

IFT Symposium

Challenges in the Development of Functional
Foods with Omega-3 fatty Acids

**Marketing Omega-3 (EPA/DHA)
in Functional Foods**

Ian Newton

Managing Director



Ceres Consulting

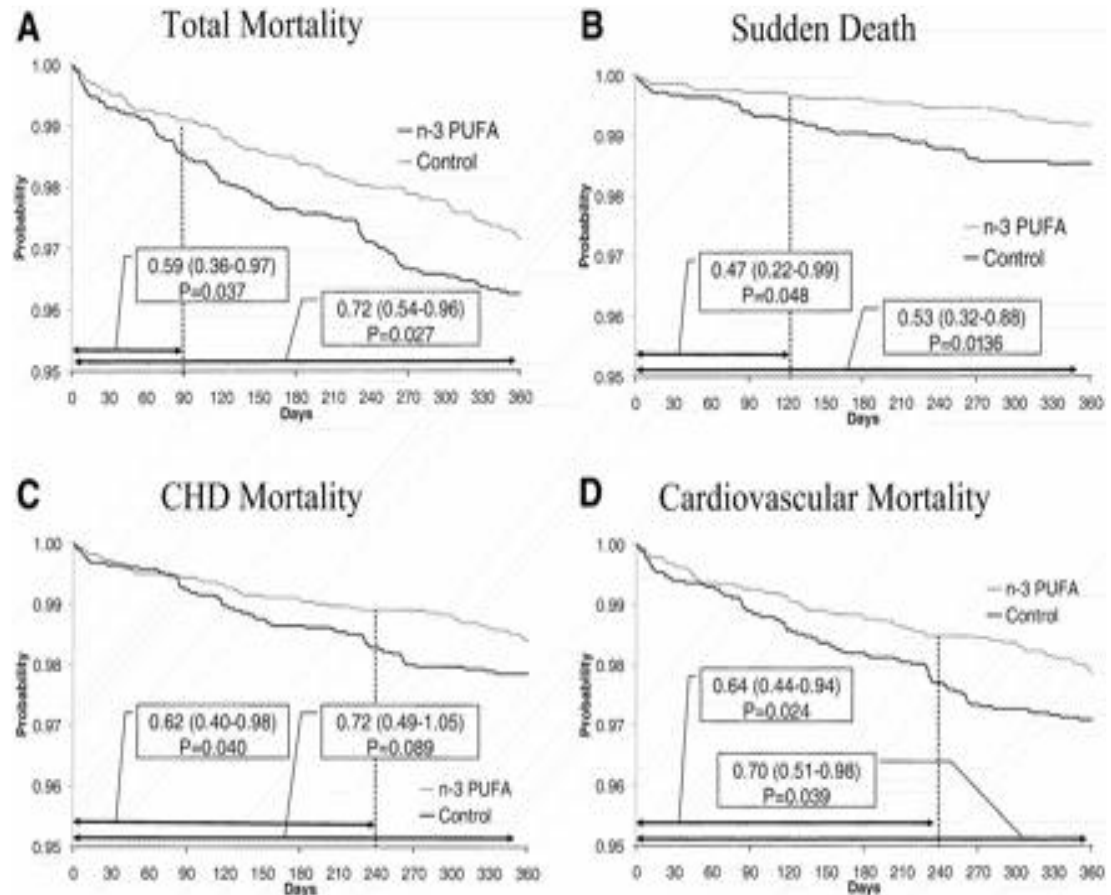
Heart Attack and Dietary Fat Intake of Eskimos vs. Danes (1976)

