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EN

ANNEX

(1) In Table 1 (Authorised novel foods) the following entry is inserted: [*OP, please insert in the EN version in alphabetical order.*]

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
L-alpha-glycerylphosphorylcholine (L-alpha-GPC)	Specified food category	Maximum levels	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘L-alpha-glycerylphosphorylcholine (L-alpha-GPC)’ or ‘L-alpha-glycerylphosphorylcholine’ 2. The labelling of food supplements containing the novel food shall bear a statement that the food supplements should not be consumed by children below 3 years of age.		Authorised on [...][<i>OP please insert the date dd.mm.yyyy - 20th day following its publication</i>]. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Chemi S.p.A., Via dei Laboratori 54, 20092 Milano, Italy. During the period of data protection, the novel food L-alpha-glycerylphosphorylcholine (L-alpha-GPC) is authorised for placing on the market within the Union only by Chemi S.p.A., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary
	Food supplements as defined in Directive 2002/46/EC for the general population, excluding food supplements for infants and young children	203.7 mg/day of GPC 100%, providing 203.7 mg of L-alpha-GPC, corresponding to an intake of 82.5 mg of choline per day. 239.65 mg/day of GPC 85%, providing 203.7 mg of L-alpha-GPC 82.5 mg of choline per day.			

					scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Chemi S.p.A. End date of the data protection: [...][<i>OP please insert the date dd.mm.yyyy – after 5 years</i>]
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(2) in Table 2 (Specifications), the following entry is inserted: [OP, please insert in the EN version in alphabetical order.]

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Authorised Novel Food	Specifications
L-alpha-glycerolphosphorylcholine (L-alpha-GPC)	Description/Definition: The novel food is a water-soluble substance obtained from the phosphatidylcholine (PC)-enriched fraction of soybean lecithin (to about 35% phosphorylcholine) sourced from non-genetically modified soy plant cultivars. It is available in two different forms of L-alpha-GPC: a viscous liquid GPC 85% and a powder Alpha Size 100P, containing 85% and 100% of the novel food, respectively. Chemical identity: Chemical (IUPAC) name: Ethanaminium, 2-[[[(2R)-2,3-dihydroxypropoxy]hydroxyphosphinyl]oxy]-N,N,N-trimethyl-, inner salt Common name: L-alpha-glycerolphosphorylcholine Synonyms, trade names, abbreviations: L-alpha-glyceryl phosphorylcholine, D-choline hydroxide 2,3-dihydroxypropylhydrogen phosphate inner salt, sn-glycero-3-phosphorylcholine, sn-glycero-3-phosphocholine, L-α-GPC, L-alpha-glycerolphosphorylcholine, L-α-glycerolphosphorylcholine, glyceryl phosphoryl choline, glycerophosphorylcholine, glycerophosphocholine, choline glycerophosphate, α-Glycerolphosphorylcholine, AGPC, A GPC GPC, GPC 85% (contains 85% of L-alpha-GPC), Alpha Size 100P (contains 100% of L-alpha-GPC) CAS Number: 28319-77-9 Molecular formula: C₈H₂₀NO₆P Molecular weight: 257.2 Da GPC 85%: Description: Highly viscous liquid of semisolid mass obtained by chemical synthesis from soy lecithin. Solubility: Highly soluble in water and ethyl alcohol. Water content (K.F.): 14% to 16%

	GPC 100%: Description: White to off-white crystalline powder obtained by chemical synthesis from soy lecithin. Solubility: Highly soluble in water. Water content (K.F.): $\leq 1\%$ GPC 85% and 100%: Specific optical rotation (20°C, 589.3 nm): -2.4° to -2.8° on dry basis L-alpha GPC content by titration (assay): 98%–102% on dry basis pH: 5.0–7.0 (10% w/v solution in water) Heavy metals: Total arsenic: < 0.1 mg/kg Anions content: Sulphate: ≤ 200 mg/kg Chloride: ≤ 200 mg/kg Free phosphate: ≤ 50 mg/kg Acetates: ≤ 1000 mg/kg Impurities: Sucrose: $\leq 0.10\%$ GPE: $\leq 0.10\%$ Pinitol: $\leq 0.10\%$ Beta-GPC: $\leq 0.10\%$ Total impurities: $\leq 0.5\%$ Glycerol: $\leq 0.5\%$ Residual solvents:
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	Methanol: ≤ 10 mg/kg Butanol: ≤ 10 mg/kg Ethanol: N/A for GPC 85%; ≤ 50 mg/kg for Alpha size 100 P n-Hexane: N/A for GPC 85%; ≤ 5 mg/kg for Alpha size 100 P Microbiological parameters: TAMC: ≤ 1000 (CFU/g) TYMC: ≤ 100 (CFU/g) <i>Escherichia coli</i>: Not detected in 10 g <i>Salmonella</i> spp: Not detected in 25 g <i>Staphylococcus aureus</i>: Not detected in 10 g Coliforms: Not detected in 10 g GPE: glycerylphosphorylethanolamine; CFU: colony forming units; TAMC: total aerobic microbial count; TYMC: total yeast and mould count; MPN: most probable number
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