
**Europe 2004:3rd. Annual Intl. Conference.
BC Functional Food and Nutraceutical
Network**

**Marketing Dietary Supplements and
Functional Foods in EU: Success of
LC Omega-3 Fatty Acids**



Heart Attack and Dietary Fat Intake of Eskimos vs. Danes (1976)

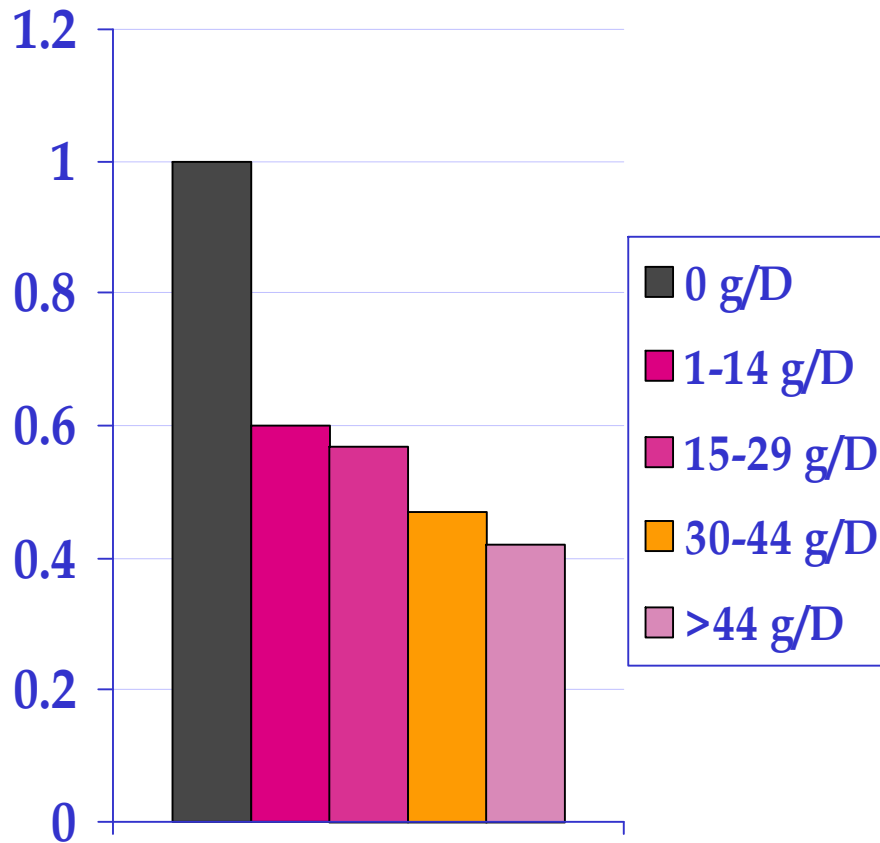
	ESKIMOS	DANES
Myocardial Infarction	3	40
Energy from fat (%)	39	42
n-6 PUFA (g/d)	5	10
n-3 PUFA (g/d)	14	3
n-3/n-6	2.8	0.3
Cholesterol (mg)	790	420



LC PUFA and CVD

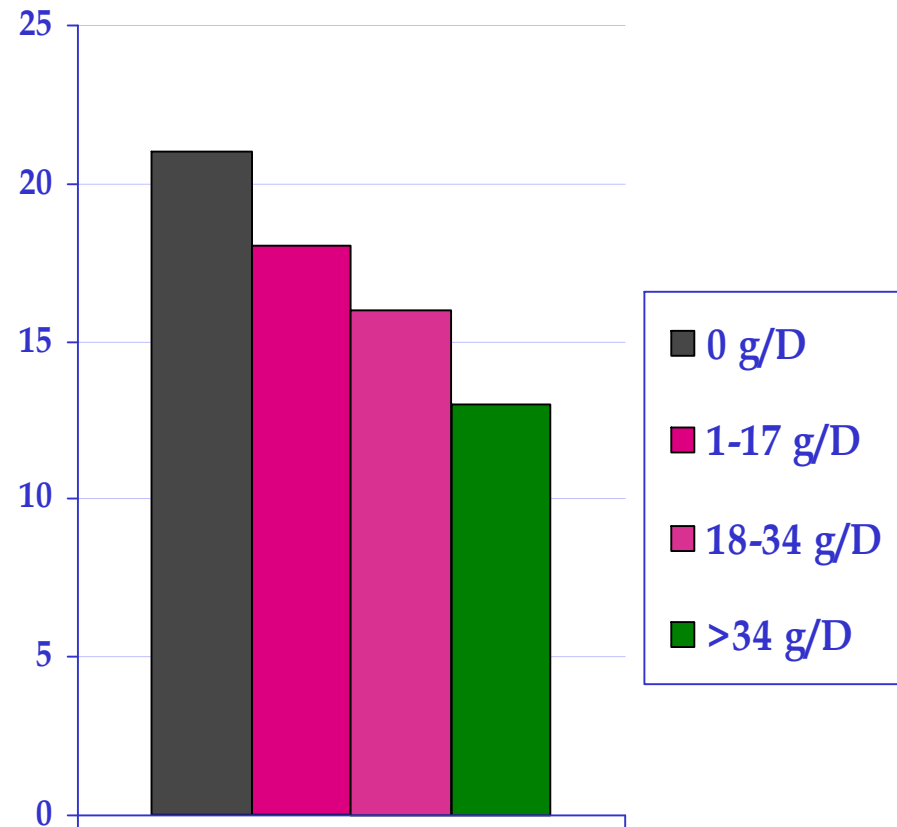
(fish consumption studies)

