

Oat beta-glucan:

An alternative cholesterol management nutrient for athletes

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SANHANES

South African National Health and Nutrition Examination Survey



August 2013

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Non-Communicable Diseases (NCDs) : hypertension, heart disease, stroke and diabetes

	Adults > 15 years	%
Hypertension	Significantly high	
Obesity	More than 2/3	66
Cholesterol	Males: abnormally high total- and LDL-cholesterol	20
	Females: abnormally high total- and LDL-cholesterol	40
Diabetes	Impaired glucose homeostasis	20

Hypercholesterolemia and increased risk of CVD



- Emerging epidemic of non-communicable diseases in South Africa:
 - Increased prevalence of diabetes and hypertension in the aging population
 - Hypercholesterolemia is most prevalent in the 25 – 34 year category
- Hypercholesterolemia is a risk factor for Cardiovascular disease (CVD). CVD refers to any disease of the heart and blood vessels. The most common ones are diseases of the heart muscle, strokes, heart attacks, heart failure and heart disease caused by high blood pressure
- Premature deaths caused by CVD in people of working age (35-64 years) are expected to increase by 41% between 2000 and 2030. The negative economic impact of this will be enormous (Steyn K 2007)

Treatment: Statins

- 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors, or statins, are an effective medication for managing elevated concentrations of low-density lipoprotein cholesterol (LDL-C). These drugs offer one of the most effective strategies for reducing cardiovascular disease and have been documented to reduce cardiac events in patients with coronary artery disease (CAD) (Magnia et al. 2015)
- The heart Protection Study (HPS) observed a 23% reduction in CAD events among 20,536 high risk patients treated with simvastatin 40mg daily for 5 years (MRC/BHF Heart protection Study, 2002)

Statins and risk of side effects

- Statins are well-tolerated in the majority of patients but can produce various side effects, The most common clinical complaint is statin related myopathy
- The National Lipid Association (NLA) recommended definition for myopathy includes presence of muscle pain, soreness, weakness and/or cramps (myalgia) plus a serum creatine kinase (CK) level 10 x the upper limit of normal
- In rare case statin can cause life-threatening muscle damage (rhabdomyolysis).
- Reported incidence of myalgia during statin therapy has varied from 1% in pharmaceutical company reports (Physicians' Desk Reference, 2002) to 25% of patients (Ganga et al. 2014)

Individuals at higher risks of developing statin-related myopathy: *(Magnia et al. 2015)*

Endogenous factors:

- Elderly aged 65 or over
- Female gender
- Low body mass index
- Diabetes mellitus
- Hypothyroidism / vitamin D deficiency / renal or hepatic disease

Exogenous factors

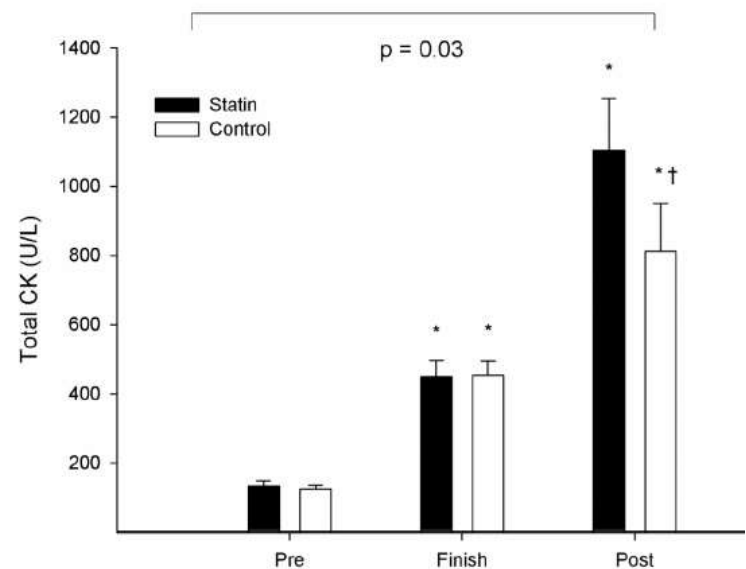
- Individuals involved in intense physical activity
- Drug-drug interactions

Statin treatment & intense physical exercise

- The most common adverse effects of statin treatment are muscle symptoms (myalgia and/or weakness).
- Muscle damage was assessed by measuring serum creatine kinase (CK) levels in individuals with and without statin treatment and running the 2011 Boston Marathon.
 - 37 statin-using athletes, 43 controls
 - CK is a serum marker of muscle damage
- The CK levels 24 hours after the exercise was significantly increased in the statin users.
- Increasing age was positively associated with the increase in CK levels.

