

*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:

(1) 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	Data Protection
	<i>Specified food category</i>	<i>Maximum levels</i>			
<b><i>Akkermansia muciniphila</i></b> <b>(pasteurised)</b>	Foods for special medical purposes as defined under Regulation (EU) No 609/2013, excluding food for special medical purposes intended for infants, children younger than 12 years of age, pregnant and lactating women	In accordance with the particular nutritional requirements of the persons for whom the products are intended, but no higher than: - $2,1 \times 10^{10}$ cells/day for the general population older than 12 years of	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘pasteurised <i>Akkermansia muciniphila</i> ’.  The labelling of food supplements containing pasteurised <i>Akkermansia muciniphila</i> shall bear a statement that those food supplements should not be consumed by:		

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		age  - $3,0 \times 10^{10}$ cells/day for the general population older than 14 years of age	a) pregnant and lactating women; b) by infants and children under 12 years of age / children and adolescents under 14 years of age / children and adolescents under 18 years of age depending on the age groups the food supplement is intended for.		
	Food supplements as defined in Directive 2002/46/EC, excluding infant and children younger than 12 years of age, pregnant and lactating women	$2,1 \times 10^{10}$ cells/day for the general population older than 12 years of age,  $3,0 \times 10^{10}$ cells/day for the general population older than 14 years of age.			