Zutphen Study: Kromhout 1985



CHD Risk

Western Elect.:Shekelle 1985

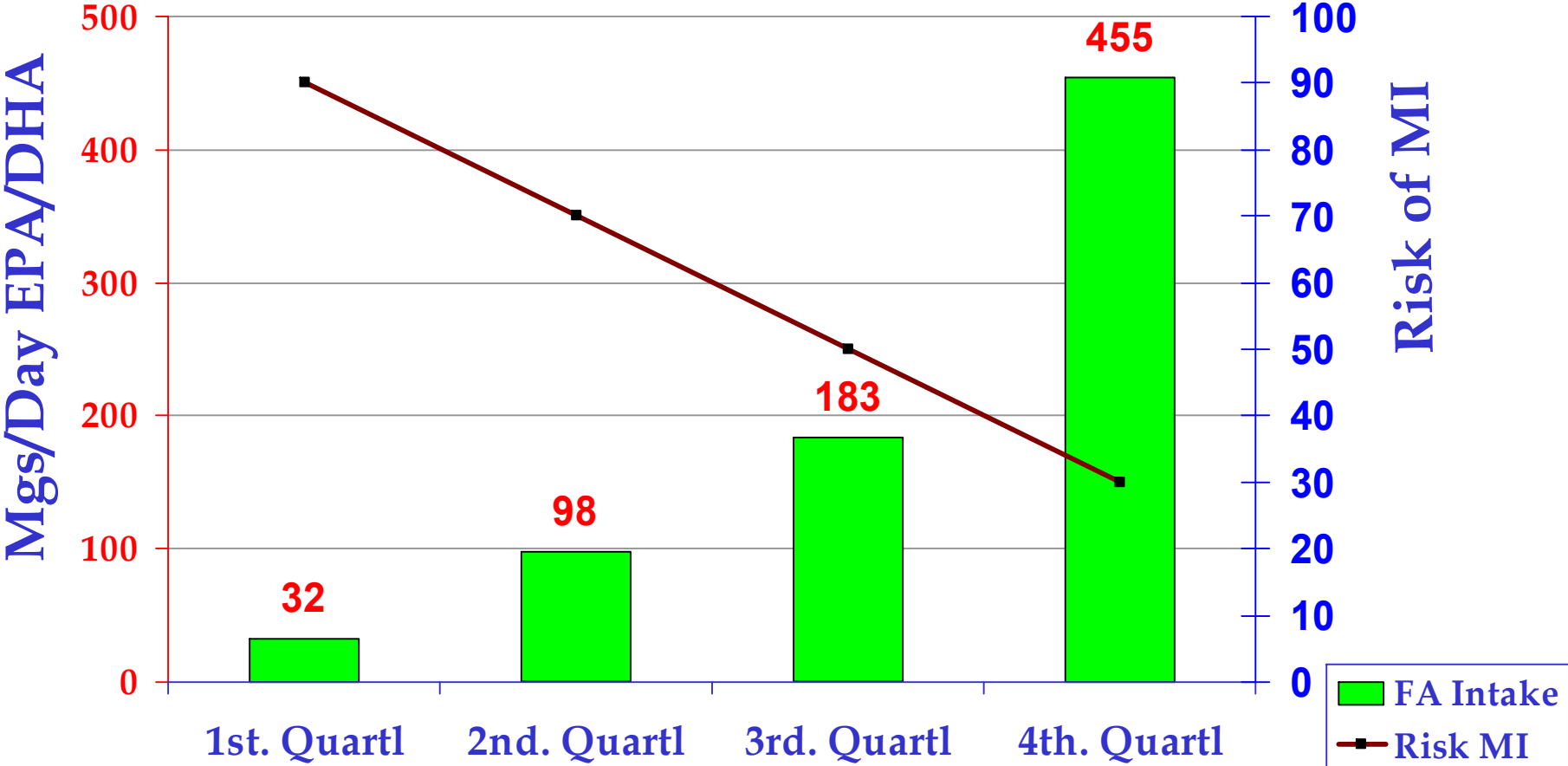


%CHD Deaths

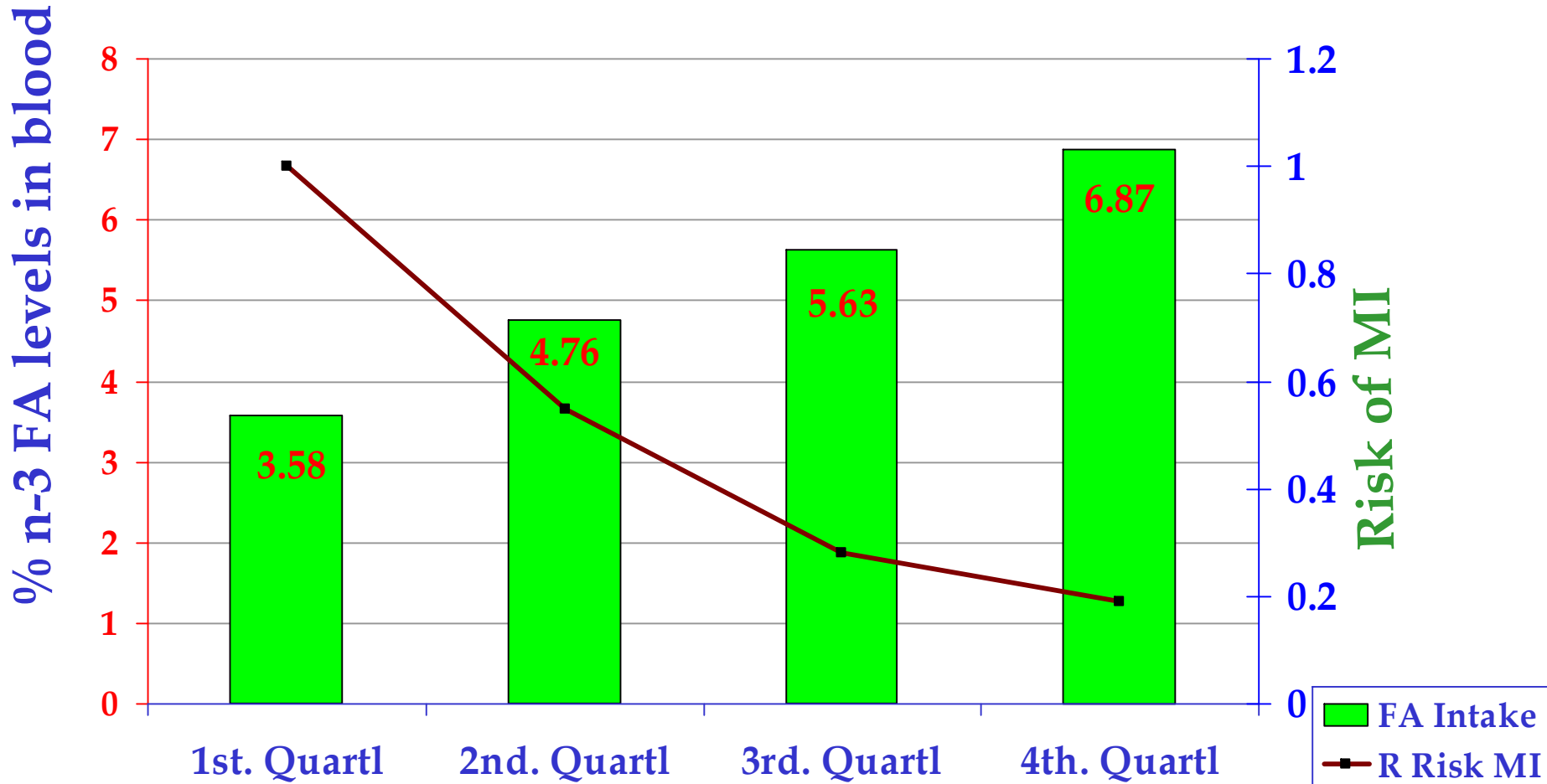


Dietary Intake of FA and Risk of Cardiac Arrest

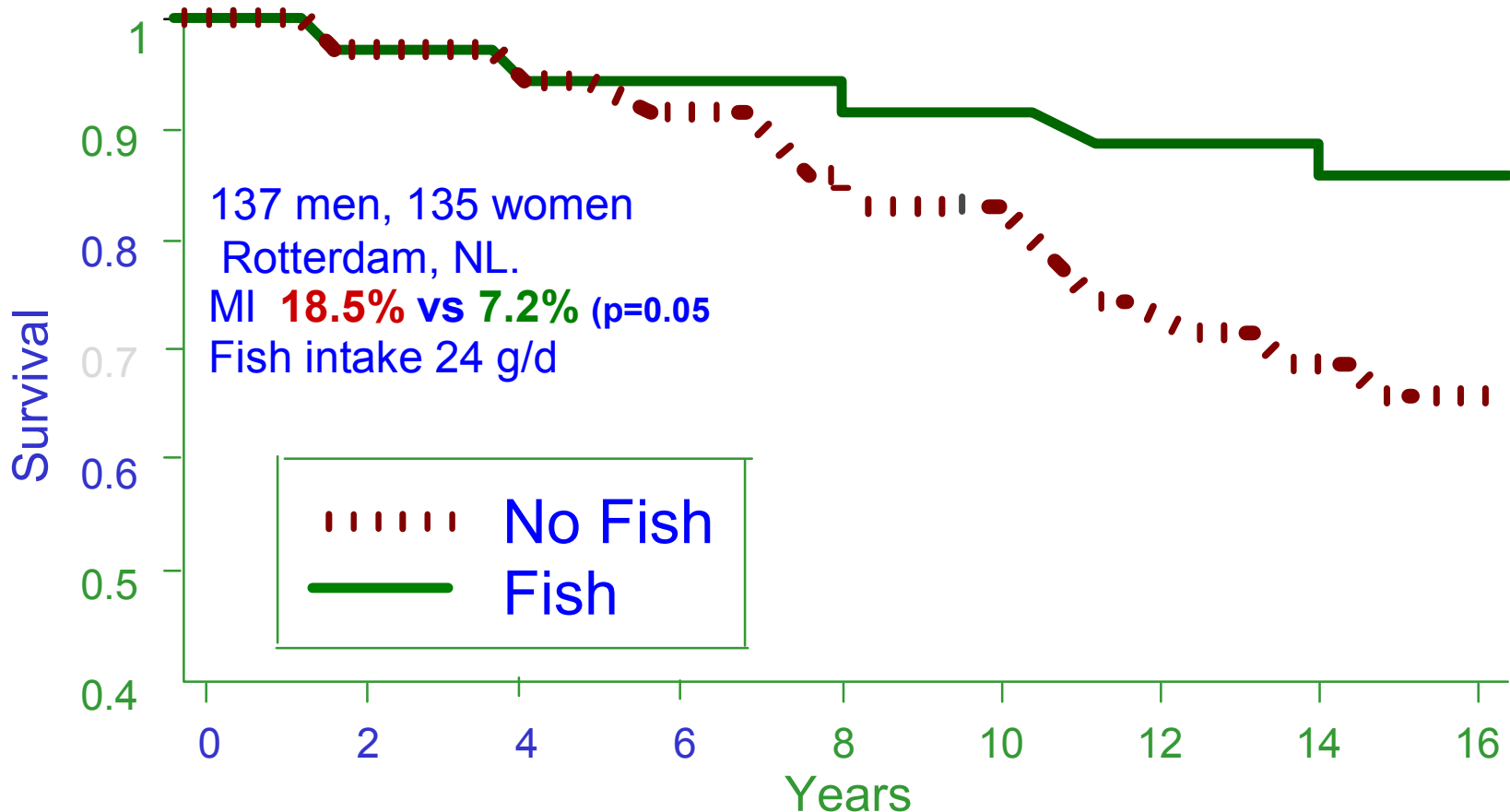
Siscovick D. 1996 JAMA:274;17



Blood Levels of FA and Risk of Sudden Death

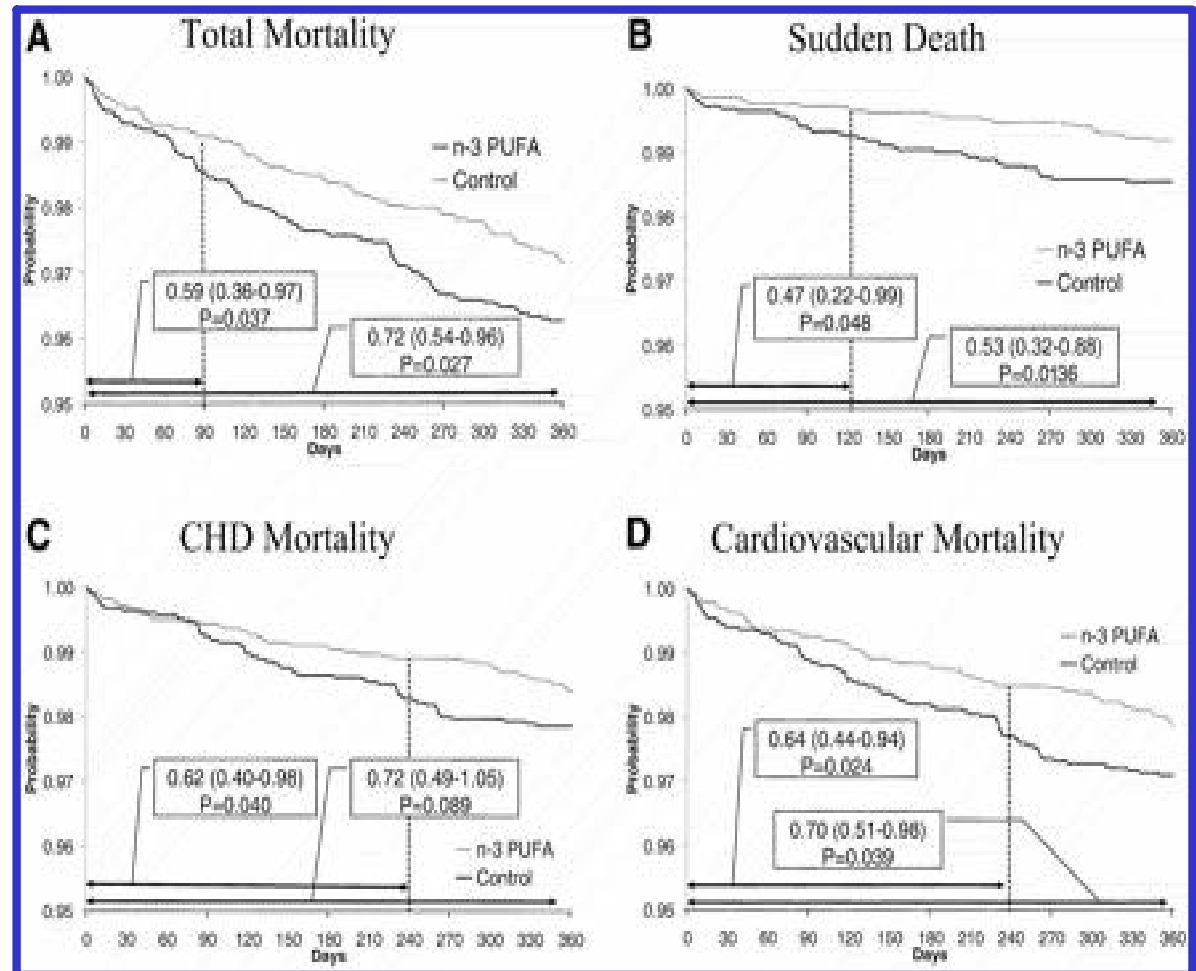


Fish Intake and Mortality from CHD: Long Term Positive Findings



Protection Against Sudden Death, CHD Mortality and Cardiovascular Mortality by 880mg/day n-3 PUFA Supplementation

- A randomized clinical intervention, GISSI Prevenzione (11,323 MI patients)
- Intervention: Daily n-3 PUFA (~882 mg EPA & DHA, 1:2), or vitamin E (300 mg), or both, or control
- Follow-up: 3.5 years