	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

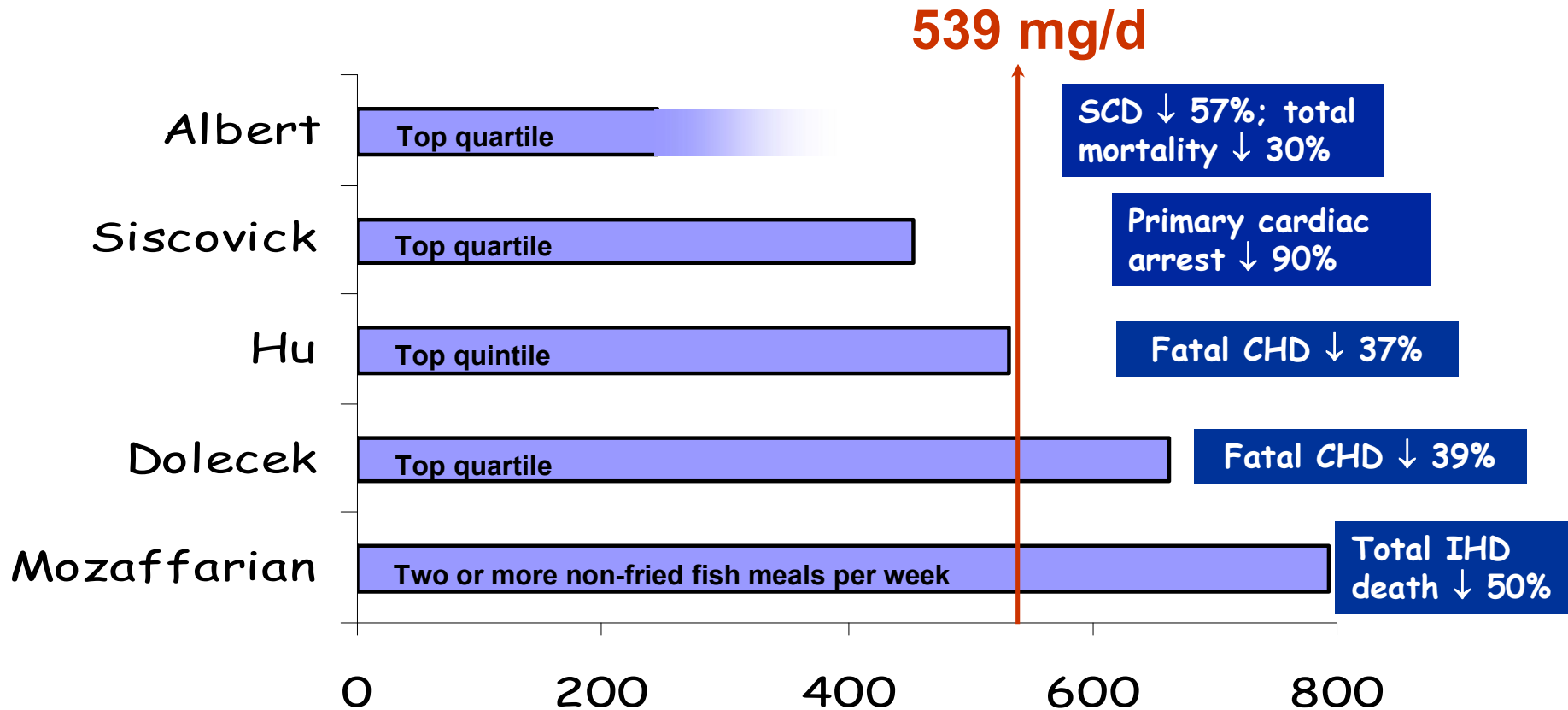


Protection Against Sudden Death, CHD Mortality and Cardiovascular Mortality by 880mg/day n-3 PUFA Supplementation

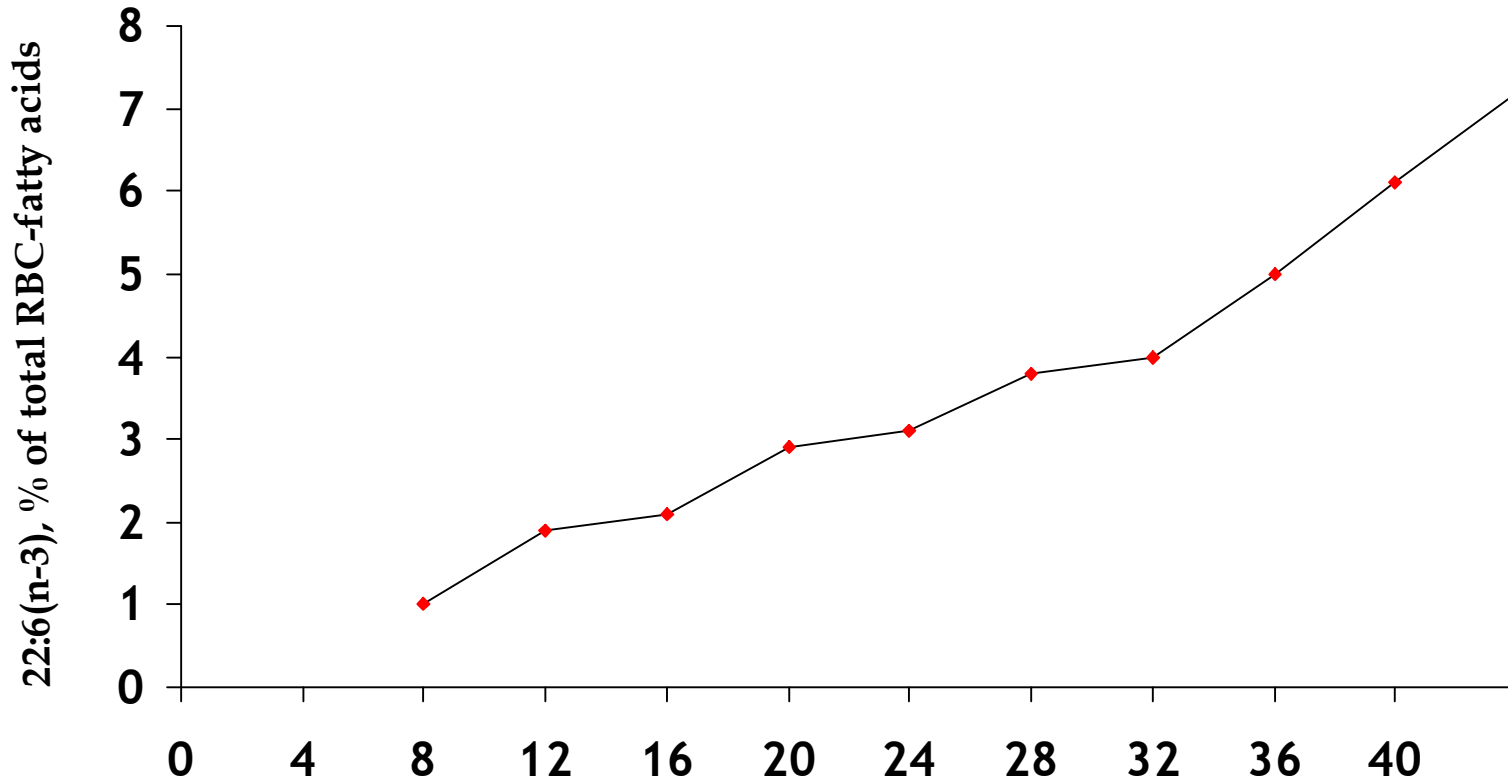
- A randomized clinical intervention, GISSI Prevenzione (11,323 MI patients)
- Intervention: Daily n-3 PUFA (~882 mg EPA & DHA, 1:2), or vitamin E (300 mg), or both, or control
- Follow-up: 3.5 years



