

NWSI 2026 No. 52**FOOD****REGULATED PRODUCTS****NOVEL FOODS**

Determination of authorisation status: authorisation of new uses, and consolidation of existing uses, for *Schizochytrium* sp. oil rich in DHA and EPA as a novel food

Explanatory note

(this note is not part of the determination)

This determination is made in relation to Wales by the Welsh Ministers in exercise of the powers conferred by Article 12(1) of Regulation [\(EU\) 2015/2283](#) of the European Parliament and of the Council on novel foods (EUR 2015/2283).

It authorises *Schizochytrium* sp. oil rich in docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) as a novel food for use in two new food categories: analogues of meat and meat products and fishery product analogues. The terms of authorisation and the conditions, requirements and specification upon which the novel food is authorised are set out in the Schedule.

This determination also consolidates, and replaces, the authorisation of all existing authorised uses of this novel food; replacing the existing authorisation that, prior to this determination, had effect pursuant to regulation 23 (savings and transitional provision: general) of the Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025. There are no changes to the scope of the existing authorised uses, but the wording is updated and clarified including:

- the food category “foods intended to meet the expenditure of intense muscular effort, especially for sportsmen” is updated to refer to “sports people”;
- within the food category “dairy analogues except drinks”, the maximum levels of DHA and EPA for “soy and imitation milk products (excluding drinks)” is updated to refer to “analogues of other milk products (excluding drinks)”.

In relation to the new authorised uses, there has been consultation as required by Article 9 of Regulation [\(EC\) No 178/2002](#) of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (EUR 2002/178).

Determination

Application and coming into force

1. This determination applies in relation to Wales, and comes into force on [DATE].

Interpretation

2. In this determination:

“Regulation 609/2013” means Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control etc. (EUR 2013/609);

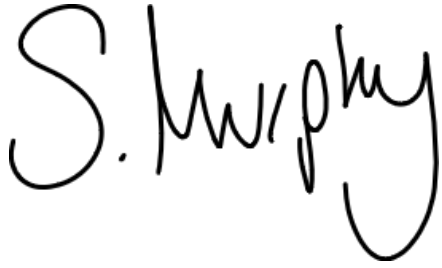
“Regulation 828/2014” means Commission Implementing Regulation (EU) No 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (EUR 2014/828);

“Regulation 2015/2283” means Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (EUR 2015/2283).

3. Any expression used both in this determination and in Regulation 2015/2283 has the same meaning as it has in that Regulation.

Determination of authorisation status of *Schizochytrium* sp. oil rich in DHA and EPA

4. *Schizochytrium* sp. oil rich in DHA and EPA is authorised as a novel food to be placed on the market in Wales, and to be used in or on food, in accordance with the conditions, requirements and specification set out in the Schedule.
5. This determination consolidates and replaces the existing authorisation for *Schizochytrium* sp. oil rich in DHA and EPA.

A handwritten signature in black ink, appearing to read "S. Murphy". The letters are cursive and fluidly connected.

5 March 2026

SCHEDULE

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements
	Specified food category	Maximum levels of DHA and EPA combined:	
Schizochytrium sp. oil rich in DHA and EPA	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 , for persons aged 18 years or above excluding pregnant women and lactating women	3000 mg/day	The designation of the novel food on the labelling of the food containing it is: 'DHA and EPA-rich oil from the microalgae <i>Schizochytrium</i> sp.'
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 , for pregnant women and lactating women aged 18 years or above	450 mg/day	
	Food for special medical purposes as defined in Regulation 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended	
	Total diet replacement for weight control as defined in Regulation 609/2013 and meal replacements for weight control	250 mg/meal	
	Milk-based drinks and similar products intended for young children (persons aged between 1 year (12 months) up to the age of 3 years (36 months))	200 mg/100g	

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	Processed cereal based food and baby food for infants and young children as defined in Regulation 609/2013	200 mg/100g	
	Foods intended to meet the expenditure of intense muscular effort, especially for sportspeople	200 mg/100g	
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Regulation 828/2014	200 mg/100g	
	Bakery products (breads, rolls and sweet biscuits)	200 mg/100g	
	Breakfast cereals	500 mg/100g	
	Cooking fats	360 mg/100g	
	Dairy analogues except drinks	600 mg/100g for cheese analogues; 200 mg/100g for analogues of other milk products (excluding drinks)	
	Dairy products except milk-based drinks	600 mg/100g for cheese; 200 mg/100g for other milk products (including milk, fromage frais and yoghurt products; excluding drinks)	

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	Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100g	
	Cereal/nutrition Bars	500 mg/100g	
	Dressings and spreadable fats	600 mg/100g	
	Analogues of meat and meat products	300 mg/100g	
	Fishery product analogues	300 mg/100g	
Specification			
<ul style="list-style-type: none"> • Acid value ≤ 0.5 mg KOH/g • Peroxide value (PV) ≤ 5.0 mEq/kg of oil • Oxidative stability: All food products containing <i>Schizochytrium sp. oil rich in DHA and EPA</i> should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC) • Moisture and Volatiles $\leq 0.05\%$ • Unsaponifiables $\leq 4.5\%$ • Trans-fatty Acids $\leq 1\%$ • DHA Content $\geq 22.5\%$ • EPA Content $\geq 10\%$ 			