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To:	General Secretariat of the Council

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Subject:	ANNEXES to the Commission Regulation (EU) .../... amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of carbomer in food supplements

Delegations will find attached document D084677/02 ANNEXES 1 to 2.

Encl.: D084677/02 ANNEXES 1 to 2



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ANNEXES 1 to 2

ANNEXES

to the

Commission Regulation (EU) .../...

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of carbomer in food supplements

ANNEX I

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

- (a) in Part B, point 3 ‘Additives other than colours and sweeteners’, the following entry is inserted after the entry for food additive E 1209:

‘E 1210	Carbomer’;
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- (b) Part E is amended as follows:

- (1) in food category 17.1 ‘Food supplements supplied in a solid form, excluding food supplements for infants and young children’, the following entry is inserted after the entry for food additive E 1209:

	‘E 1210	Carbomer	200 000’;		
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- (2) in food category 17.2 ‘Food supplements supplied in a liquid form, excluding food supplements for infants and young children’, the following entry is inserted after the entry for food additive E 969:

	‘E 1210	Carbomer	30 000’.		
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ANNEX II

In the Annex to Regulation (EU) No 231/2012 the following entry is inserted after the entry for E 1209:

‘E 1210 CARBOMER

Synonyms	carbomer, carboxypolymethylene; carbomer homopolymer		
Definition	High-molecular mass polymers obtained by polymerisation of acrylic acid and crosslinking with allyl pentaerythritol. The polymers are synthesised in ethyl acetate using a peroxide to initiate free-radical polymerisation.		
CAS No	9007-20-9 (primary CAS), 9003-01-4 (secondary CAS)		
Chemical name	Carbomer homopolymer, allyl pentaerythritol cross-linked		
Chemical formula	$-(\text{CH}_2\text{-CH})_m\text{-(XM)}_p$ COOH		
	m: number of monomer units; XM: crosslinker, p: number of crosslinker units, with m>>p		
Weight average molecular weight			
Assay	Carboxylic acid content not less than 56% and not more than 68% (on dried substance)		
Description	White or almost white, fluffy, hygroscopic powder or granules		
Identification			
Attenuated total reflective infra-red spectroscopy Proton nuclear magnetic resonance spectroscopy	Characteristic of the compound		
Viscosity (Brookfield viscosimetry, 20 rpm) 25 °C	Type B	Type A	Type A
	29 400-39 400 mPa.s	4 000-11 000 mPa.s	
Physical form	powder	powder	granules
Pass through 40 mesh, % 425 µm	-	-	95 min
Pass through 100 mesh, % 150 µm	-	-	10 max

Solubility	Insoluble in water. Water-swellable and forms hydrogels in aqueous dispersions.
Purity	
Residual monomers	Acrylic acid not more than 100 mg/kg
Residual crosslinker	tri and tetra-allyl pentaerythritol not more than 1000 mg/kg
Residual solvent	Ethyl acetate not more than 0,5% w/w
2-ethylhexanol	not more than 100 mg/kg
2-ethylhexylacetate	not more than 100 mg/kg
Lower molecular weight fraction <1000 Da	Not more than 0,75% w/w
Loss on drying	Not more than 2%
Sulphated ashes	Not more than 2,5%

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