

APPROVALS FOR HEALTH CLAIMS

Swedish Oat Fiber has been at the forefront of legislative questions regarding health claims related to oat beta glucans. Many of the approved claims have been based on dossiers provided by Swedish Oat Fiber through its subsidiary CreaNutrition AG (nowadays part of Swedish Oat Fiber's regular business). This has led to numerous approvals and notifications all over the world, both of the products and the people behind the products. You may see some of them in the list below.

Labelling and consumer safety

The current regulation on nutrition and health claim ruled by the European Commission is aiming to ensure a high level of protection for consumers and to facilitate their choice of healthier products. The product put on the market must be safe and adequately labelled.

In order to bear the claim the product must fulfill the conditions of use stated in the specific regulation (see below).

Furthermore, the use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim (Article 5, see the link or the text below).

It is also important to have in mind the following (Article 6, see the link or the text below): "The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this Regulation."

By using SWEOAT beta glucan products you will be safe as a food manufacturer, always being certain to have the best support and documentations behind a health claim on your product. It is specifically the SWEOAT beta glucan ingredients that have been used in clinical studies in food matrices which have been examined by EFSA as a base for its recommendation.

<http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32006R1924> (the text can be found after the table below).

SWEDISH OAT FIBER AB	www.sweoat.com	VAT No: 556509014801
Båtafjordsvägen 12		Org.nr: 556509-0148
SE-432 63 Bua, Sweden		
Phone: +46 340 66 12 30		Styrelsens säte: Göteborg
Email: info@sweoat.com		Företaget har F-skattebevis

Approval	Claim/Heading	Conditions	Links
EU EFSA Claim Art. 13.1 Cholesterol	"Regular consumption of beta glucans contributes to maintenance of normal blood cholesterol concentrations"	3 g per day, minimum 1 g per serving	http://www.efsa.europa.eu/en/efsajournal/pub/1254.htm
EU EFSA Claim Art. 14 Cholesterol	"Oat beta glucan has been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of heart disease".		http://www.efsa.europa.eu/en/efsajournal/pub/1885.htm
EU EFSA Claim Art. 13.1 Blood glucose	"Consumption of beta-glucans from oats contributes to the reduction of the glucose rise after a meal"	4 g per 30 g of available carbohydrates	http://www.efsa.europa.eu/en/search/doc/2207.pdf
EU EFSA Claim Art. 13.1 Fiber	"Fiber: Oat grain fibre contributes to an increase in faecal bulk."		http://www.efsa.europa.eu/en/efsajournal/pub/2249.htm
USA FDA Claim CFR 101.81 CHD disease	"Soluble fiber from certain foods and risk of coronary heart disease (CHD)."		http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/CFRSearch.cfm?fr=101.81
Australia & New Zealand FSANZ Claim Standard 1.2.7 Cholesterol	Reduction of Cholesterol.		http://www.foodstandards.gov.au/consumer/labelling/nutrition/Pages/default.aspx
Indonesia BPOM Cholesterol	Oats soluble fiber could help in lowering blood cholesterol.		http://www.pom.go.id/new/index.php/home/en
Indonesia BPOM Diabetes	Oats soluble fiber could help controlling blood glucose content on diabetic mellitus type II		
Indonesia BPOM Digestive system	Oats soluble fiber could help improving the colon health		
Malaysia MOH Cholesterol	Beta-glucan from oat helps lower or reduce cholesterol	0.75g per serving. i. Source of beta glucan shall be from oat and barley. ii. The food to be added with beta-glucan shall also contain total dietary fibre for not less than amount required to claim as "source": 3 g per 100 g (solids), 1.5 g per 100 ml (liquids) iii. There shall be written on the label these following statement "Amount recommended for cholesterol lowering effect is 3g/day"	http://fsq.moh.gov.my/v4/index.php/component/k2/item/152
Malaysia MOH Blood glucose	Oat soluble fiber (beta-glucan) helps to lower the rise of blood glucose provided it is not consumed together with other food		
South Korea KFDA Cholesterol	3g of Oat Fiber in a daily dose improves cholesterol levels		http://www.mfds.go.kr/eng/index.do?sessionid=CCB1yyrYuul4RIgE4FEGkKuzKwLy8HqYnDii2VFertmCECECqGaj3yoJSrcNaJzy
South Korea KFDA Blood sugar	3g of Oat Fiber in a daily dose helps to suppress the rise of blood sugar level after a meal		

Cutouts from:

REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

- Of 20 December 2006 – on nutrition and health claims made on foods

<http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32006R1924>

Article 5

General conditions

1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:
 - (a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific data;
 - (b) the nutrient or other substance for which the claim is made:
 - (i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data; or
 - (ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;
 - (c) where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;
 - (d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;
 - (e) compliance with the specific conditions set out in Chapter III or Chapter IV as the case may be.
2. The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.
3. Nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions.

Article 6

Scientific substantiation for claims

1. Nutrition and health claims shall be based on and substantiated by generally accepted scientific data.
2. A food business operator making a nutrition or health claim shall justify the use of the claim.
3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this Regulation.