- Statin use increased the susceptibility to exercise-induced muscle injury
- This susceptibility is further enhanced by age

Effect of statins on CK levels before and after a marathon run



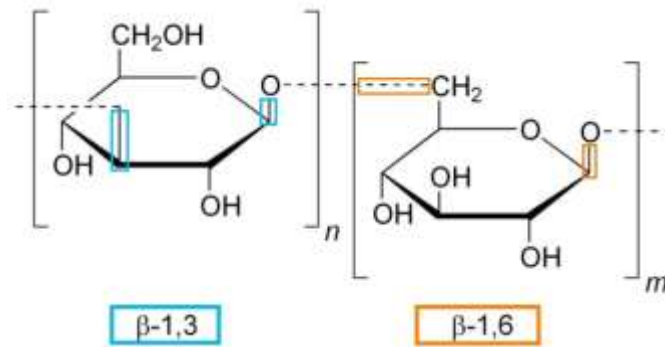
Total CK before (Pre), immediately after (Finish), and 24 hours after (post) a marathon run in statin users and controls

Statin side effects & physical activity

- Muscle symptoms such as pain and/or weakness are the most common side effect of long term statin treatment (10% - 25% of patients treated in clinical practice) (Ganga et al. 2014)
- The prevalence of muscle symptoms can increase among statin users who also exercise (Magnia et al. 2015)
- Statin-related muscle symptoms (pain, weakness, injury) may be exacerbated by intense physical activity.
- Athletes may need to stop statin treatment when involved in vigorous physical exercise.
- Seek alternative treatment options

