantum satis</i>		
	E 501	Potassium carbonates	<i>quantum satis</i>		
	E 503	Ammonium carbonates	<i>quantum satis</i>		
	E 507	Hydrochloric acid	<i>quantum satis</i>		only for pH adjustment
	E 524	Sodium hydroxide	<i>quantum satis</i>		only for pH adjustment
	E 525	Potassium hydroxide	<i>quantum satis</i>		only for pH adjustment
	E 1404	Oxidized starch	50 000		
	E 1410	Monostarch phosphate	50 000		
	E 1412	Distarch phosphate	50 000		
	E 1413	Phosphated distarch phosphate	50 000		
	E 1414	Acetylated distarch phosphate	50 000		
	E 1420	Acetylated starch	50 000		
	E 1422	Acetylated distarch adipate	50 000		
	E 1450	Starch sodium octenyl	50 000		

		succinate			
		(1): The additives may be added individually or in combination			
		(4): The maximum level is expressed as P <sub>2</sub> O <sub>5</sub>			
		(14): If more than one of the substances E 322, E 471, E 472c and E 473 are added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present in with the other substances together in that foodstuff			
		(16): E 304, E 306, E 307, E 308 and E 309 are authorised individually or in combination			
		(21): E 410, E 412, E 414, E 415 and E 440 are authorised individually or in combination			

\* Category of products established for the sole purpose of regulating the use of additives in the concerned food.’;

7. in Part E, the entry for category 06.4.2 (Dry pasta) is replaced by the following:

<b>‘06.4.2 Dry pasta</b>					
	Group I	Additives			only gluten-free pasta (as food specially produced to reduce the gluten content of gluten-containing ingredients or substitute the gluten-containing ingredients) and pasta intended for hypoproteic diets’

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8. in Part E, the heading of category 13 (Foods intended for particular nutritional uses as defined by Directive 2009/39/EC) is replaced by the following:

<b>‘13</b>	<b>Foods intended for specific groups as defined by Regulation (EU) No 609/2013’</b>
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9. in Part E, the entry for category 13.1 (Foods for infants and young children) is replaced by the following:

<b>‘13.1</b>	<b>Foods for infants and young children</b>
	INTRODUCTION PART, APPLIES TO ALL SUBCATEGORIES
	The maximum levels of use indicated refer to foods ready for consumption prepared following manufacturers’ instructions
	E 307, E 325, E 330, E 331, E 332, E 333, E 338, E 340, E 410, E472c and E 1450 shall be used in conformity with the limits set in the Annex to Regulation (EU) No

	609/2013, in the Annexes to Commission Delegated Regulation (EU) 2016/127*, in the Annexes to Commission Delegated Regulation (EU) 2016/128** and in the Annexes to Commission Directive 2006/125/EC***
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\* OJ L 25, 2.2.2016, p. 1, ELI: [http://data.europa.eu/eli/reg\\_del/2016/127/oj](http://data.europa.eu/eli/reg_del/2016/127/oj).

\*\* OJ L 25, 2.2.2016, p. 30, ELI: [http://data.europa.eu/eli/reg\\_del/2016/128/oj](http://data.europa.eu/eli/reg_del/2016/128/oj).

\*\*\* OJ L 339, 6.12.2006, p. 16, ELI: <http://data.europa.eu/eli/dir/2006/125/oj>.’;

10. in Part E, the heading of category 13.1.1 (Infant formulae as defined by Directive 2006/141/EC) is replaced by the following:

<b>‘13.1.1</b>	<b>Infant formulae as defined by Regulation (EU) No 609/2013’</b>
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11. in Part E, footnote (15) to categories 13.1.1 and 13.1.2 is replaced by the following:

‘(15): E 339 and E 340 are authorised individually or in combination and in conformity with the limits set in the Annex to Regulation (EU) No 609/2013, in the Annexes to Delegated Regulation (EU) 2016/127, in the Annexes to Delegated Regulation (EU) 2016/128 and in the Annexes to Directive 2006/125/EC’

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12. in Part E, footnote (43) to categories 13.1.1 and 13.1.2 is replaced by the following:

‘(43): E 331 and E 332 are authorised individually or in combination and in conformity with the limits set in the Annex to Regulation (EU) No 609/2013, in the Annexes to Delegated Regulation (EU) 2016/127, in the Annexes to Delegated Regulation (EU) 2016/128 and in the Annexes to Directive 2006/125/EC’

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13. in Part E, footnote (44) to categories 13.1.1 and 13.1.2 is replaced by the following:

‘(44): In conformity with the limits set in the Annex to Regulation (EU) No 609/2013, in the Annexes to Delegated Regulation (EU) 2016/127, in the Annexes to Delegated Regulation (EU) 2016/128 and in the Annexes to Directive 2006/125/EC’

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14. in Part E, the heading of category 13.1.2 (Follow-on formulae as defined by Directive 2006/141/EC) is replaced by the following:

<b>‘13.1.2</b>	<b>Follow-on formulae as defined by Regulation (EU) No 609/2013’</b>
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15. in Part E, the heading of category 13.1.3 (Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC) is replaced by the following:

<b>‘13.1.3</b>	<b>Processed cereal-based foods and baby foods as defined by Regulation (EU) No 609/2013’</b>
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16. in Part E, the entry for category 13.1.4 (Other foods for young children) is deleted;
17. in Part E, the heading of category 13.1.5 (Dietary foods for infants and young children for special medical purposes as defined by Directive 1999/21/EC and special formulae for infants) is replaced by the following:

<b>‘13.1.5</b>	<b>Foods for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for infants and young children’</b>
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18. in Part E, the heading of category 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants) is replaced by the following:

<b>‘13.1.5.1</b>	<b>Foods for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for infants’</b>
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19. in Part E, the heading of category 13.1.5.2 (Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC) is replaced by the following:

<b>‘13.1.5.2</b>	<b>Foods for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for young children’</b>
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20. in Part E, the heading of category 13.2 (Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)) is replaced by the following:

<b>‘13.2</b>	<b>Foods for special medical purposes as defined by Regulation (EU) No 609/2013 (excluding products from food category 13.1.5)’</b>
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21. in Part E, the heading of category 13.3 (Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)) is replaced by the following:

<b>‘13.3</b>	<b>Total diet replacement for weight control food as defined by Regulation (EU) No 609/2013’</b>
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22. in Part E, the entry for category 18 (Processed foods not covered by categories 1 to 17, excluding foods for infants and young children) is replaced and new entries for categories 18.1 to 18.3 are inserted as follows:



<b>18</b>	<b>Processed foods not covered by categories 1 to 17</b>				
<b>18.1</b>	<b>Processed foods not covered by categories 18.2 and 18.3, excluding foods for infants and young children</b>				
	Group I	Additives			
<b>18.2</b>	<b>Meal replacement for weight control as referred to in Regulation (EU) No 432/2012</b>				
	Group I	Additives			
	Group II	Colours at <i>quantum satis</i>	<i>quantum satis</i>		
	Group III	Colours with combined maximum limit	50		
	Group IV	Polyols	<i>quantum satis</i>		
	E 104	Quinoline Yellow	10	(61)	
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(61)	
	E 124	Ponceau 4R, Cochineal Red A	10	(61)	
	E 160d	Lycopene	30		
	E 200-213	Sorbic acid – potassium sorbate; Benzoic acid – benzoates	1 500	(1) (2)	
	E 338-452	Phosphoric acid — phosphates — di-, tri- and polyphosphates	5 000	(1) (4)	
	E 405	Propane-1, 2-diol alginate	1 200		
	E 432-	Polysorbates	1 000	(1)	

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	E 473-474	Sucrose esters of fatty acids — sucroglycerides	5 000	(1)	
	E 475	Polyglycerol esters of fatty acids	5 000		
	E 477	Propane-1,2-diol esters of fatty acids	1 000		
	E 481-482	Stearoyl-2-lactylates	2 000	(1)	
	E 491-495	Sorbitan esters	5 000	(1)	
	E 950	Acesulfame K	450		
	E 951	Aspartame	800		
	E 952	Cyclamic acid and its Na and Ca salts	400	(51)	
	E 954	Saccharin and its Na, K and Ca salts	240	(52)	
	E 955	Sucralose	320		
	E 959	Neohesperidine DC	100		
	E 960a – 960d	Steviol glycosides	270	(1) (60)	
	E 961	Neotame	26		
	E 962	Salt of aspartame-acesulfame	450	(11)a (49) (50)	
	E 960	Advantame	8		
		(1): The additives may be added individually or in combination			
		(2): The maximum level is applicable to the sum and the levels are			