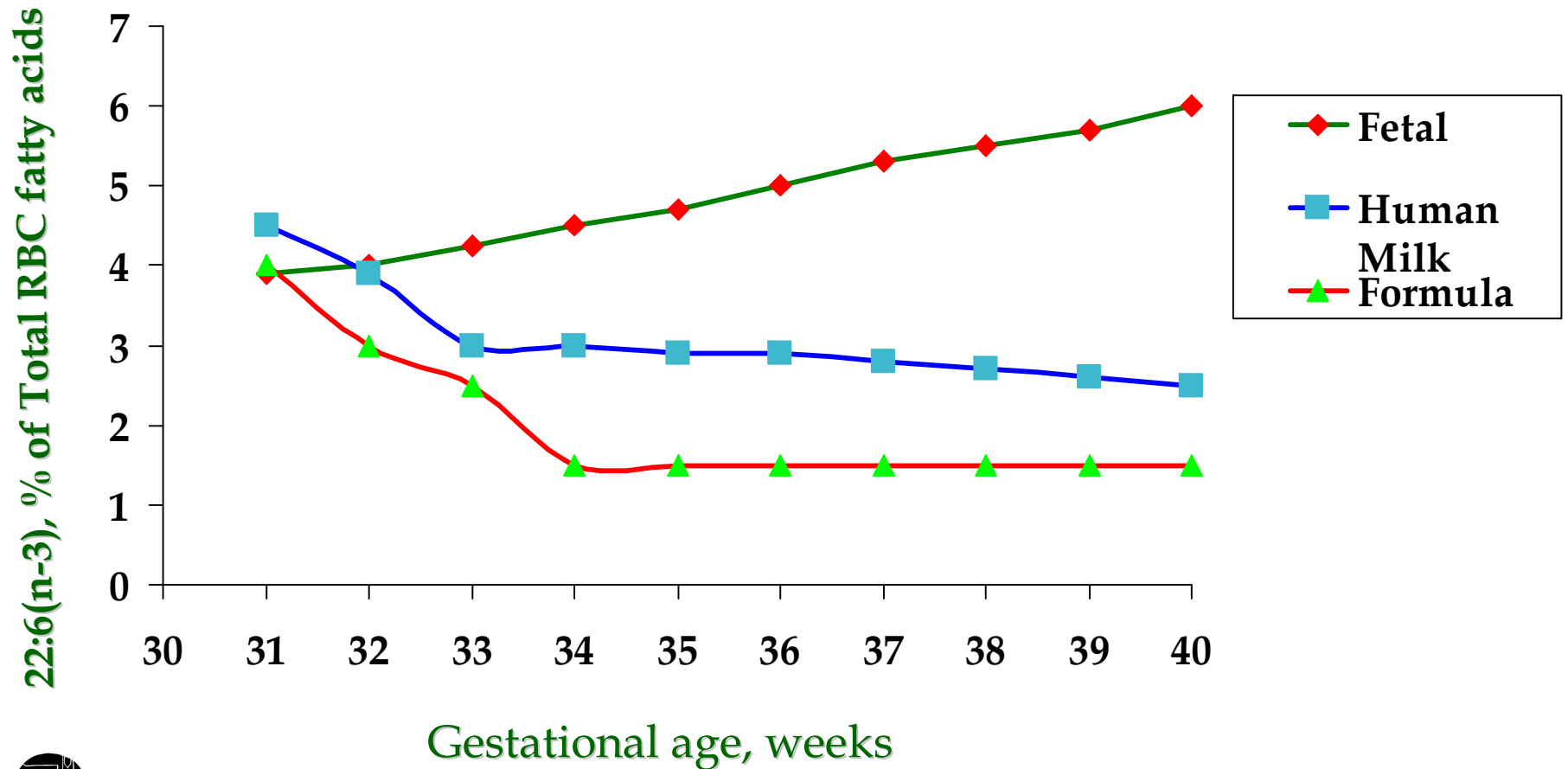
EPA and DHA *Intakes* Associated with Lowest Risk for CHD in US Epidemiology Studies