European Society for Cardiology

- Guidelines for CVD prevention

Oily fish and omega-3 fatty acids have particular protective properties

- Guidelines for management of ST-elevation infarction / secondary prevention

Class I: Supplementation with 1 g fish oil n-3 polyunsaturated fatty acids /day

- Guidelines for prevention of sudden cardiac death

Class IIa: EPA + DHA

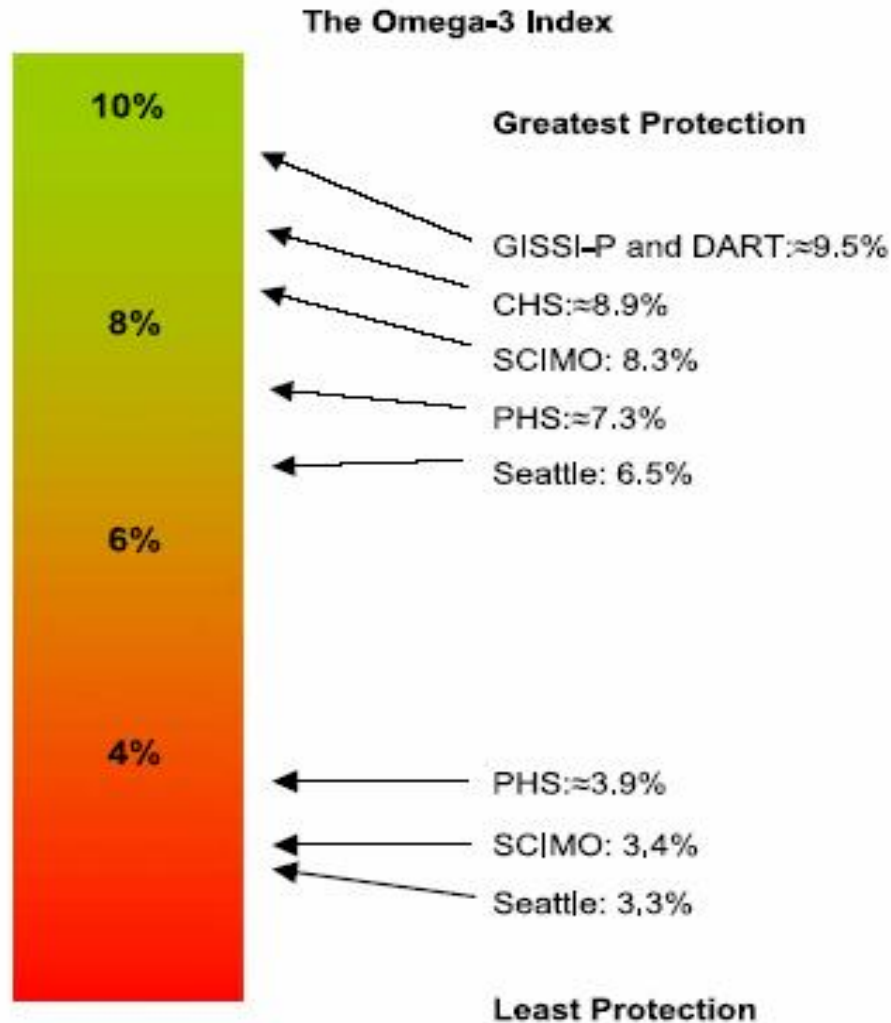
De Backer G et al. Eur Heart J 2003, 24:1601

Van de Werf et al. Eur Heart J 2003, 24:28

Priori SG et al Eur Heart J 2003, 24:13



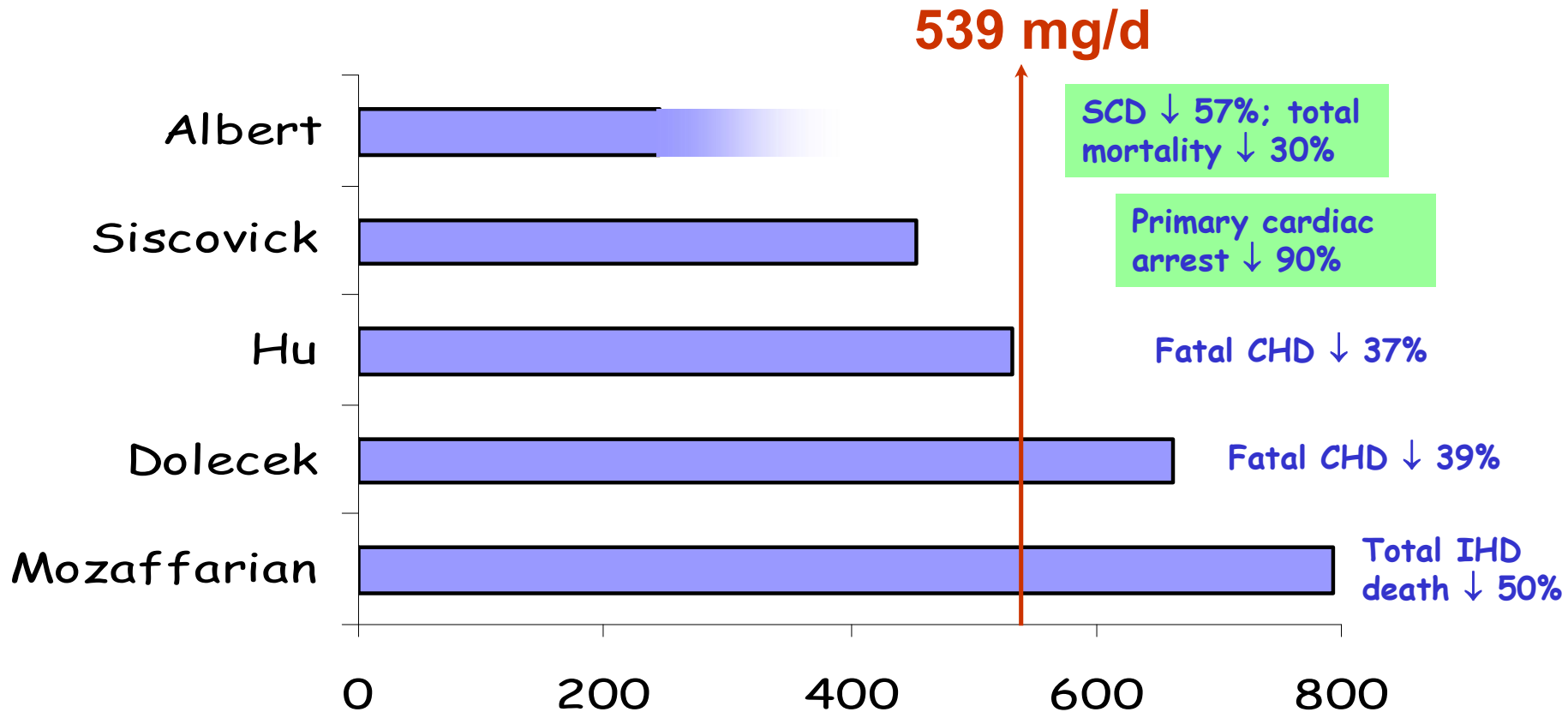
The Omega-3 Index



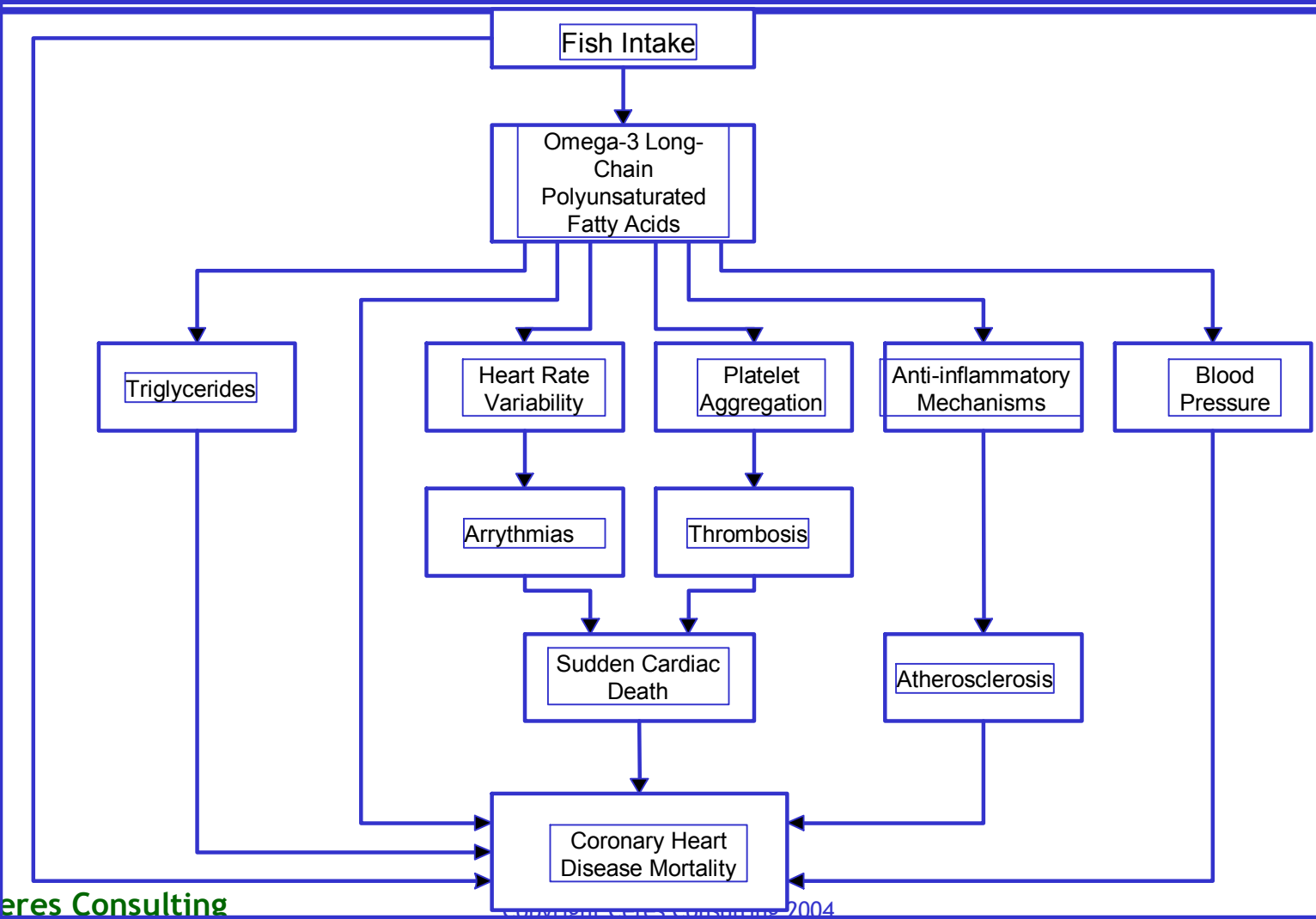
Omega-3 index of >8% associated with lowest risk of CHD, whereas an Index of <4% is associated with the highest risk



EPA and DHA Intakes Associated with Lowest Risk for CHD in US Epidemiology Studies



