

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

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ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:  
In Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Haematococcus pluvialis algal powder containing astaxanthin'	Specified food category	Maximum levels (expressed as mg astaxanthin/100 g or 100 mL	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Haematococcus pluvialis algal powder'  The labelling of foods containing Haematococcus	
	Dairy analogues, including beverage whiteners	0.75		

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	Fruit beverages, except products defined in Part I of Annex I to Directive 2001/112/EC	0.25	<i>pluvialis</i> algal powder shall bear a statement that the foods should not be consumed if food supplements containing astaxanthin esters are consumed on the same day by from 3 years and older, and adolescents under 18 years of age.	
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(1) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

Authorised Novel Food	Specification
' <i>Haematococcus pluvialis</i> algal powder containing astaxanthin'	<p><b>Description:</b></p> <p>The novel food is an algal powder from the homogenised, crushed, pasteurized, and spray-dried biomass of cultivated <i>Haematococcus pluvialis</i>. <i>H. pluvialis</i> is member of the phylum <i>Chlorophyta</i>, class <i>Chlorophyceae</i>, order <i>Volvocales</i>, and family <i>Haematococcaceae</i>.</p> <p><b>Characteristics/Composition:</b></p> <p>Fat (%): 40-50</p> <p>Protein (%): 7-10</p> <p>Carbohydrates (%): 30-40</p> <p>Fibre (%): 8-13</p> <p>Ash (%): 1.0-3.4</p> <p>Specification of carotenoids (% w/w)</p> <p>Total astaxanthins: 5.0-5.6 %</p> <p>9-cis-astaxanthin* : 13-30 %</p> <p>13-cis-astaxanthin* : 2-6 %</p> <p>Astaxanthin monoesters** : 70-80 %</p> <p>Astaxanthin diesters** : 15-28 %</p> <p>Beta-Carotene: &lt; 0.05 %</p> <p>Lutein: &lt; 0.05 %</p> <p>Canthaxanthin: &lt; 0.05 %</p> <p><b>Microbiological criteria:</b></p> <p>Total aerobic plate count: &lt; 10 000 CFU***/g</p>

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	Yeasts and moulds: < 100 CFU/g Coliforms: < 1 CFU/g E.coli: Negative Salmonella sp.: Negative Staphylococcus: Negative
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\*% of total ATX (covering all ATX isomers; note: all-trans ATX, which is not among specification parameters, is the predominant isomer with more than 60% of total ATX. Thus, the sum of 9-cis and 13-cis is below 40%)

\*\*% of total ATX (covering all esterified and free ATX, only small quantities of free ATX are present in the novel food).

\*\*\* CFU: Colony Forming Units'

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