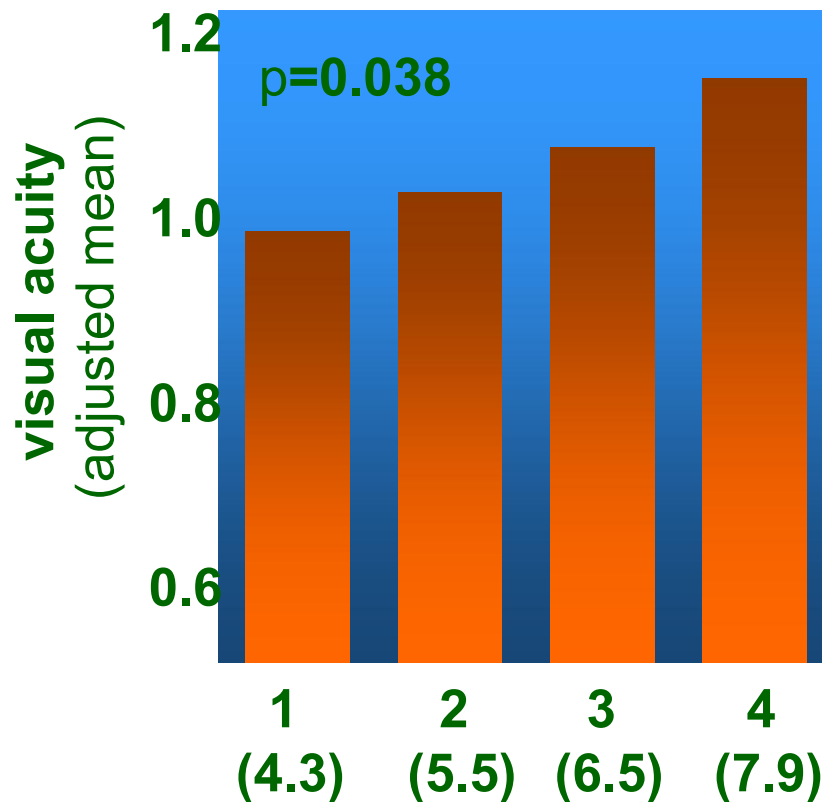
Fetal DHA Status Increases Exponentially During Gestation