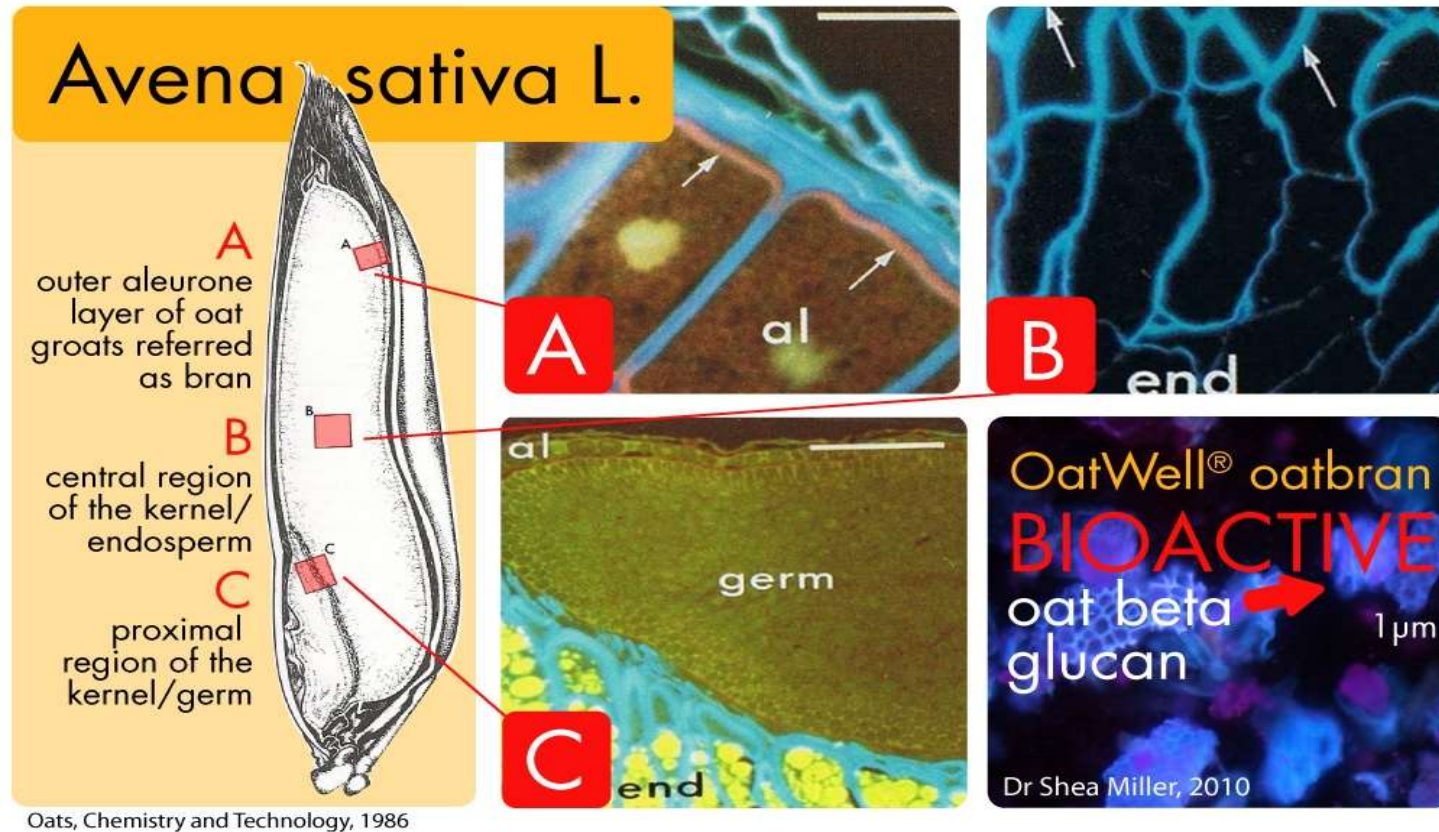
What are beta-glucans

- β -Glucans are polysaccharides that contain only glucose as structural components, and are linked with β -glycosidic bonds – categorized as fibre



- One of the most common sources of $\beta(1,3)$ D-glucan for supplement use is derived from the cell wall of baker's yeast
- $\beta(1,3)(1,4)$ -glucans are also extracted from the bran of some grains, such as **oats** and barley, and to a much lesser degree in rye and wheat
- The $\beta(1,3)$ D-glucans from yeast are often insoluble.
- ***Those extracted from grains tend to be both soluble and insoluble.***

