SCHEDULE 4

Regulation 7

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 Table 1 (authorised novel foods), for the entry for UV-treated baker's yeast (Saccharomyces cerevisiae) substitute the following entry—

"UV- treated baker's yeast (Saccharomy cerevisiae)	Yeast- leavened	Maximum levels of Vitamin D# 5 μg/100 g 5 μg/100 g	The designation of the novel food on the labelling of food containing it is "vitamin D yeast" or "vitamin D# yeast".	novel food relabelling containing vitamin D or "vitamin st". signation novel in the reg of food must be inactivated for use in infant formula, follow-on formula, processed cereal-based food and food for special medical purposes. signation novel in the reg of food region in D yeast" remin D# selling novel ust bear ment that dis only differ and it not be	
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003(1)	In accordance with any relevant requirements contained in regulations applying in relation to Scotland 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# yeast". The labelling of the novel food must bear a statement that the food is only intended for baking and it should not be eaten raw.		

 ⁽¹⁾ S.S.I. 2003/278, to which there are amendments not relevant to these Regulations.
 (2) S.I. 2019/651, as relevantly amended by S.I. 2020/1476.

		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 D# in the final homebaked product is not exceeded.	
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	
Soups and salads	5 μg/100 g	it is "vitamin D yeast" or "vitamin	
Fried or extruded cereal, seed or root-based products	5 μg/100 g	D# yeast''.	
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			
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	$3 \mu g/100 g$		

⁽³⁾ EUR 2013/609, as relevantly amended by S.I. 2019/651.

Spices, seasonings, condiments, sauce ingredients, dessert sauces/	10 μg/100 g	
toppings		
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 by Regulation (EU) No. 609/2013	5 μg/100 g	
Meal replacement for weight control	5 μg/100 g	
Food for special medical purposes as defined by Regulation (EU) No. 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended"	

2. In Table 2 (specifications) for the entry for UV-treated baker's yeast (Saccharomyces cerevisiae) substitute the following entry—

	Description/Definition
yeast (Saccharomyces	
cerevisiae)	Baker's yeast (Saccharomyces cerevisiae) is treated with
	ultraviolet light to induce the conversion of ergosterol to vitamin
	D# (ergocalciferol). Vitamin D# content in the yeast concentrate
	varies between 800,000 - 3,500,000 IU vitamin D/100g (200-875
	μg/g). The yeast is inactivated for use in infant formula, follow-on

formula, processed cereal-based food, and food for special medical purposes as defined by Regulation (EU) No. 609/2013. The yeast can be active or inactive for use in other foods.

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.

Tan-coloured, free-flowing granules.

Vitamin D#

Chemical name: (5Z,7E,22E)-(3S)-9,10-secoergosta-5,7,10(19),22-

tetraen-3-ol

Synonym: Ergocalciferol

CAS No.: 50-14-6

Molecular weight: 396.65 g/mol

Microbiological criteria for the yeast concentrate

Coliforms: $\leq 10^3 \text{ CFU/g}$

Escherichia coli: ≤ 10 CFU/g

Salmonella spp: Absence in 25 g

CFU: Colony Forming Units.".