Omega-3 LC-PUFA and CVD Disease



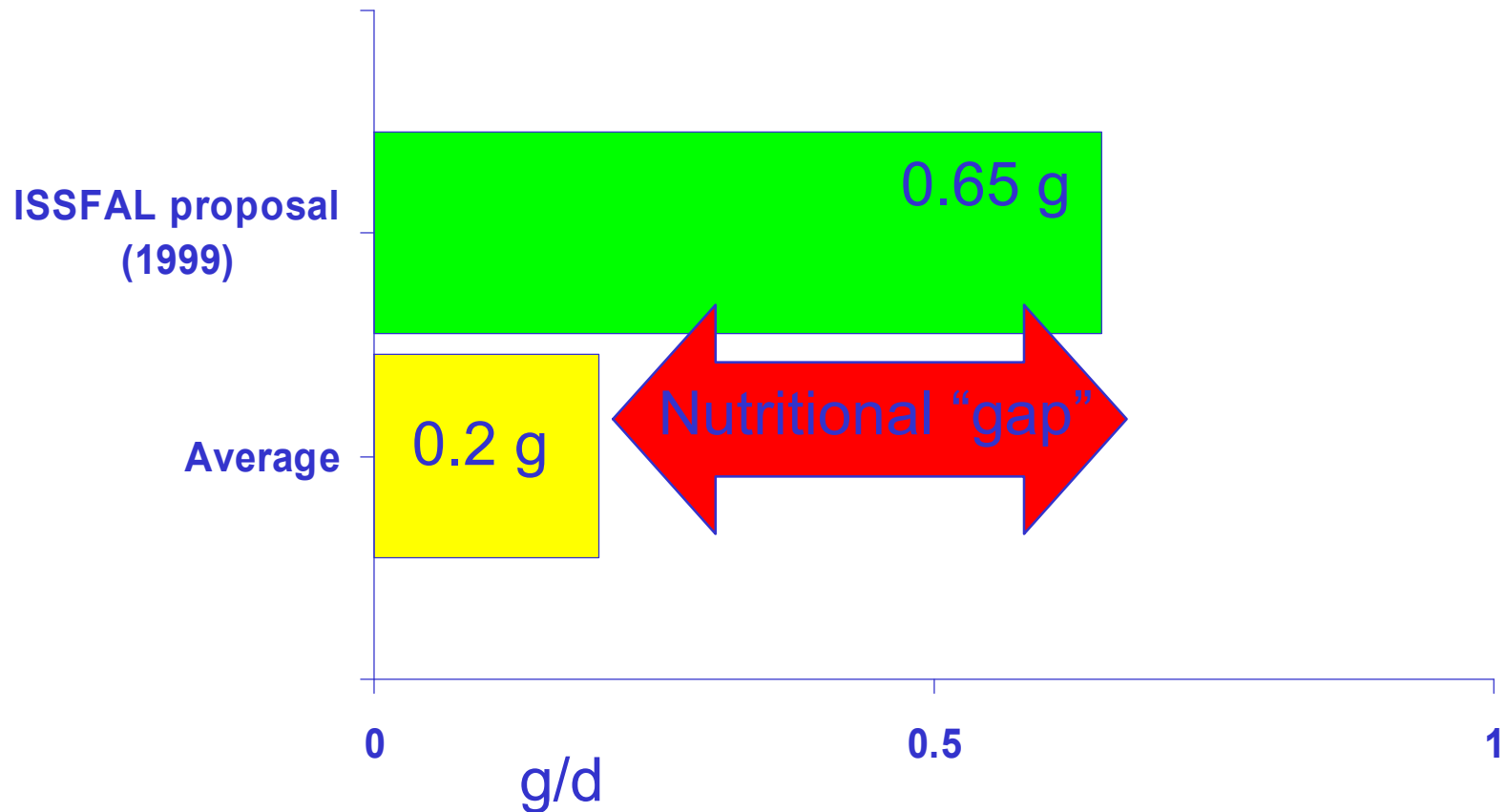
CONCLUSIONS on CVD

- Solid body of epidemiological evidence in different populations showing a risk reduction of CVD
- Reduction of CVD mortality and overall mortality in dietary intervention studies
- Dose trend in intervention studies using pharmacological dosages in high risk patients
- PUFAs are considered as safe
- Good rationale that PUFAs have a potential to reduce the risk of CVD and/or the risk of cardiac arrhythmias



Intake versus Recommendation

The Gap in Omega-3 LC PUFA



Intakes of Essential Fatty Acids (g/day)

	Linoleic acid	Alpha-linolenic acid	Ratio
Belgium	13.7	1.55	8.8
Denmark	10.5	2.1	5.0
France	7.5	0.55	13.7
Germany	8.6	0.8	10.7
Greece	9.6	0.65	14.8
Italy	14.5	0.8	18.1
Netherlands	16.1	1.45	11.1
Spain	21.6	0.8	27.0
Sweden	6.0	1.2	5.0
U.K.	11.4	1.4	8.1

Adapted from Briefing Paper BNF, July 1999 (TRANSFAIR Study)



LC-Omega-3 Dose and Safety

- **FDA GRAS limit: 3 g/day** (Federal Register 1997; 62(108):30751-7)
- **Omega-3 LC-PUFA can -**
 - reduce platelet aggregation
 - dilate blood vessels
 - moderate inflammation
 - *i.e. possible mechanisms for how n-3 LC-PUFA may reduce CHD risk*
- **At Omega-3 LC-PUFA intakes > 3 g/d, these properties have been said to lead to prolonged bleeding times**
 - Bleeding times still tended to be in the high-normal range
 - To date, not associated with adverse effects in numerous studies using n-3 LC-PUFA supplementation for extended periods



Summary of Use Recommendations

- **British Nutrition Foundation**
 - Recommended intake of 1.25 g/d DHA + EPA
 - Usual US dietary intake is about 0.25 g/d DHA + EPA
 - Dietary gap is 1 g/d EPA + DHA (~ 4 g/d ROPUFA 30 food oil)
- **American Heart Association (October 5, 2000)**
 - Two servings of fatty fish per week recommended
 - 3 - 4 g/d EPA + DHA may help by lowering triglycerides
 - 0.85 - 2.9 g/d EPA +DHA may help in secondary prevention
- **ISSFAL**
 - Adults: 0.65 g/d DHA + EPA (~ 2.6 g/d ROPUFA 30 food oil)



Global Dietary Recommendations for Omega-3 Fatty Acids

	ALA	EPA + DHA	n-6:n-3
U.S., 2002	1.2 to 1.6 g/d	Up to 10 % of ALA	
Canada, 1990	1.2 - 1.6 g/d		
U.K., 1992	1 % en	0.5 % en	
Australia, 1992	Moderate increases in plant and fish sources		
Sweden/WHO 1996	1.7-2.8g/d		
Japan, 1997			2:1



Recommended Intakes of n-3 Fatty Acids

FATTY ACID	FAO/WHO 1994/1998	Germany1 2000	Canada2 1990	Nordic3 1996	UK/BNF4 1992	EANS5 1998	ISSFAL6 1999
Linoleic Acid							
(en%)	4-10	2.5*	-	2.5*	6.0	-	2-3
(g/d)	10	-	-	-	-	-	4-6
α-Linolenic acid							
(en%)	-	-	-	-	1.0	-	1.0
(g/d)	-	-	-	-	0.2**	2	2.2
EPA + DHA							
(en%)	-	-	-	-	0.5	-	0.3
(g/d)	-	-	-	-	-	0.2	0.65
n-3 PUFA							
(en%)	-	0.5	-	0.5	-	-	-
(g/d)	-	-	1.2-1.6	-	-	-	-
Ratio n-6 to n-3	5-10:1	5:1	-	-	-	-	-



New Maximum Levels of Use for Fish Oil

Category of food ¹	Proposed maximum level of use
Baked goods and baking mixes (1)	5.0 percent
Cereals (4)	4.0 percent
Cheese products (5)	5.0 percent
Condiments (8)	5.0 percent
Egg products (11)	5.0 percent
Fats and oils (12), but not in infant formula	12.0 percent
Fish products (13)	5.0 percent
Frozen dairy desserts (20)	5.0 percent
Gravies and sauces (24)	5.0 percent
Meat products (29)	5.0 percent
Milk products (31)	5.0 percent
Nut products (32)	5.0 percent
Snack foods (37)	5.0 percent
Soup mixes (40)	3.0 percent
Nonalcoholic beverages (3)	0.5 percent
Chewing gum (6)	3.0 percent
Confections and frostings (9)	5.0 percent
Dairy product analogs (10)	5.0 percent
Gelatins and puddings (22)	1.0 percent
Pastas (23)	2.0 percent
Hard candy (25)	10.0 percent
Jams and jellies (28)	7.0 percent
Plant protein products (33)	5.0 percent
Poultry products (34)	3.0 percent
Processed fruit juices (35)	1.0 percent
Processed vegetable juices (36)	1.0 percent
Soft candy (38)	4.0 percent
White granulated sugar (41)	4.0 percent
Sugar substitutes (42)	10.0 percent
Sweet sauces, toppings, and syrups (43)	5.0 percent

Fr/vol.67, No. 38/ Tuesday, February 26, 2002 Proposed Rules



What Levels of EPA/DHA Should be Used for Fortification?

- AHA recommendations are approx. 500mgm EPA+DHA/day
- Omega-3 Working Gp.of CRN Health Claim petition to the FDA recommended 500mg/day, divided into four servings
=125mg per RAAC (serving)
- Other possibilities
 - Using “good source” levels of (10%) of the RDA
= 50mg/serving
 - Using “excellent source” levels (20%) of the RDA
=100mg/serving

Since a health claim is involved an efficacious dose should be utilized, therefore 100-125mg would seem to be reasonable.



FDA LC-Omega-3 Qualified Health Claim for Food

Text of New Qualified Omega-3 Claim (September 8th. 2004)

“Supportive but not conclusive research shows that consumption of EPA & DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of (food) provides (x) grams of EPA and DHA omega-3 fatty acids.”

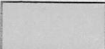


Daily supply of omega-3 LC-PUFA



Fortification levels with ROPUFA '30' n-3 Food Oil

Food	Serving size	0.25%	0.5%	1.0%	1.5%	2.0%	2.5%	3.0%	3.5%	4.0%
Margarine	25 g	15 mg	31 mg	62 mg	93 mg	125 mg	156 mg	182 mg	Technically not feasible	
Bread	100 g	62 mg	125 mg	Technically not feasible						
Milk	300 ml	162 mg	Technically not feasible							

 Covers at least 20 % EPA + DHA, ISSFAL Workshop recommendations 1999



Enrichment of Foods with ROPUFA n-3 Oil/Powder

	Formu- lations	Level of addition	Direction of uses	Shelf life
Fat spreads 60-80% fat cont.	Oil	3.0 %	• Fat blend	4 months (4° C)
25-60% fat cont.	Oil	2.0 %	• Fat blend	3 months (RT)
Vegetable oils	Oil	1-2 %	• direct addition to oil	6-12 months (depend. on packag.)
UHT milk <i>skimmed:</i>	Oil	0.2 %	• Pre-emulsion with milk	<i>Full fat/Semi</i>
				3-4 months (RT)
				<i>Skimmed:</i>
				2-3 months (RT)
Yoghurts	Oil	0.6 %	• <i>Set type:</i> Homogenisation step before pasteurisation	
			• <i>Stirred type:</i> After fermentation/before mixing step	



Enrichment of Foods with ROPUFA n-3 Oil/Powder

	Formulations	Level of addition	Direction of uses	Shelf life
Cookies/Cakes	Oil	1.0 %	<ul style="list-style-type: none">• Fat blend	6 - 9 months
Bread	Oil	0.3 %	<ul style="list-style-type: none">• Fat blend• Mixed with flour premix	Normal shelf-life for bread
	Powder	1.0 %	<ul style="list-style-type: none">• Flour premix/flour improver premix	
Fruit Juices	Oil	0.1 %	<ul style="list-style-type: none">• Fruit concentrate before homogenisation	6 months
Instant bev. powders (chocolate/malt based products)	Powders	1-1.5 %	<ul style="list-style-type: none">• Dry mixing	12 months