Functionality of oat beta-glucan

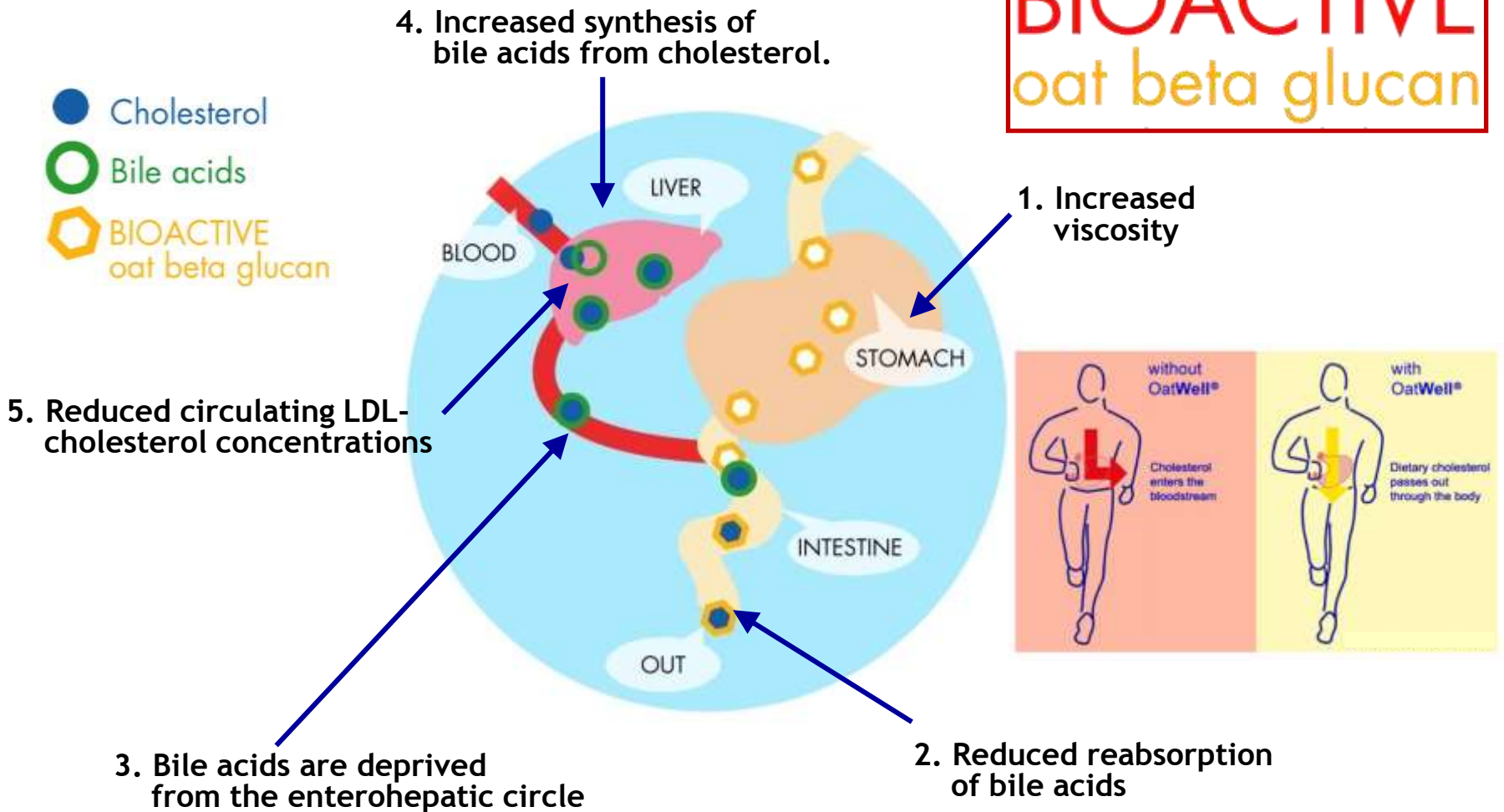


Functional key-parameters of oat beta-glucan to ensure the adequate viscosity in the gut:

- Beta-glucan concentration, Molecular weight, Solubility / Viscosity

Targeting Cholesterol: Mechanism of action

BIOACTIVE
oat beta glucan



Oat β -glucan: Effect on total cholesterol

A meta-analysis

Background:

- Previous meta-analysis did not select studies based on dose and physico-chemical characteristics of the product tested

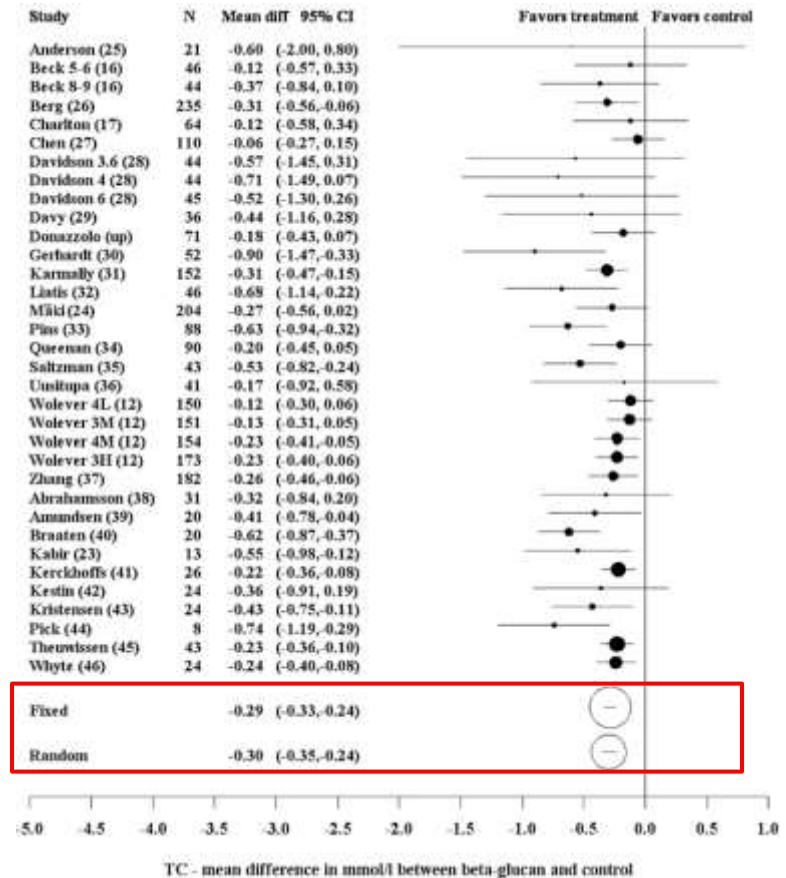
Study design:

- 28 studies were included in the analysis of total cholesterol
- Included studies with a β -glucan dose of ≥ 3 g/d
- Excluded studies identified as having used a oat β -glucan product with a MW < 100 kDa

Results:

- Total cholesterol decreased by 0.30 mmol/L
- LDL-cholesterol decreased by 0.25 mmol/L
- No significant effect on HDL-cholesterol triglyceride levels

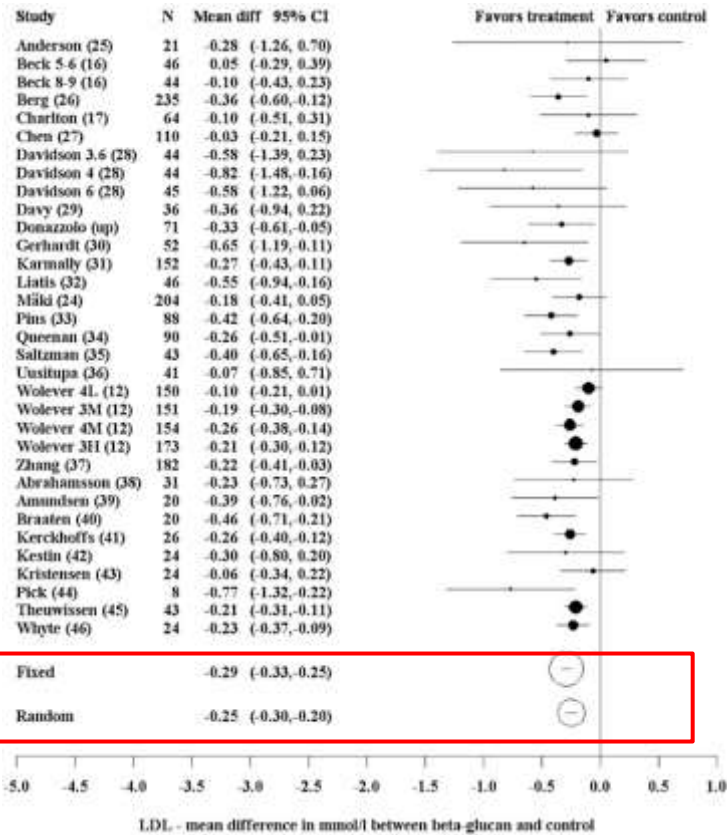
Total cholesterol



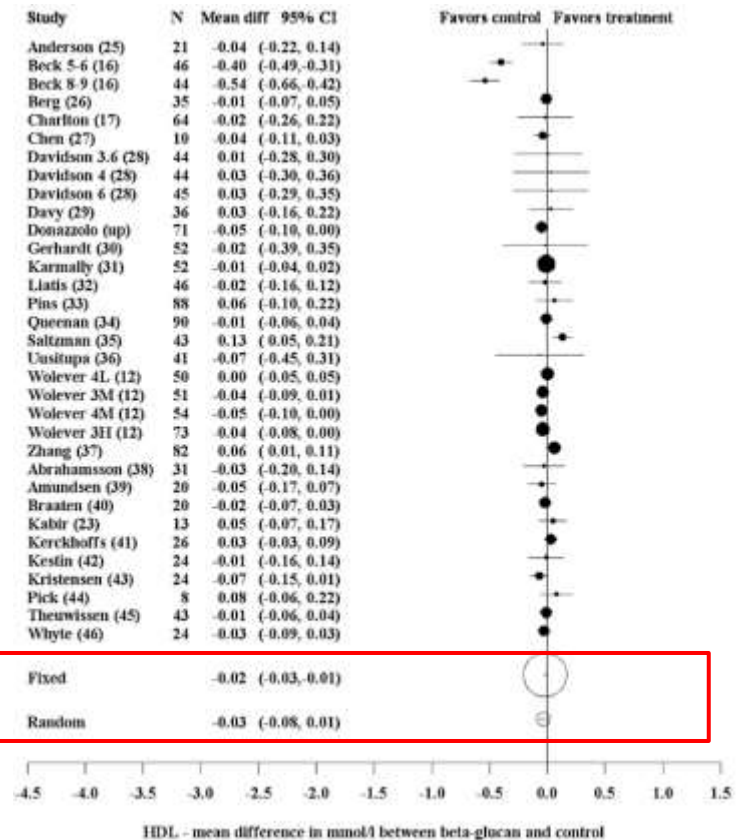
Oat β -glucan at doses of 3g/d robustly decreased total cholesterol levels