DHA Status of Preterm Infants Compared to Fetal Levels

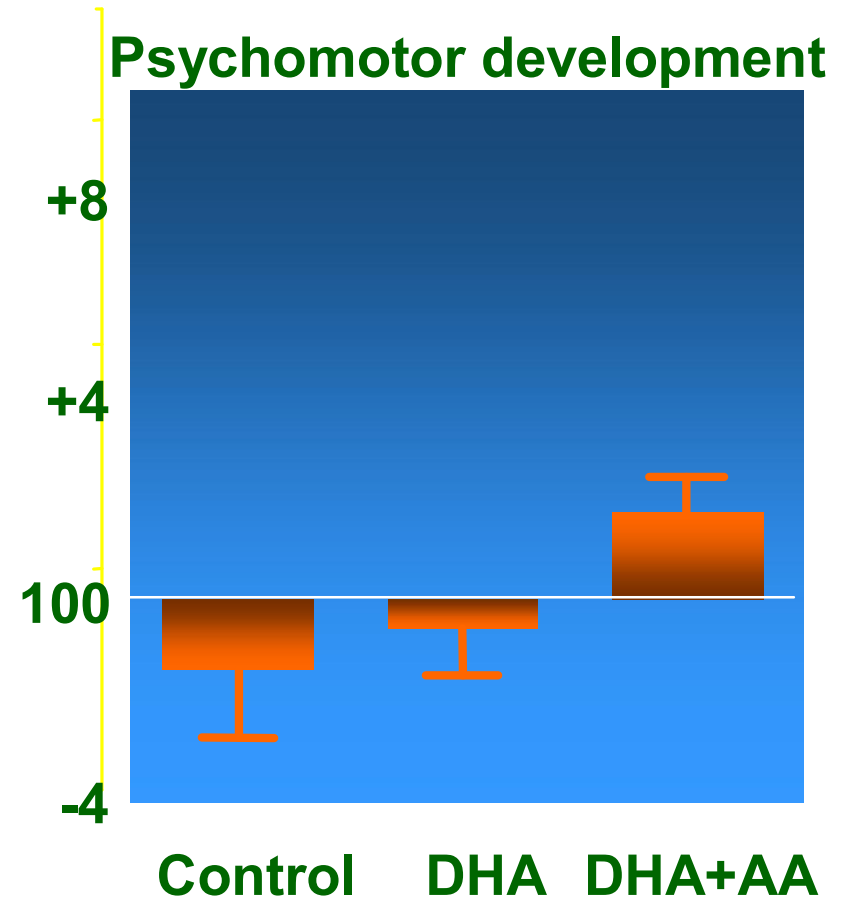
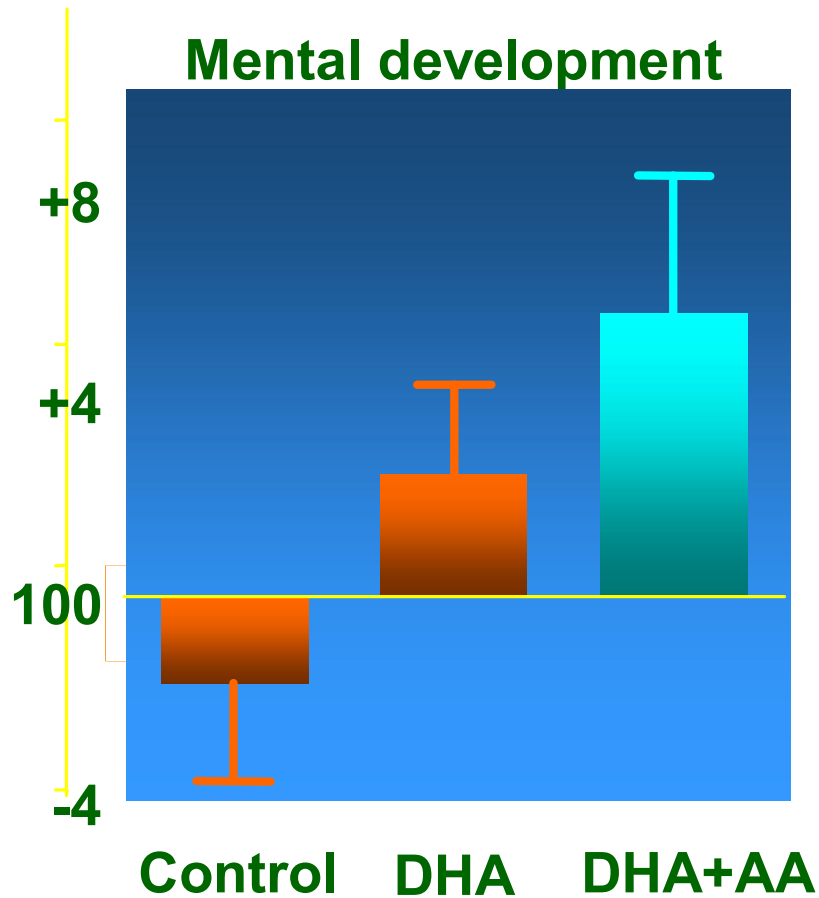


Visual acuity at 8 years of age is related to DHA status at birth (n=56)

