

SCHEDULE 4

Regulation 6

Amendments to the list of novel foods in the Annex to Commission
Implementing Regulation (EU) 2017/2470 for the authorisation of
UV-treated baker's yeast (*Saccharomyces cerevisiae*) as a novel food

1. In Commission Implementing Regulation (EU) 2017/2470, the Annex (list of novel foods) is amended as follows.

2. In Table 1 (authorised novel foods), for the entry for “UV-treated baker's yeast (*Saccharomyces cerevisiae*)” substitute—

“UV-treated baker's yeast (<i>Saccharomyces cerevisiae</i>)”	<i>Specified food category</i>	<i>Maximum levels of vitamin D₂</i>		The novel food must be inactivated for use in infant formula, follow-on formula, processed cereal-based food and food for special medical purposes.
	Yeast-leavened breads and rolls	5 µg/100 g	The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D ₂ yeast”.	
	Yeast-leavened fine bakery wares	5 µg/100 g		
	Food supplements as defined in the Food Supplements Regulations (Wales) 2003(1)	In accordance with any relevant requirements contained in regulations applying in relation to Wales and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(2)		
	Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dry yeast	The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D ₂ yeast”.	The labelling of the novel food must bear a statement that the food is

(1) S.I. 2003/1719 (W. 186), to which there are amendments not relevant to these Regulations.

(2) S.I. 2019/651, amended by S.I. 2020/1476 and 2023/28.

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		<p>only intended for baking and should not be eaten raw.</p> <p>The labelling of the novel food must bear instructions for use for the final consumer to ensure a maximum concentration of 5µg/100g of vitamin D₂ in the final home-baked product is not exceeded.</p>
Dishes, including ready-to-eat meals (excluding soups and salads)	3 µg/100 g	The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D ₂ yeast”.
Soups and salads	5 µg/100 g	
Fried or extruded cereal, seed or root-based products	5 µg/100 g	
Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013(3)	In accordance with Regulation (EU) No 609/2013	
Processed cereal-based food as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013	

(3) EUR 2013/609, amended by S.I. 2019/651 and 2023/28. S.I. 2019/651 was amended by S.I. 2020/1476 and 2023/28.

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Processed fruit products	1.5 µg/100 g
Processed vegetables	2 µg/100 g
Bread and similar products	5 µg/100 g
Breakfast cereals	4 µg/100 g
Pasta, doughs and similar products	5 µg/100 g
Other cereal-based products	3 µg/100 g
Spices, seasonings, condiments, sauce ingredients, dessert sauces/toppings	10 µg/100 g
Protein products	10 µg/100 g
Cheese	2 µg/100 g
Dairy desserts and similar products	2 µg/100 g
Fermented milk or fermented cream	1.5 µg/100 g
Dairy powders and concentrates	25 µg/100 g
Milk-based products, whey and cream	0.5 µg/100 g
Meat and dairy analogues	2.5 µg/100 g
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	5 µg/100 g

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Meal replacement for weight control	5 µg/100 g
Food for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended”

3. In Table 2 (specifications) for the entry for “UV-treated baker’s yeast (*Saccharomyces cerevisiae*)” substitute—

<p>“UV-treated baker’s yeast (<i>Saccharomyces cerevisiae</i>)”</p>	<p>Description/Definition</p> <p>Baker’s yeast (<i>Saccharomyces cerevisiae</i>) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D₂ (ergocalciferol). Vitamin D₂ content in the yeast concentrate varies between 800,000 - 3,500,000 IU vitamin D/100 g (200-875 µg/g).</p> <p>The yeast is inactivated for use in infant formula, follow-on formula, processed cereal-based food, and food for special medical purposes as defined in Regulation (EU) No 609/2013. The yeast can be active or inactive for use in other foods.</p> <p>The yeast concentrate is blended with regular baker’s yeast in order not to exceed the maximum level in the pre-packed fresh or dry yeast for home baking.</p> <p>Tan-coloured, free-flowing granules.</p> <p>Vitamin D₂</p> <p>Chemical name: (5Z,7E,22E)-(3S)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol</p> <p>Synonym: Ergocalciferol</p> <p>CAS No.: 50-14-6</p> <p>Molecular weight: 396.65 g/mol</p> <p>Microbiological criteria for the yeast concentrate</p> <p>Coliforms: ≤ 10³ CFU/g</p> <p><i>Escherichia coli</i>: ≤ 10 CFU/g</p>
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	<i>Salmonella</i> spp.: Absence in 25 g CFU: Colony Forming Units”.
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