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ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) The following last column is added in Table 1 (Authorised novel foods):

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Data protection

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(2) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

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Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	Specified food category	Maximum levels			
Cranberry extract powder	Food Supplements as defined in Directive 2002/46/EC for the adult population	350 mg/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be "cranberry extract powder"		Authorised on dd.mm.yyyy (20th day following its publication). This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Ocean Spray Cranberries Inc. One Ocean Spray Drive Lakeville-Middleboro, MA, 02349, USA. During the period of data protection the novel food, cranberry extract powder, is

					authorised for placing on the market within the Union only by Ocean Spray Cranberries Inc. unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Ocean Spray Cranberries Inc. End date of the data protection: dd.mm.yyyy (5 years).
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(3) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

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Authorised Novel Food	Specification
Cranberry extract powder	Description/Definition: Cranberry extract powder is a water-soluble phenolic-rich powder extract prepared through an ethanolic extraction from the juice concentrate of sound, mature berries of the cranberry cultivar <i>Vaccinium macrocarpon</i>. Characteristics/Composition Moisture (% w/w): ≤ 4 Proanthocyanidins - PACs (% w/w dry weight) - OSC-DMAC method(1),(3): 55.0-60.0 or - BL-DMAC method(2),(3): 15.0-18.0 Total phenolics (GAE(4), % w/w dry weight)(3) - Folin-Ciocalteu method: > 46.2 Solubility (water): 100%, with no visible insoluble particles Ethanol Content (mg/kg): ≤ 100 Screen Analysis: 100% through 30 mesh screen Appearance and aroma, as powder: Free-flowing, deep red colour. Earthy aroma with no burnt character. Heavy metals: Arsenic (ppm): < 3 Microbiological criteria: Yeast: < 100 CFU(5)/g Mould: < 100 CFU/g Aerobic plate count: < 1000 CFU/g

	Coliforms: < 10 CFU/g <i>Escherichia coli</i> : < 10 CFU/g <i>Salmonella</i> : Absent in 375 g
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- (1) OS DMAC (4-dimethylaminocinnamaldehyde) method (Ocean Spray Cranberries, Inc)
Martin MA, Ramos S, Mateos R, Marais JPJ, Bravo-Clemente, L, Khoo C and Goya L. Food Res Intl 2015 71: 68-92.
Modified from Cunningham DG, Vannozzi S, O'Shea E, Turk R (2002) In: Ho C-T, Zheng QY (eds) Quality Management of Nutraceuticals ACS Symposium series 803, Washington DC. *Quantitation of PACs by DMAC Color Reaction* pp 151-166.
- (2) BL-DMAC 4-dimethylaminocinnamaldehyde) method (Brunswick Lab)
Multi-laboratory validation of a standard method for quantifying proanthocyanidins in cranberry powders. Prior RL, Fan E, Ji H, Howell A, Nio C, Payne MJ, Reed J. *J Sci Food Agric*. 2010 Jul;90(9):1473-8.
- (3) The different values for these three parameters are due to the different methods used.
- (4) GAE: Gallic Acid Equivalents
- (5) CFU: Colony Forming Units