Enrichment of Foods with ROPUFA n-3 Oil/Powder

	Formu- lations	Level of addition	Direction of uses	Shelf life
Meat based products	Oil Powder	0.2 % 0.5-0.8 %	Injections Dry mixing with spices	3 months
Surimi	Oil	2.0 %	mixing to surimi pasté	9 months (chilled)



Microencapsulation

Beadlet Cross section

maize starch

Inner phase
(0.2 - 0.4 μm)
with stabilizer (Tocopherols,
Rosemary Extract)

Matrix:
Gelatin
Carbohydrate
Sodium Ascorbate

0.4 mm

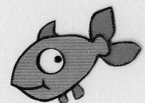
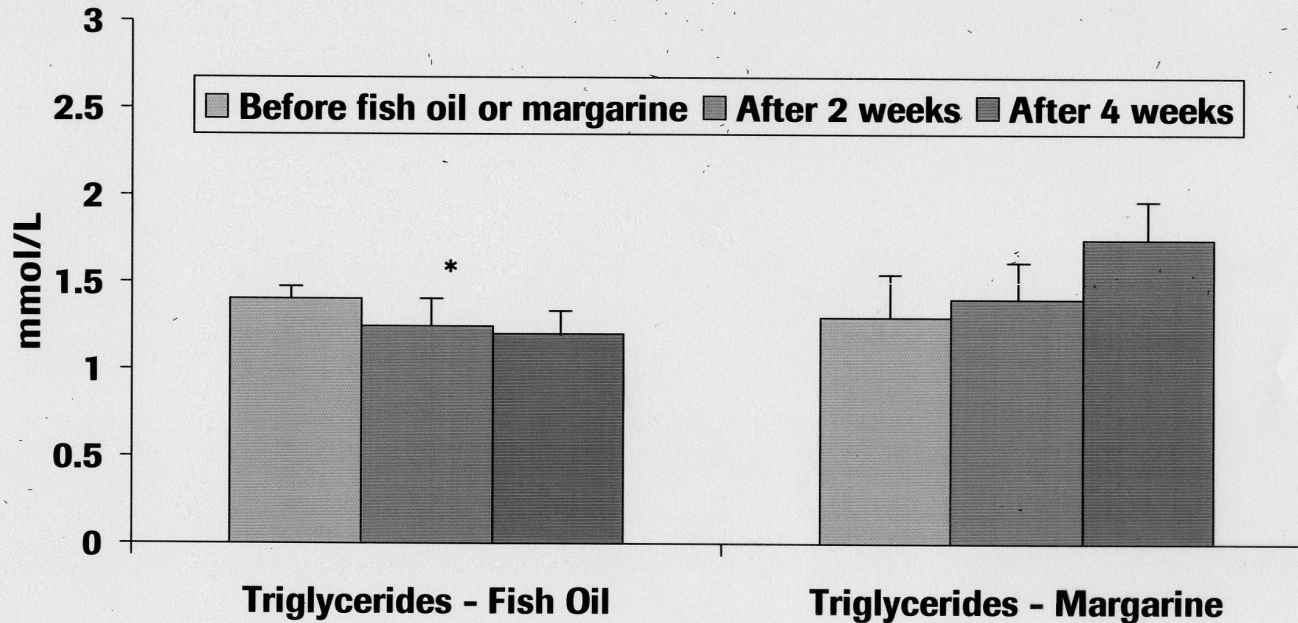


Functional Foods are Effective

Roche

Vitamins

Effect of Dietary Supplementation with Fish Oil or Margarine in Bread on Serum Triglycerides.



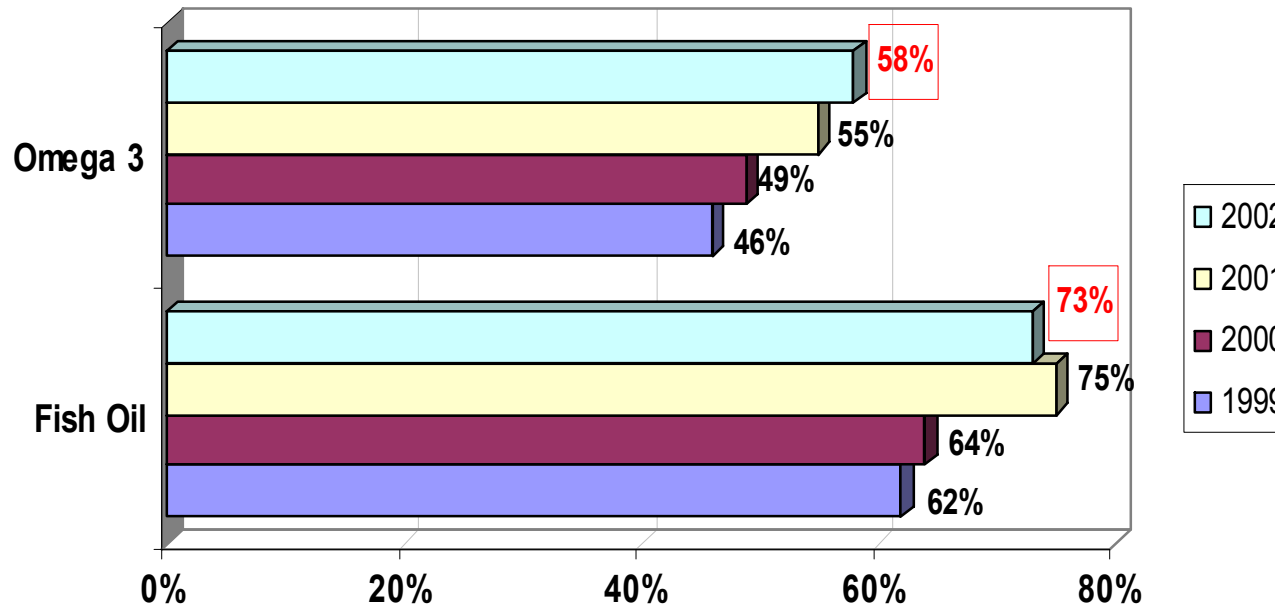
Effects of Bread Containing Fish Oil Consumption on Biological Parameters of Hyperlipidemic Subjects

- 36 people with hyperlipidemia divided in 3 groups
- daily consumption of 100 g of oat fibre bread (with 0.5 g EPA + DHA) for 4 weeks
- Results :
 - triglycerides decreased by 22 %
 - HLD cholesterol increased by 10 %
 - no difference between oat or wheat fibre bread

Published in NUTRITION RESEARCH 21 p. 1403 - 1410 (2001)



LC-PUFA Consumer Awareness (USA)



Demographics of Consumer Awareness (2002)

74% female vs 56% male

75% ages 35 to 65+

80% have incomes >\$50K

80% from West Coast; 76% from East Coast; 74% from South

84% are college grads and 72% have had some college education



Omega-3 Awareness in European Countries

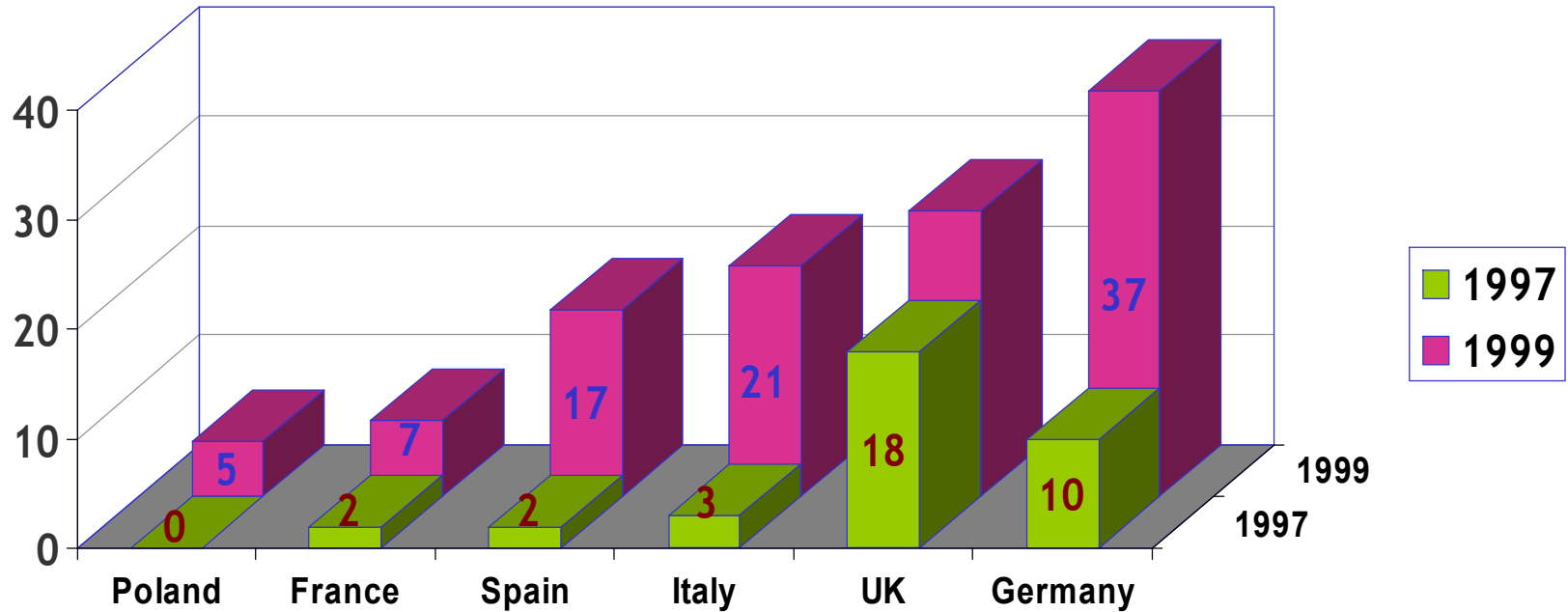
	<u>Spain</u>	<u>GB</u>	<u>Germany</u>	<u>Italy</u>	<u>Netherlands</u>	<u>France</u>
Omega-3	64 %	38 %	38 %	21 %	12 %	32 %
Fish Oil	29 %	48 %	45 %	16 %	43 %	19 %
Cod Liver Oil	45 %	78 %	72 %	36 %	60 %	66 %
PUFA	22 %	2 %	37 %	1 %	1 %	9 %
Long Chain Omega-3	11 %	3 %	11 %	1 %	2 %	9 %
PUFA						
EPA	2 %	6 %	1 %	1 %	4 %	2 %
DHA	2 %	6 %	1 %	1 %	1 %	10 %

Source: IPSOS Research for DNP (2003)



