

*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  |
|--|--|------------------------------|--|--------------------|--|
| <b><i>Rhizomucor pusillus</i> biomass powder</b> | <b><i>Specified food category</i></b>                  | <b><i>Maximum levels</i></b> | The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ <i>Rhizomucor pusillus</i> biomass powder’.<br><br>The labelling of food supplements containing ‘ <i>Rhizomucor pusillus</i> biomass |                    | Authorised on [...] [OP, please insert the date dd.mm.yyyy - 20th day following its publication]. This inclusion is based on proprietary scientific evidence and scientific data |
|  | Fried or extruded cereal, seed, or root-based products | 30g/100g                     |  |                    |  |

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|  |                 |           |   |  |   |
|--|-----------------|-----------|---|--|---|
|  | Biscuits        | 10g/100g  | powder' shall bear a statement that they should not be consumed by persons under 18 years of age, and pregnant and lactating women. |  | protected in accordance with Article 26 of Regulation (EU) 2015/2283.<br><br>Applicant: "The Protein Brewery B.V.", Goeseelsstraat 10, 4817 MV, Breda, Netherlands. During the period of data protection, the novel food <i>Rhizomucor pusillus</i> biomass powder is authorised for placing on the market within the Union only by "The Protein Brewery B.V." unless a subsequent applicant obtains authorisation for the novel food |
|  | Cereal bars     | 35g/100g  |   |  |   |
|  | Dairy analogues | 20g/100g  |   |  |   |
|  | Whey powder     | 100g/100g |   |  |   |

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|  |   |          |  |  |   |
|--|---|----------|--|--|---|
|  | Energy drinks, fermented milk-based drinks and fermented non-alcoholic drinks | 10g/100g |  |  | <p>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 “The Protein Brewery B.V.”.</p> <p>End date of the data protection: [...] <i>[OP please insert the date dd.mm.yyyy – after 5 years]</i>.</p> |
|  | Mexican tortillas and steamed breads<br>Ready to eat meals                    | 20g/100g |  |  |   |
|  | Chocolate confectionery   | 15g/100g |  |  |   |

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|  |  |          |  |  |  |
|--|--|----------|--|--|--|
|  | Cocoa-based spreads  | 20g/100g |  |  |  |
|  | Meal replacements for weight control   | 40g/meal |  |  |  |
|  | Food supplements as defined in Directive 2002/46/EC, for the general adult population, excluding pregnant and lactating women. | 6g/day   |  |  |  |

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(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

| Authorised novel food                            | Specification   |
|--|---|
| <b><i>Rhizomucor pusillus</i> biomass powder</b> | <p><b>Description:</b></p> <p><u>The novel food is a dry whitish odourless powder derived from the filamentous fungus <i>Rhizomucor pusillus</i> (strain CBS 143028).</u></p> <p><u>The novel food is the biomass of the fungus <i>Rhizomucor pusillus</i> (strain CBS 143028), which has been produced via fermentation The biomass is then harvested, dried and milled into a whitish odourless powder which is finally pasteurised to inactivate the viable fungus cells. <i>Rhizomucor pusillus</i> is a filamentous fungus belonging to the Fomitopsidaceae family.</u></p> <p><b>Characteristics/Composition:</b></p> <p>Moisture: 3-10g/100g</p> <p>Crude protein content (N x 6,25): 44-68g/100g</p> <p>Total fat content: 4-8g/100g</p> <p>Total dietary fibre: 25-39g/100g</p> <p>Total digestible carbohydrates: ≤ 3g/100g</p> <p>Ash: ≤ 6 g/100g</p> <p><b>Microbiological criteria:</b></p> <p>Total aerobic microbial count: ≤10<sup>3</sup> CFU*/g</p> <p><i>Bacillus cereus</i>: ≤100 CFU/g</p> <p><i>Clostridium perfringens</i>: &lt;10 CFU/g</p> <p>Coagulase-positive staphylococci: ≤50 CFU/g</p> <p>Enterobacteriaceae: ≤10 CFU/g</p> <p><i>Escherichia coli</i>: ≤10 CFU/g</p> |

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|  | <p><i>Listeria monocytogenes</i>: Not detected in 25 g</p> <p><i>Salmonella</i> spp.: Not detected in 25 g</p> <p>Yeasts and moulds: &lt;100 CFU/g</p> <p>*CFU = Colony Forming Units</p> <p><b>Heavy Metals:</b></p> <p>Arsenic (As): ≤0.1 mg/kg</p> <p>Cadmium (Cd): ≤0.1 mg/kg</p> <p>Lead (Pb): ≤0.1 mg/kg</p> <p>Mercury (Hg): ≤0.1 mg/kg</p> <p><b>Mycotoxins:</b></p> <p>Aflatoxins (B1, B2, G1, G2): &lt;0.1 µg/kg</p> <p>Diacetoxyscirpenol: &lt;20 µg/kg</p> <p>Fumonisin (B1, B2): &lt;100 µg/kg</p> <p>HT2 Toxin: &lt;7.5 µg/kg</p> <p>T2 Toxin: &lt;7.5 µg/kg</p> <p>Nivalenol: &lt;150 µg/kg</p> <p>Ochratoxin A: &lt;1.0 µg/kg</p> <p>Deoxynivalenol (DON): &lt;150 µg/kg</p> <p>Zearalenone: &lt;20 µg/kg</p> |
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