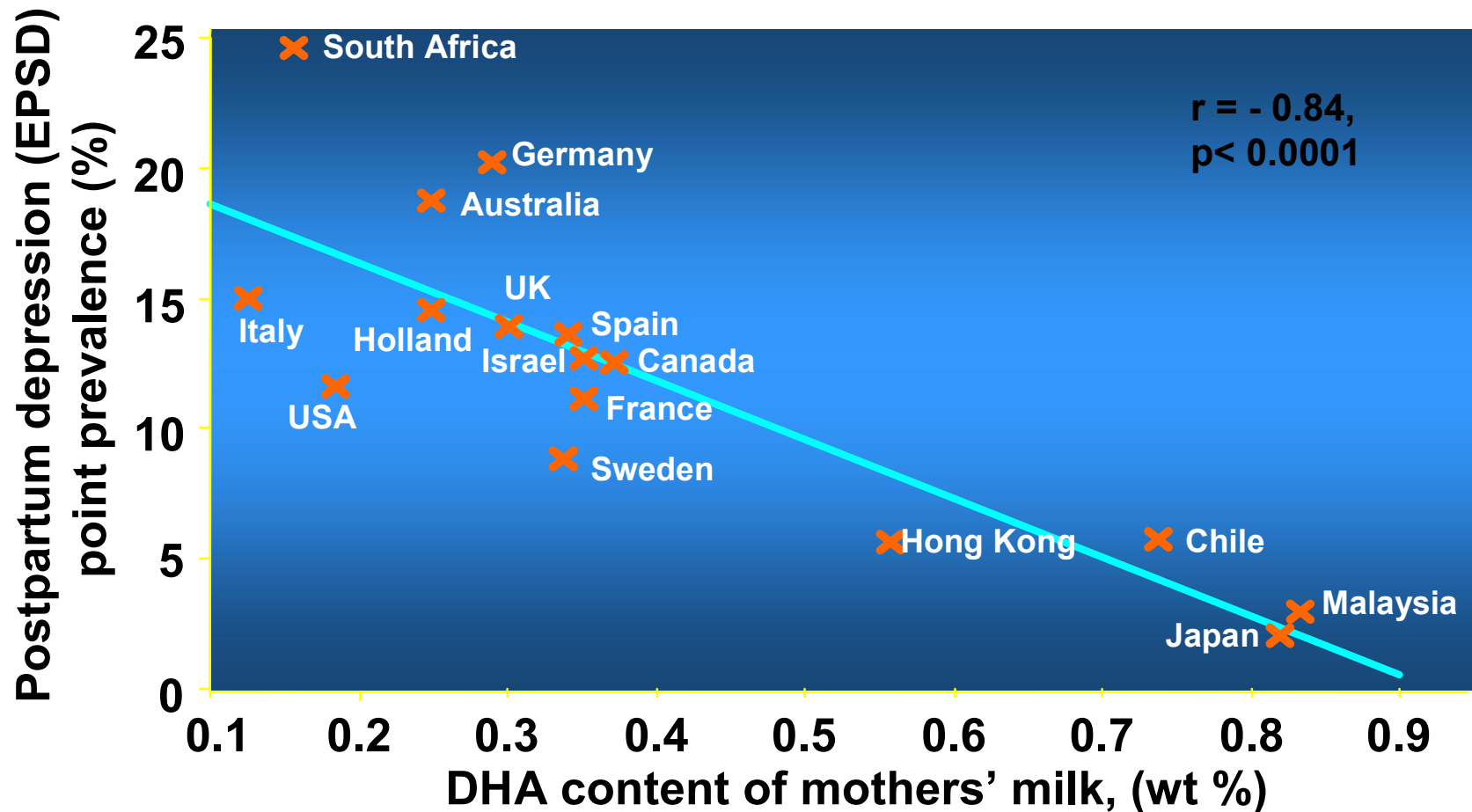


Administration for 17 weeks formula with DHA and AA improves mental development of term infants at 18 months

(Birch *et al.*, 2000)



Prevalence of postpartum depression is negatively associated with maternal DHA status