Oat β -glucan: Effect on LDL and HDL cholesterol levels

LDL cholesterol



HDL cholesterol



Oat β -glucan reduced LDL cholesterol relative to control, by 0.25 mmol/l

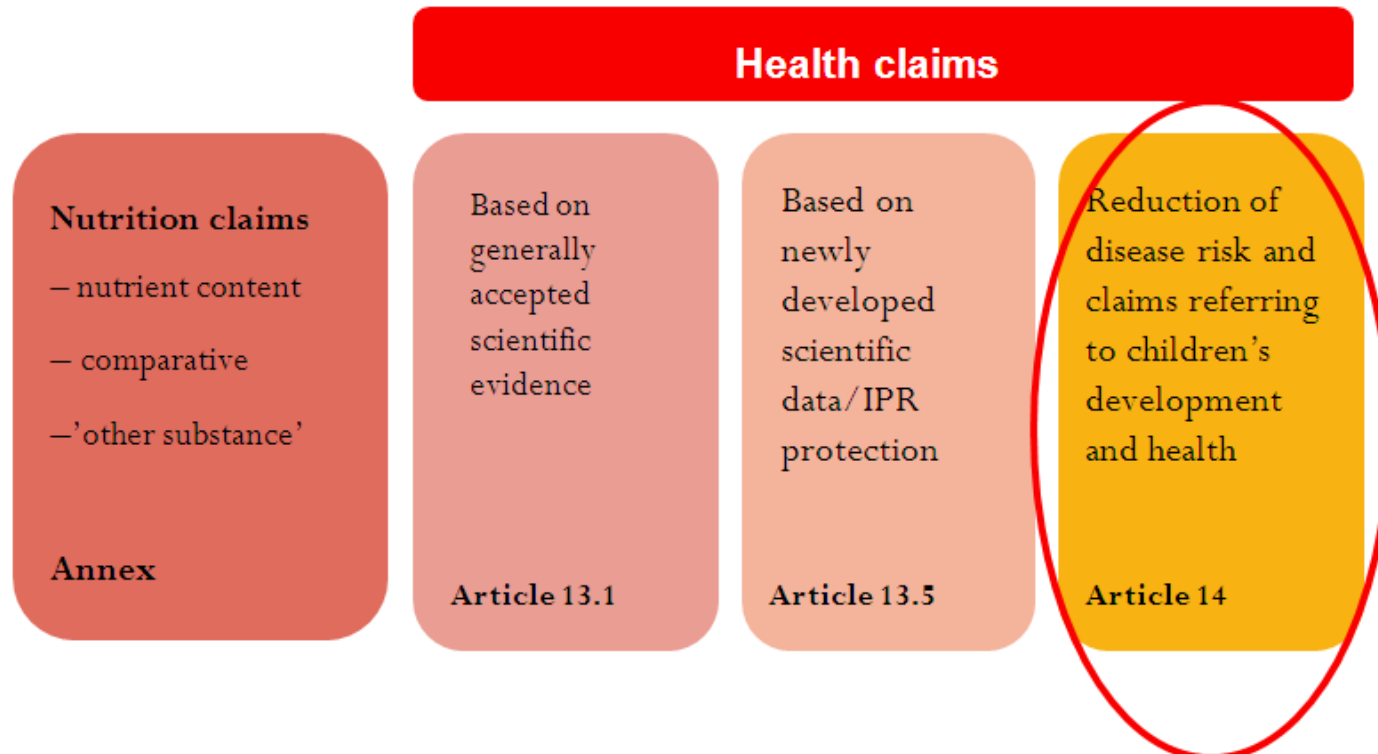


EC Regulation*

European classification of claims on foods

*THE REGULATION (EC) °No 1924/2006

- ... to ensure a high level of protection for consumers and to facilitate their choice, products on the market should be safe and adequately labeled.



LDL Cholesterol reduction



nutrient function claims



L 296/26

EN

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15.11.2011

COMMISSION REGULATION (EU) No 1160/2011 of 14 November 2011

on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk

ANNEX I

PERMITTED HEALTH CLAIM

Application — Relevant provisions of Regulation (EC) No 1924/2006	Applicant — Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk	CreaNutrition AG, Business Park, 6301 Zug, Switzerland	Oat beta-glucan	Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of oat beta-glucan. The claim can be used for foods which provide at least 1 g of oat beta glucan per quantified portion.		Q-2008-681

glucan per day :

European Food Safety Authority (EFSA) art. 14: Facts & Figures of oat beta-glucan

- Eligible source:** oats or oat bran
- Physicochemical properties:** high molecular weight, solubility and increased viscosity within food matrix
- Significant quantity:** 3g oat beta-glucan per day
- Bioavailability:** oat beta-glucan is in a form that is available to be used by the body
- Wording of the claim:** “to lower/reduce cholesterol”, “cholesterol lowering may reduce the risk of heart disease”

Science & Regulatory

Scientific evidence:

- Over 50 human studies
- 3 Meta analysis
- Proven physiochemical properties of bioactive oat beta-glucan

Regulatory approvals:

- EFSA (art. 14) / FDA / FASANZ / HC

Opinion leaders:

- Supported by WHO
- International cholesterol lowering education programmes (National Cholesterol Education Program; JAMA, 2001)