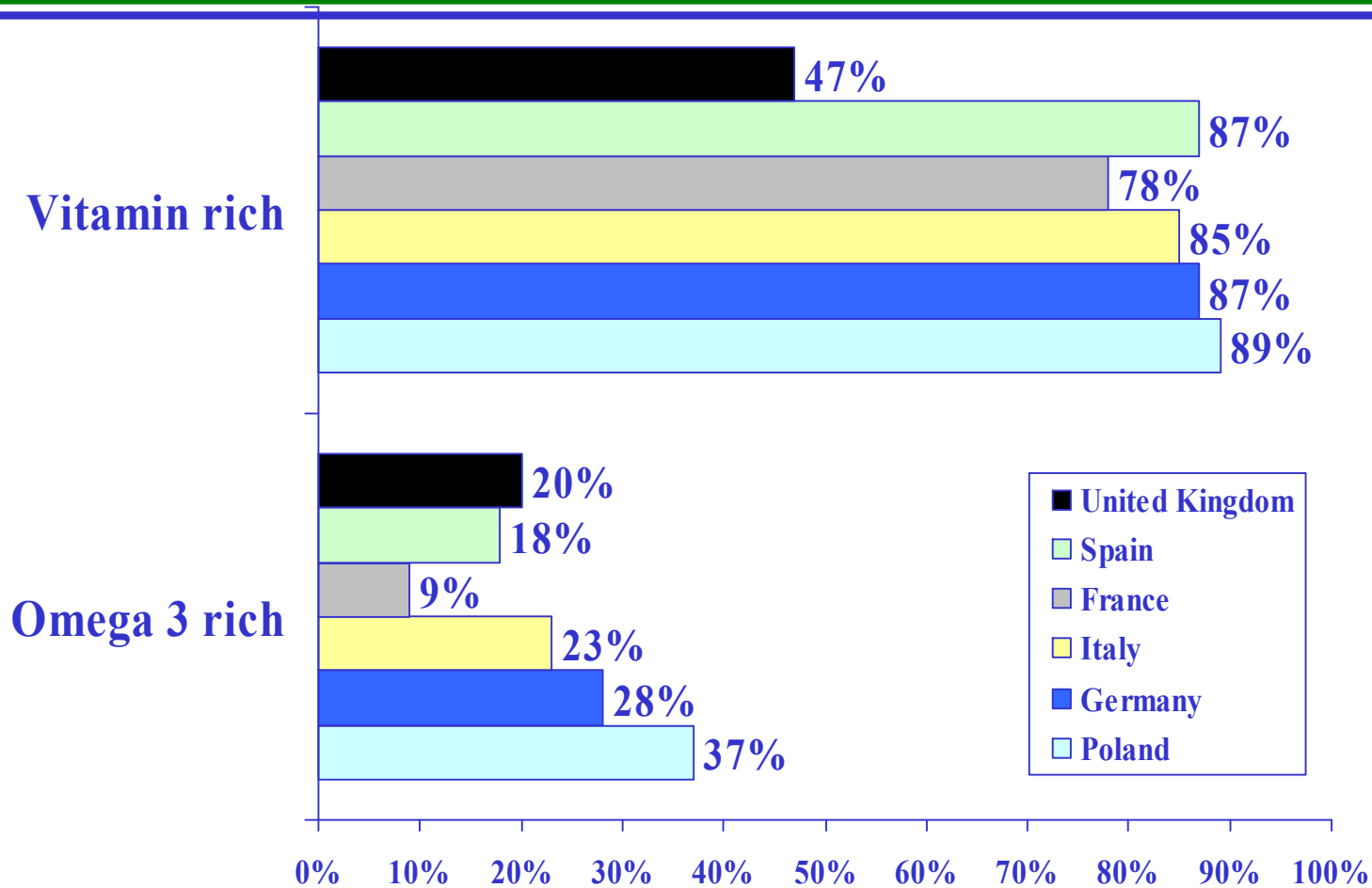
Awareness Study Europe

Have you heard of OMEGA 3, as a food ingredient?



How important to you are the following food health claims?

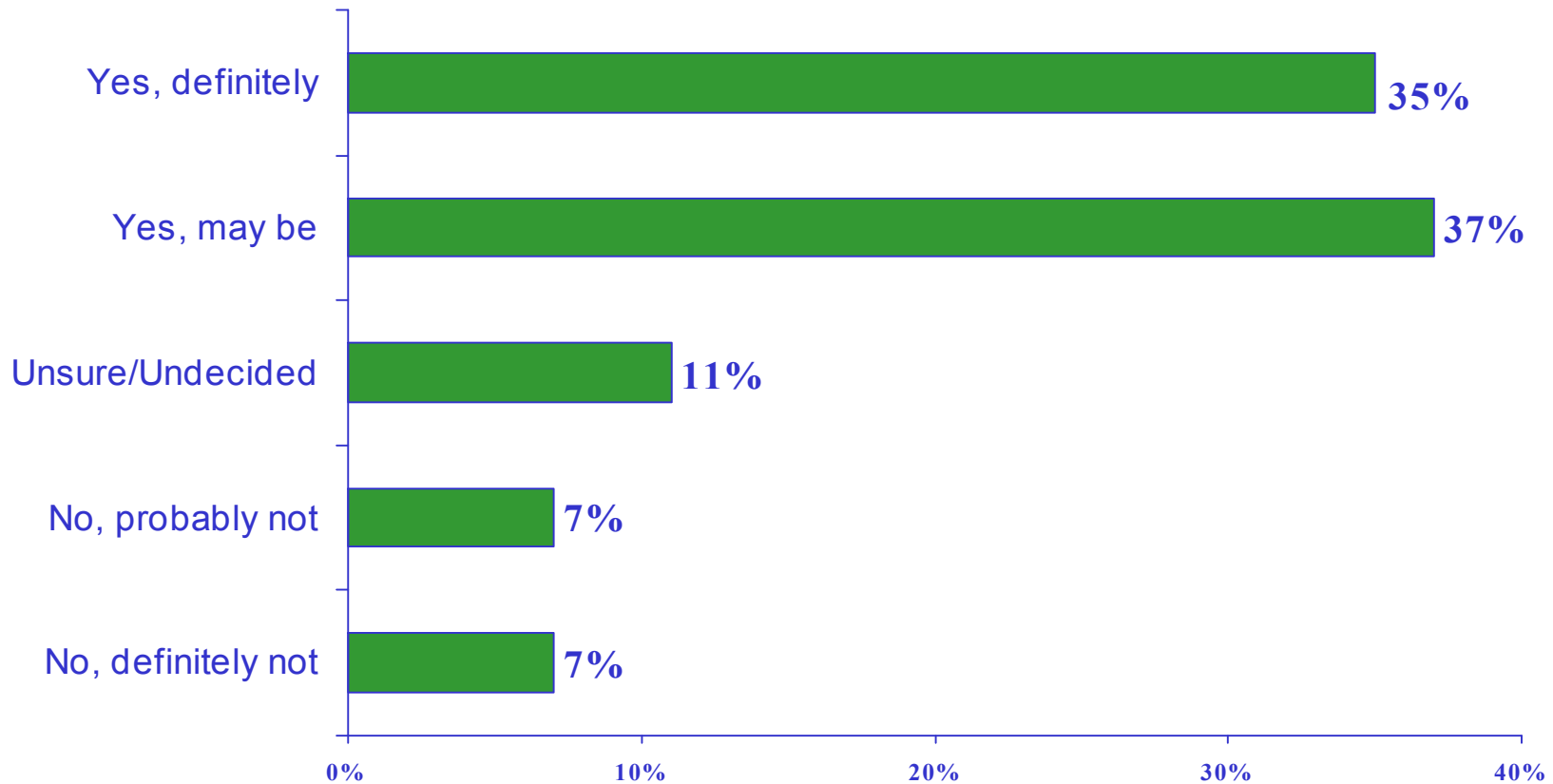
(% of very important/important)



Source: Gallup 99



If Omega 3 was included in certain foods without a major price difference, would you buy them?



Based on those spontaneously unaware of Omega 3 - read out description of qualities



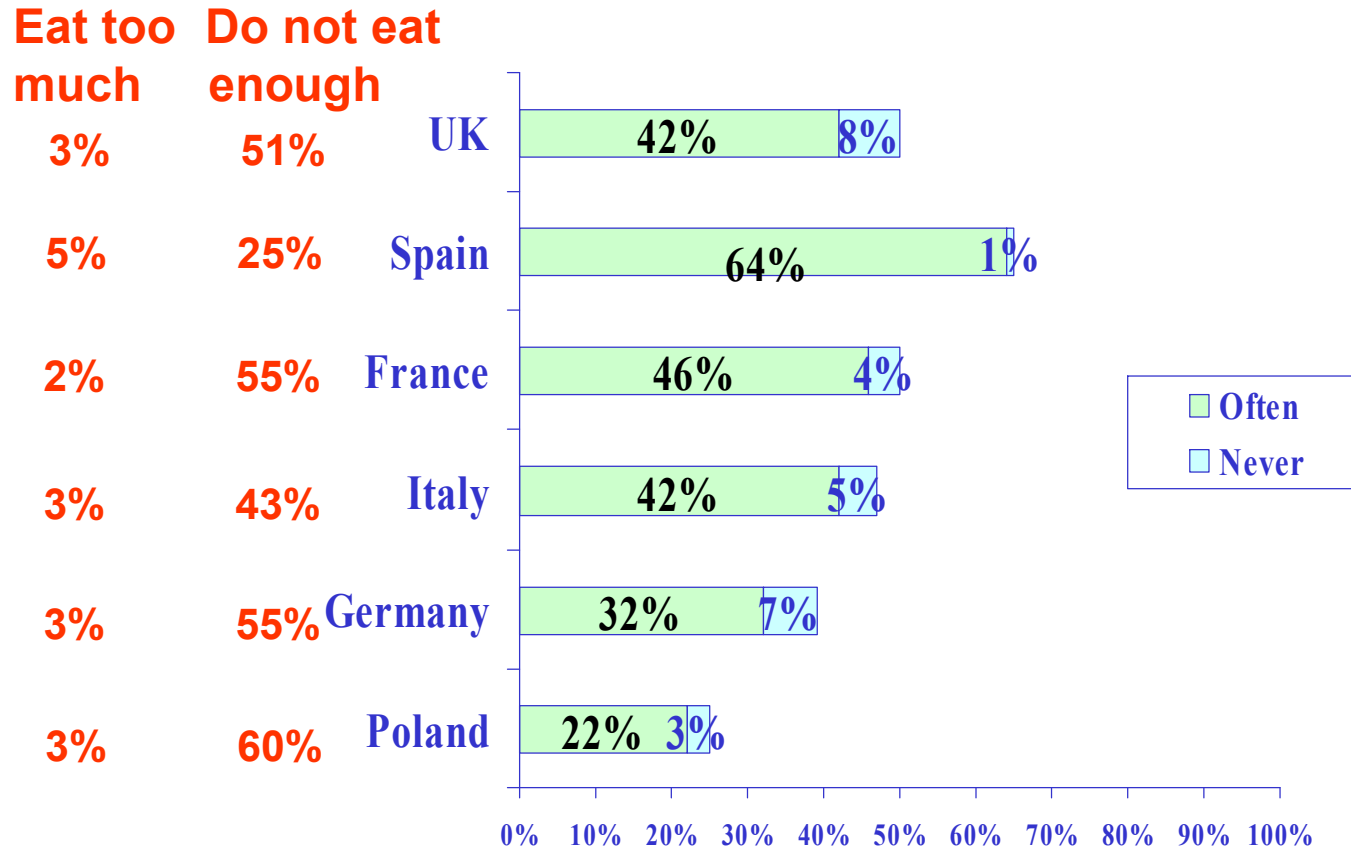
Consumers' Interest for Testing Food Fortified with Omega-3