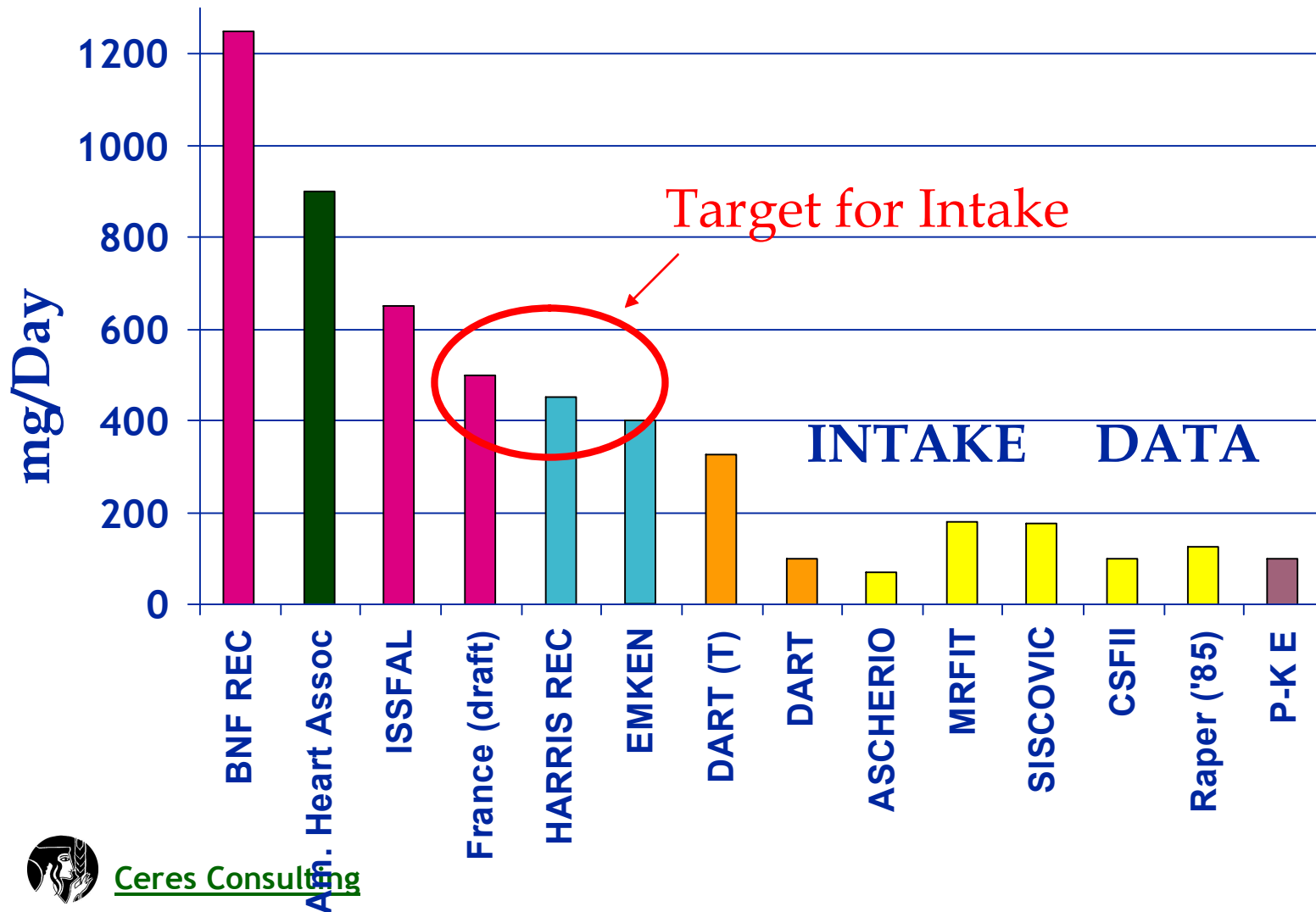
Clinical Conditions with Possible Involvement of n-3 PUFA

- Coronary heart disease
- Blood lipid disorders
- Hypertension
- Atherosclerosis
- Thrombosis
- Vasospasm
- Arthritis
- Cancer
- Allergic asthma
- Autoimmune diseases
- Inflammatory diseases
- Psoriasis



LC OMEGA-3 PUFA INTAKE/RECS

(mg/day) (Cardiovascular disease)



New Daily Recommended Intakes (DRIs) for PUFAs: Still Strong Input from Oil Producers

PUFA	Men g/ day	Women g/ day	Pregnancy g/ day	Lactation g/ day
Linoleic Acid (n-6)	17	12	13	13
α -Linolenic Acid (n-3)	1.6	1.1	1.4	1.3
DHA/EPA	0.16	0.11	0.14	0.13



Petition to FDA for a Health Claim for Omega-3 LC Pufa Foods

- 500mg/day long chain fatty acids
- Based on 4 meal occasions, therefore 125 mg of long chain omega-3 fatty acids (EPA/DHA) per RACC
- foods must be a low fat, low saturated fat, low trans fat, low cholesterol food
- Supported by and similar to AHA recs., other countries, respected researchers

Qualified Health Claim already for DS



American Heart Association Scientific Statements: Fish Consumption, Fish Oil, Omega-3 Fatty Acids and Cardiovascular Disease, 2002

Population

Patients w/o documented CHD

Patients w/ documented CHD

Patients needing TG lowering

Recommendation

Eat a variety of fish (preferably oily) at least twice a week, include oils and foods rich in ALA

Consume 1 gm of EPA+DHA per day, preferably from fish, supplements could be used in consultation with a physician

Two - four gm of EPA+DHA per day provided as capsule under a physician's care



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



New Maximum Levels of Use for menhaden Oil and other fish oils (ethyl esters)

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



Market Leaders Driving the Category

- Pronova
- Roche/DSM
- OmegaProtein
- Ocean Nutrition
- BASF
- Martek (infant nutrition primarily)



Council for Responsible Nutrition - OMEGA-3 WORKING GROUP OBJECTIVES

Define Min. Industry Standards, assays, analytical methods.