- American Dietetic Association
- European Society of Cardiology and European Arteriosclerosis Society (ESC/EAS)

ESC/EAS Guidelines for the management of dyslipidaemias

The Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS)

Developed with the special contribution of: European Association for Cardiovascular Prevention & Rehabilitation[†]

6.4 Dietary supplements and functional foods active on plasma lipid values

Dietary fibre

Available evidence consistently demonstrates a TC- and LDL-C-lowering effect of **water-soluble fibre from oat bran (β -glucan)**. Foods enriched with this fibre are well tolerated, effective and recommended for LDL-C-lowering.

Summary:

Oat β -glucan & cholesterol-lowering

- Meta-analysis from Whitehead et al.
 - Included 28 studies using products with a MW \geq 100 kDa and a dose $>$ 3g/d
 - Concluded that \geq 3g/d of oat β -glucan lowered LDL and total cholesterol by 0.25 mmol/L and 0.30 mmol/L respectively
- Not all oat β -glucan products decrease blood cholesterol levels
- EFSA approved health claims for cholesterol lowering and reduction of risk of CVD at doses of at least 3 g/d oat β -glucan and using product that ensure that efficacy is conserved.

Conclusion

- The results from the SANHANES data made public in August 2013 typically display a cholesterol crisis.
- Statins, are an effective medication for managing elevated concentrations of low-density lipoprotein cholesterol (LDL-C).
- Muscle symptoms are the most common side effect of long term statin treatment & these symptoms may be exacerbated by intense physical activity.
- Oat beta-glucans are a source of treatment for reducing cholesterol. An EFSA article 14 claim exists for oat beta-glucans inferring a reduction in the risk of heart disease
- Oat beta-glucan is thus a potential alternative cholesterol management nutrient for athletes

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