	<u>Spain</u>	<u>GB</u>	<u>Germany</u>	<u>Italy</u>	<u>Netherlands</u>	<u>France</u>
Interested	35 %	37 %	31 %	32 %	46 %	39 %
Not interested	51 %	52 %	63 %	50 %	50 %	52 %
Don't know	14 %	11 %	6 %	18 %	4 %	9 %



Frequency of eating FISH

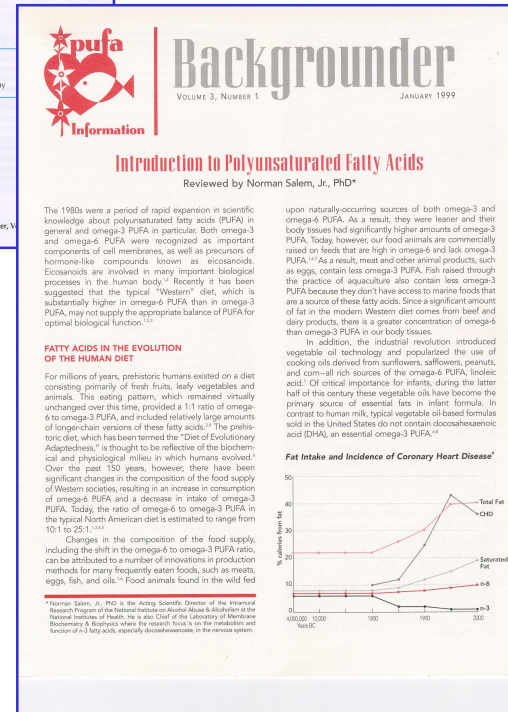
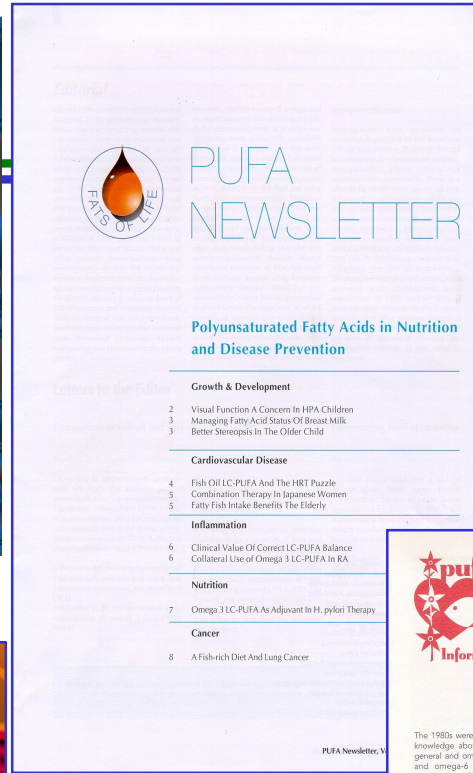
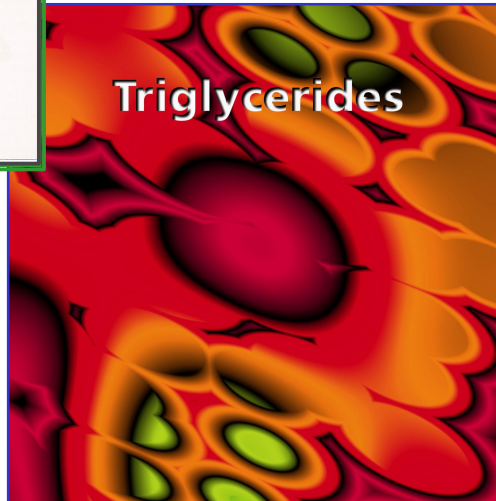
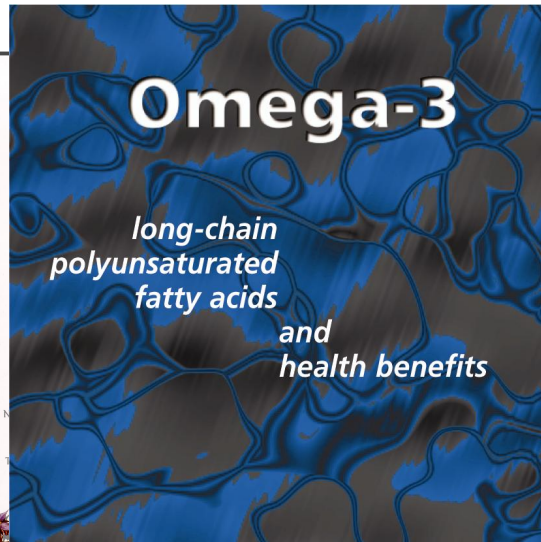
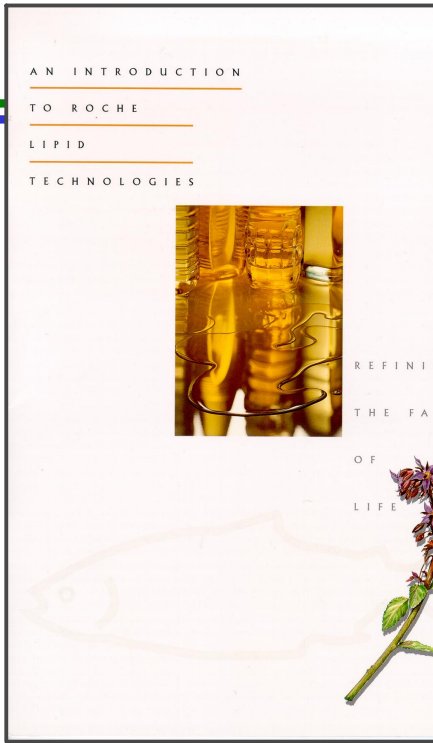
- plus perception of over/under eating



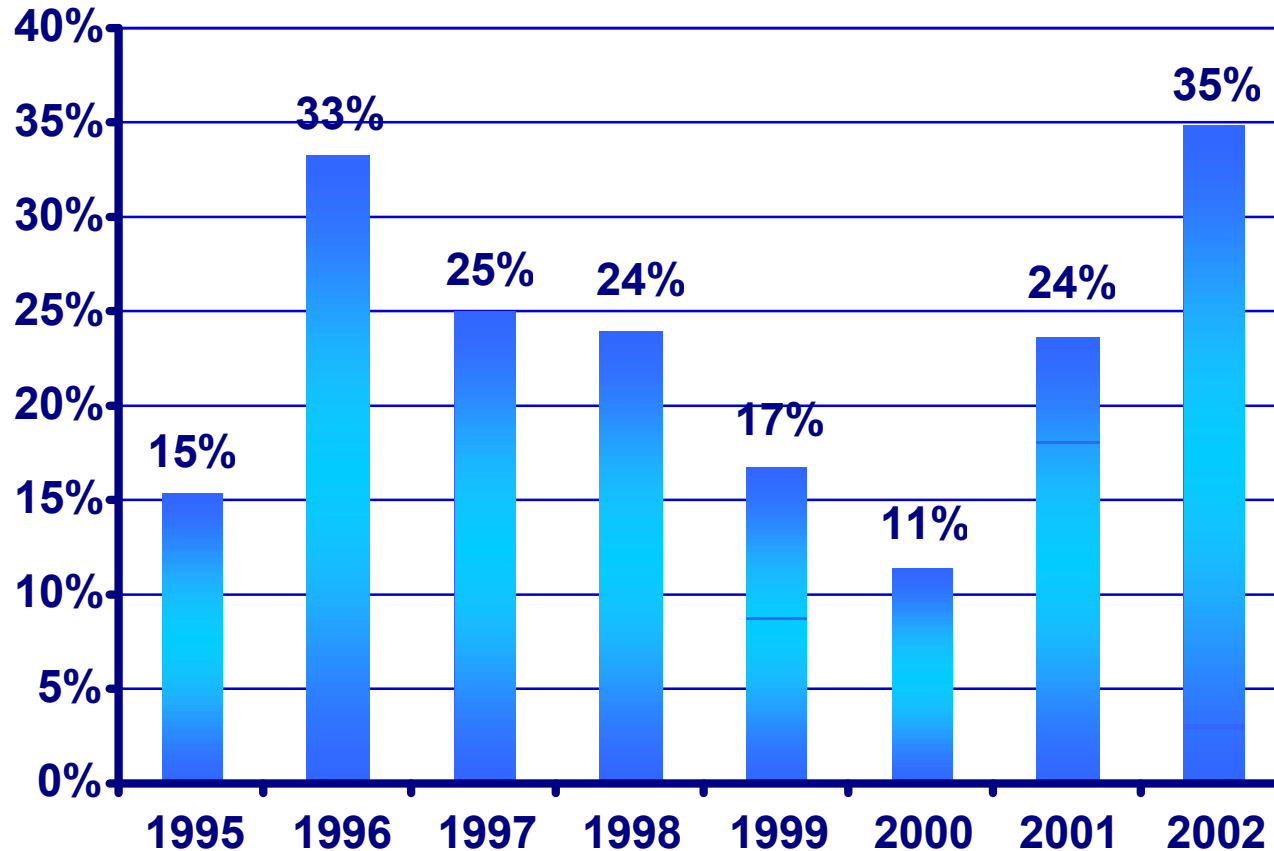
Based on total sample



Scope of Available Literature (Roche/DSM)



Annual Growth in Sales in Fish Oil (USA)



Omega-3 Battle Looming

JULY 2004

Canada set for omega-3 milk battle

Omega-3 producers of all types will have their eyes on Canada in the coming months, where the state of Ontario is to be the stage for an important contest between similar products that are both touting the benefits of omega-3s. Ontario will become the first market in the world in which rival omega-3 fortified milks – one marine-source, one vegetable-source – will be found side-by-side on the supermarket shelf.

While scientists and omega-3 producers tend to believe that most consumers, when they get the right communications, will pick the product that provides the dose of DHA and EPA they need (only available from the product made with marine-source omega-3), that is an assumption as-yet unsupported by evidence from the market. The Canadian contest will be the first real-life test of this hypothesis with the two parties using different approaches in ingredients, pricing and communicating the health benefits. Which brand wins will be as much about strategy as about science.

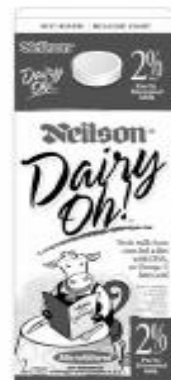
Natrel, the Canadian dairy producer which last year launched Natrel Omega-3, Canada's first omega-3 milk drink, is extending its distribution to Ontario, where it will be in head-on competition with Neilson Dairy Oh's Dairy Oh!



Canadian children. In terms of claims, the Neilson DHA milk is permitted to say: *"Omega-3 fatty acids contribute to good health, growth and development. DHA, an omega-3 fatty acid, supports normal development of the brain, eyes and nerves."*

Natrel's Omega-3 brand, on the other hand, carries no health claim. But from the outset instead of advertising, the company has been using a vigorous PR campaign in which it talks in its press releases about how: *"Consumption of Omega-3 and Omega-3 products such as Natrel Omega-3 will help: Promote the reduction of blood cholesterol; Prevent certain illnesses, such as cardiovascular disease; Foster brain and visual development in children; Improve immune reactions against allergies, and Reduce the risks of the formation of blood clots."*

Price-wise Neilson's Dairy Oh! is priced at a 10% premium to regular milk while Natrel Omega-3 stands at a 25% premium in its home state of Quebec.