		expressed as the free acid			
		(4): The maximum level is expressed as P <sub>2</sub> O <sub>5</sub>			
		(11): Limits are expressed as (a) acesulfame K equivalent or (b) aspartame equivalent			
		(49): The maximum usable levels are derived from the maximum usable levels for its constituent parts, aspartame (E 951) and acesulfame-K (E 950)			
		(50): The levels for both E 951 and E 950 are not to be exceeded by use of the salt of aspartame-acesulfame, either alone or in combination with E 950 or E 951			
		(51): Maximum usable levels are expressed in free acid			
		(52): Maximum usable levels are expressed in free imide			
		(60): Expressed as steviol equivalents			
		(61): The total quantity of E 104, E 110, E 124 and the colours in Group III shall not exceed the maximum listed for Group III			
‘18.3	Foods specially produced to reduce the gluten content of gluten-containing ingredients or substitute the gluten-containing ingredients’				
	The maximum levels of use indicated refer to foods ready for consumption prepared following manufacturers’ instructions				
	Group I	Additives			Including dry pasta
	Group II	Colours at <i>quantum satis</i>	<i>quantum satis</i>		
	Group IV	Polyols	<i>quantum satis</i>		
	E 338-452	Phosphoric acid — phosphates — di-, tri- and polyphosphates	5 000	(1) (4)	
	In addition, all additives in the gluten containing counterparts are authorised				
		(1): The additives may be added individually or in combination			
		(4): The maximum level is expressed as P <sub>2</sub> O <sub>5</sub> ’			

## ANNEX II

Annex III to Regulation (EC) No 1333/2008 is amended as follows:

1. in the definitions, point 1 is replaced by the following:

‘1. “nutrients” for the purposes of this Annex means vitamins, minerals and other substances added for nutritional purposes, as well as substances added for physiological purposes as covered by Regulation (EC) No 1925/2006 of the European Parliament and of the Council\*, Directive 2002/46/EC and Regulation (EU) No 609/2013.

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\* OJ L 404, 30.12.2006, p. 26, ELI: <http://data.europa.eu/eli/reg/2006/1925/oj>.’;

2. in Part 5, Section A, the introductory wording is replaced by the following:

‘Food additives added in nutrients except in nutrients intended to be used in foodstuffs listed in Part E, point 01.10, of Annex II and foodstuffs for infants and young children listed in Part E, point 13.1, of Annex II.’;

3. in Part 5, Section B, the introductory wording is replaced by the following:

‘Food additives added in nutrients intended to be used in foodstuffs listed in Part E, point 01.10, of Annex II and foodstuffs for infants and young children listed in Part E, point 13.1, of Annex II.’;

4. in Part 5, Section B, the table is replaced by the following:

<b>‘E number of the food additive</b>	<b>Name of the food additive</b>	<b>Maximum level</b>	<b>Nutrient to which the food additive may be added</b>	<b>Food category</b>
E 301	Sodium ascorbate	100 000 mg/kg in vitamin D preparation and 1 mg/l maximum carry-over in final food	Vitamin D preparations	Infant formulae and follow-on formulae as defined by Regulation (EU) No 609/2013
		50 000 mg/kg in microencapsulated vitamin A preparation and 1 mg/l maximum carry-over in final food	Microencapsulated vitamin A preparations	Infant formula and follow-on formula as defined by Regulation (EU) No 609/2013

		Total carry-over 75 mg/l	Coatings of nutrient preparations containing polyunsaturated fatty acids	Foods for infants and young children, and foods mentioned in Part E, point 01.10, of Annex II
E 304(i)	Ascorbyl palmitate	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded	All nutrients	Foods for infants and young children, and foods mentioned in Part E, point 01.10, of Annex II
E 306 E 307 E 308 E 309	Tocopherol-rich extract Alpha-tocopherol Gamma-tocopherol Delta-tocopherol	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded	All nutrients	Foods for infants and young children, and foods mentioned in Part E, point 01.10, of Annex II
E 322	Lecithins	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded	All nutrients	Foods for infants and young children, and foods mentioned in Part E, point 01.10, of Annex II
E 330	Citric acid	<i>quantum satis</i>	All nutrients	Foods for infants and young children, and foods mentioned in Part E, point 01.10, of Annex II

