

*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.*

## **ANNEX**

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

DRAFT

*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.*

(1) in Table 2 (Specifications), the following entry is inserted: *[OP, please insert in the EN version in alphabetical order.]*

Authorised Novel Food	Specification	Data protection
Phytosterols/phytostanols	<p><b>Description/Definition:</b> Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.</p> <p><b>Composition (with GC-FID or equivalent method):</b>  <math>\beta</math>-sitosterol: &lt; 81 %  <math>\beta</math>-sitostanol: &lt; 35 %  campesterol: &lt; 40 %  campestanol: &lt; 15 %  stigmasterol: &lt; 30 %  brassicasterol: &lt; 3,0 %  other sterols/stanols: <math>\leq 3,0</math> %  delta-7-stigmastenol: <math>\leq 4,0</math> %</p> <p><b>Contamination/Purity</b> (GC-FID or equivalent method): Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.</p>	<p>Authorised on <i>[OP please insert the date dd.mm.yyyy - 20th day following its publication]</i>.</p> <p>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Advanced Organic Materials SA, Street 14, No 507, Parque Industrial Pilar, B1629, Provincia de Buenos Aires, Argentina.</p> <p>During the period of data protection, the novel food phytosterols/phytostanols is authorised for placing on the market within the Union only by Advanced Organic Materials SA, 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 Advanced Organic Materials SA.</p> <p>End date of the date protection: <i>[OP please insert the date dd.mm.yyyy – after 5 years]</i></p>