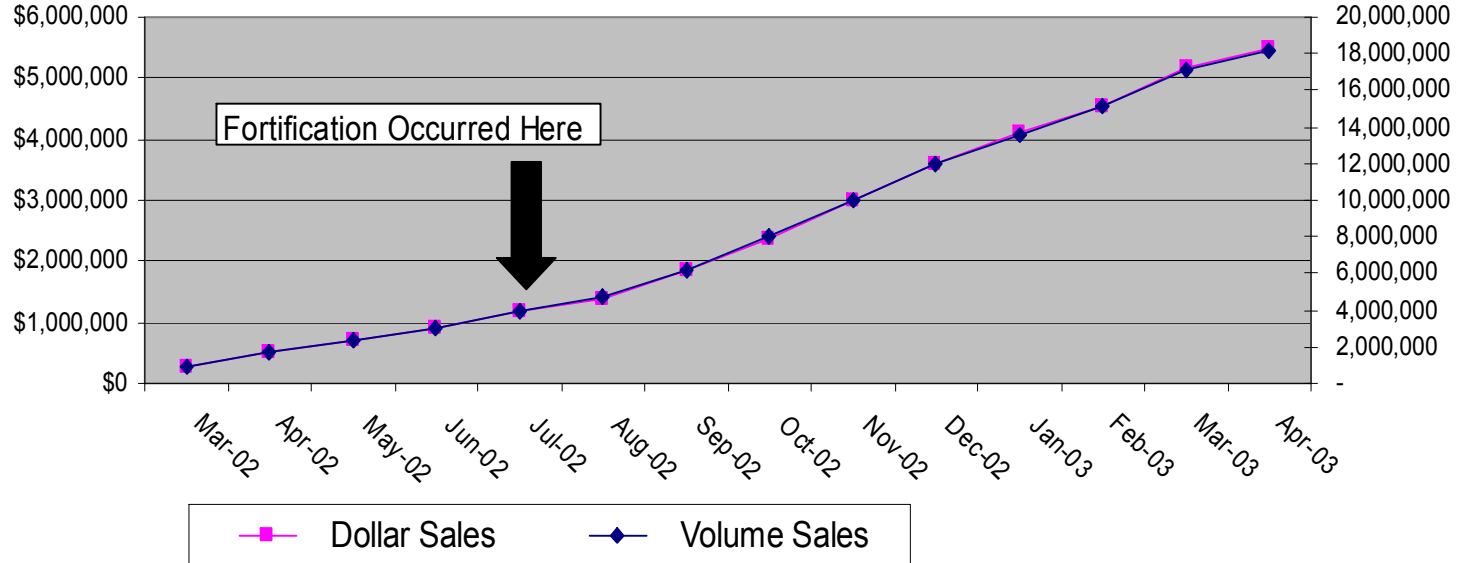
COMMENT: Some will argue that this will be a poor test from which to draw conclusions, since the Neilson product provides only 20mg of DHA per 250ml serving compared to 125mg per 250ml serve for most DHA-fortified milks. However, it is questionable whether time-pressed consumers will notice or

- Differences between omega-3 and EPA/DHA
- Conversion ALA to EPA/DHA relatively low (~3-5%)
- Levels of LC PUFA per serving for US health claim an issue



Addition of LC-omega-3 Fuels Growth in New Products

Enfamil Lipil Concentrate 13oz Reformulated with Omega 3 - FDMx



Margarines/Spreads...the first entrants

Company: Vandemoortele

Brand:	Vitelma
Product:	Progress Margarine
Category:	Dairy
Country:	Belgium
Pack Size:	250.00g
Packaging:	Plastic pot/cup
Storage:	Chilled

Product Description

Vitelma brand is Progress margarine with 65% fat and Omega 3 which contributes to the healthy functioning of the cardiovascular system.

Ingredients

Fat ingredients (65%), colza oil, sunflower oil, vegetable oil, **marine oil**, water, emulsifier: mono- and diglycerides of fatty acids; preserving agent: potassium sorbate; flavour, acidifying agent: citric acid; vitamin A, vitamin D3; colouring: beta carotene



Arla

Brand Name: Gaio
Country: Finland
Euro Price: 1.67
Pack Size: 250g
Storage: Chilled



Description

A light margarine (40% fat) with a healthy balance between different fatty acids (46% rapeseed oil, 45% milk fat, 9% fish oil) and omega-3. It carries the Green Keyhole logo which indicates healthy eating.

Ingredients

Water, rapeseed oil, butter oil, skimmed milk, **fish oil**, gelatine, salt (1.5%), emulsifier (E471, E472c), preservative (E202), antioxidants (ascorbic acid, E310, E385), acidity regulator (citric acid), flavour, vitamins (A and D)



Continuing Global Launch of New Products - Margarine



Nutrition

Per 100g: energy 2,250kJ, 60g fat of which 16g saturated, 0.5g trans, 14g polyunsaturated, 5g omega-3, 4,40mg short chain (ALA), 600mg long chain (EPA, DHA), 27g monounsaturated, 380mg sodium, 380mg potassium, 1,000µg vitamin A, 10µg vitamin D

Company: Goodman Fielder Milling & Baking

Country: New Zealand

Launch: Jan-2003



Parmalat

Il latte del cuore

Description

UHT milk which contains Omega 3 and vitamins C, E & B₆. Available in a one litre Tetra Slim pack. **It contains 60 mg/100 ml DHA + EPA.**

Claim:

Parmalat milk omega3 is enriched with a significant amount of of omega 3 and with vits C, E, B₆. The omega 3 are polyunsaturated fatty acids which help to improve the blood fluidity and to reduce the triglycerides level therefore contributing to reduce the risk of CVD.

Thanks to the omega 3 also drinking a glass of milk can help you to take care of your well-being.



The Rising of Omega-3!



www.puleva.es



Trabajamos por el bienestar de la familia



Ceres Consulting

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Puleva

Product: PulevaOmega 3
Category: Dairy
Country: Spain
Europrice: 0.78
Packsizes: 500ml
Packaging: TetraBrik carton

Description

A UHTskimmed milkenrichedwith omega-3fattyacid,and vitamins E, A,D

Ingredients

Skimmedmilk,sunfloweroil with a high "bily" grade,lactose,lactoseproteins, oliveoil, soya oil,emulsifier,**oil of marine origin**,vitamin E, A, D

Dieta cardiosaludable

- Lácteos desnatados o semidesnatados.
- Aceite de oliva (rico en ácido oleico).
- Pescado azul (rico en ácidos grasos Omega-3)
- Cereales, frutas, verduras y legumbres.

Puleva Omega3

- Es leche desnatada.
- Contiene ácido oleico, componente esencial del aceite de oliva.
- Contiene ácidos grasos esenciales Omega-3.



PULEVA OMEGA³

(VALOR NUTRICIONAL)

	x 100 ml		x 200 ml	
V. ENERGÉTICO	kcal	38	76	140
	kJ	237	474	852
Proteínas	g	2.2	4.4	8.8
H. de carbono	g	1.2	2.4	4.8
Grasas	g	1.4	2.8	5.6
- Saturadas	g	0.3	0.6	1.2
- Monoinsaturadas	g	1.2	2.4	4.8
- Poliinsaturadas	g	0.8	1.6	3.2
VITAMINAS Y MINERALES				
- Calcio	mg	130	260	520
		(10% CDR)*	(40% CDR)	(140% CDR)
- Vitamina B ₁₂	µg	0.28	0.56	1.12
		(28% CDR)	(56% CDR)	(112% CDR)
- Vitamina A	µg	130	260	520
		(15% CDR)	(30% CDR)	(60% CDR)
- Vitamina D	µg	0.3	0.6	1.2
		(12% CDR)	(24% CDR)	(48% CDR)
- Vitamina E	mg	1.5	3.0	6.0
		(15% CDR)	(30% CDR)	(60% CDR)
- Vitamina B ₆	mg	0.3	0.6	1.2
		(10% CDR)	(20% CDR)	(40% CDR)
- Ácido Fólico	µg	30	60	120
		(15% CDR)	(30% CDR)	(60% CDR)

*CDR: "Nutrientes Obligatorios"



Candia Milk

Brand Name: Candia
Product: Candia aux Oméga 3 Milk
Category: Dairy
Sub-Category: Milk
Country: France

Product Description:

A semi-skimmed milk enriched with omega 3 fatty acids. It is said to help keep the heart and arteries functioning well. It is available in 500ml bottles.



Pinar Milk

Brand name: Pinar Denge

Product: UHT milk

Country: Turkey

Launch date: April 2002

Shelf Life: 3 months



More Milk and Beverages

OJ from UK
with added fish
oil to provide
LCP for better
brain power



Milna Toddler Biscuits

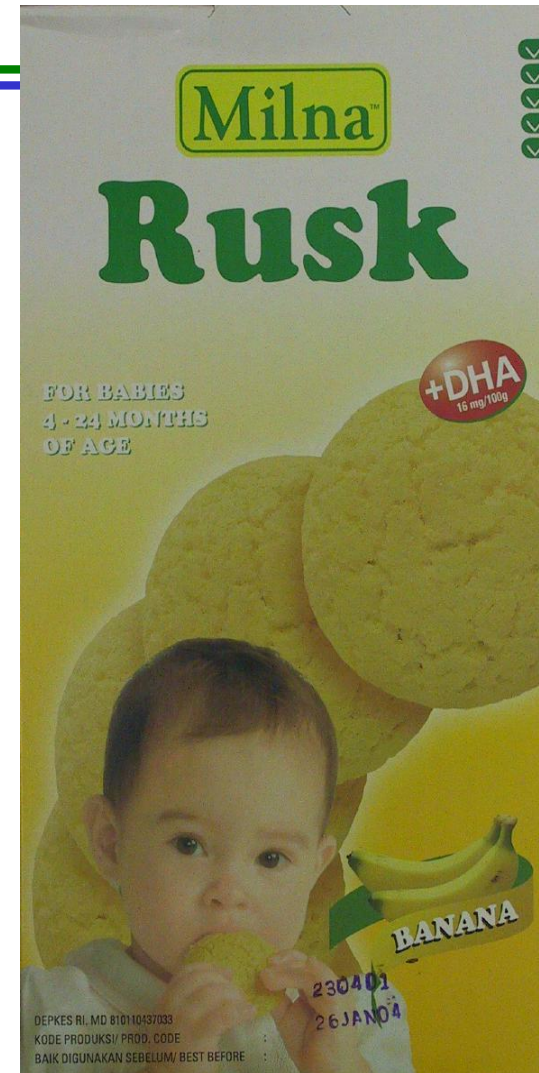


Milna Rusk Biscuits

Ingredients:

Wheat Flour, Sugar, Banana, Vegetable oil, Ammonium Bicarbonate, Calcium Carbonate, Emulsifier, **DHA** Iron and Vitamins

Claim: this healthy snack helps to promote brain development, facilitates growth of teeth and train your baby to feed himself



Summary on the Success of Omega-3 LC PUFA in Europe

Developing new ingredients and foods takes:

- Time
- Science
- Government support (claims, fortification, DRI's)
- NGO support (alliances)
- Driving consumer awareness (PR)
- Food companies willing to launch foods (small vs large)
- MONEY



Thank You