E 331	Sodium citrates	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded and the conditions of use specified therein are respected	All nutrients	Foods for infants and young children and foods mentioned in Part E, point 01.10, of Annex II
E 332	Potassium citrates	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded and the conditions of use specified therein are respected	All nutrients	Food for infants and young children and foods mentioned in Part E, point 01.10, of Annex II
E 333	Calcium citrates	Total carry-over 0,1 mg/kg expressed as calcium and within the limit of calcium level and calcium/phosphorus ratio as set for the food category	All nutrients	Foods for infants and young children, and foods mentioned in Part E, point 01.10, of Annex II
E 341(iii)	Tricalcium phosphate	Maximum carry-over of 150 mg/kg expressed as P <sub>2</sub> O <sub>5</sub> and within the limit for calcium, phosphorus, and the calcium:phosphorus ratio as set in Delegated Regulation (EU) 2016/127	All nutrients	Infant formulae and follow-on formulae as defined by Regulation (EU) No 609/2013
		Maximum level of 1 000 mg/kg expressed as P <sub>2</sub> O <sub>5</sub> from all uses in final food mentioned in Part E, point 13.1.3, of Annex II is respected	All nutrients	Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013

E 401	Sodium alginate	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in point 13.1.3 of Part E of Annex II is not exceeded	All nutrients	Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013
E 402	Potassium alginate	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded	All nutrients	Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013
E 404	Calcium alginate	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in point 13.1.3 of Part E of Annex II is not exceeded	All nutrients	Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013
E 414	Gum arabic (acacia gum)	150 000 mg/kg in the nutrient preparation and 10 mg/kg carry-over in final product	All nutrients	Foods for infants and young children, and foods mentioned in Part E, point 01.10, of Annex II
E 415	Xanthan gum	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in point 13.1.3 of Part	All nutrients	Processed cereal-based foods and baby foods

		E of Annex II is not exceeded		for infants and young children as defined by Regulation (EU) No 609/2013
E 421	Mannitol	1 000 times more than vitamin B12, 3 mg/kg total carry-over	As carrier for vitamin B12	Foods for infants and young children, and foods mentioned in Part E, point 01.10, of Annex II
E 440	Pectins	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded	All nutrients	Follow-on formulae and processed cereal-based foods and baby foods for infants and young children as defined Regulation (EU) No 609/2013
E 466	Sodium carboxy methyl cellulose, cellulose gum	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded  Only until 26 April 2027*	All nutrients	Food for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for infants and young children
E 471	Mono- and diglycerides of fatty acids	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded and the conditions of	All nutrients	Foods for infants and young children and foods mentioned in



		use specified therein are respected		Part E, point 01.10, of Annex II
E 472c	Citric acid esters of mono- and diglycerides of fatty acids	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in Part E, points 01.10 and 13.1, of Annex II is not exceeded	All nutrients	Infant formulae and follow-on formulae for infants and young children in good health
E 551	Silicon dioxide	10 000 mg/kg in nutrient preparations	Dry powdered nutrient preparations	Foods for infants and young children and foods mentioned in Part E, point 01.10, of Annex II
E 1420	Acetylated starch	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in point 13.1.3 of Part E of Annex II is not exceeded	All nutrients	Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013
E 1450	Starch sodium octenyl succinate	Carry-over 100 mg/kg	Vitamin preparations	Foods for infants and young children and foods mentioned in Part E, point 01.10, of Annex II
		Carry-over 1 000 mg/kg	Polyunsaturated fatty acid preparations	
E 1451	Acetylated oxidised starch	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in point 13.1.3 of Part E of Annex II is not exceeded	All nutrients	Processed cereal-based foods and baby foods for infants and young

				children as defined by Regulation (EU) No 609/2013'
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\* OJ L, 2025/666, 7.4.2025, ELI: <http://data.europa.eu/eli/reg/2025/666/oj>.'.