- Amounts of EPA and DHA to be specified in mg/gm.
- Specifications for oxidative by-products
 - Peroxide value - Maximum 5 meq/kg
 - Anisidine value - Maximum 20
 - TOTOX value - Maximum 26
- Contaminants specified maximum levels
 - PCB's - Total polychlorinated biphenyls (PCBs): Less than 0.09 mg/kg
 - Dioxins - Maximum 2 pg WHO-PCDD/F-EQ/g
 - Heavy metals (Pb,Hg) - Less than 0.1 mg/kg
- Work toward USP (USP) monograph for Long Chain Omega-3s
- Education program



Public Information Programs

Most Credible Info Sources

- Health associations 84%
- Physicians 81%
- Dietitians 75%
- Pharmacists 72%
- Nurses 66%
- Health newsletters 64%
- Govt agencies 62%



Health Professional Opportunities

Pharmacist/Patient Fact Sheet -

One Minute Counselors

- Pharmacist : New Recommendations for
- Omega-3 Fatty Acids
- Patient: Understanding The Good Fats

American Dietetic Association

Dietary Practice Groups - SCAN and NCC

- **Nutrition in Complementary Care**

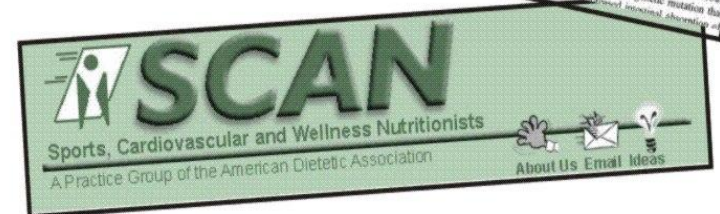
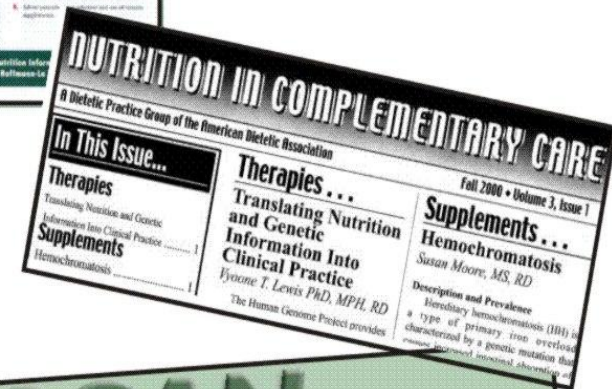
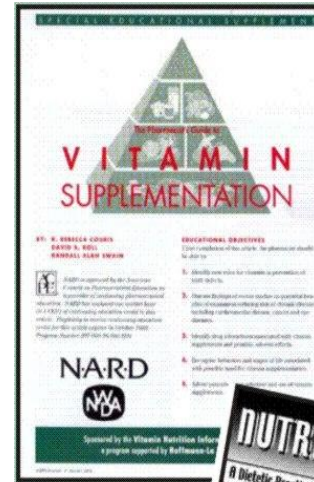
- *Sponsoring Executive Meeting*
- *Developing articles for newsletter*

Dietitians in the New Jersey Chapter of ADA

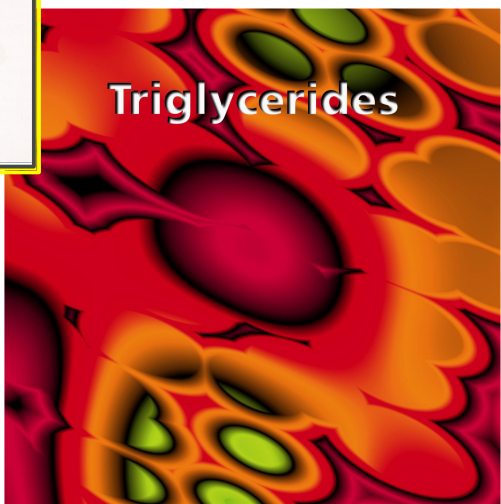
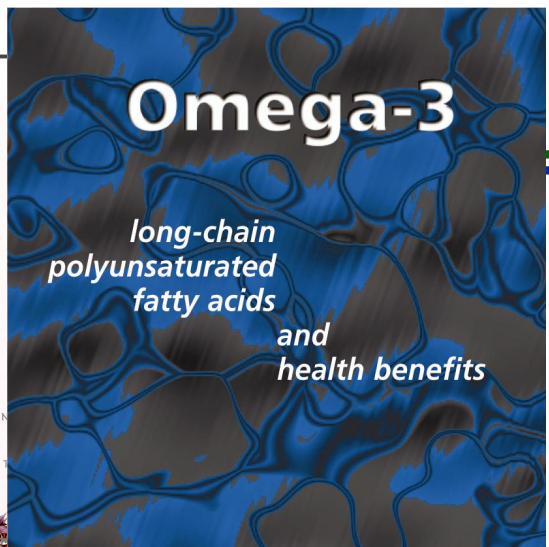
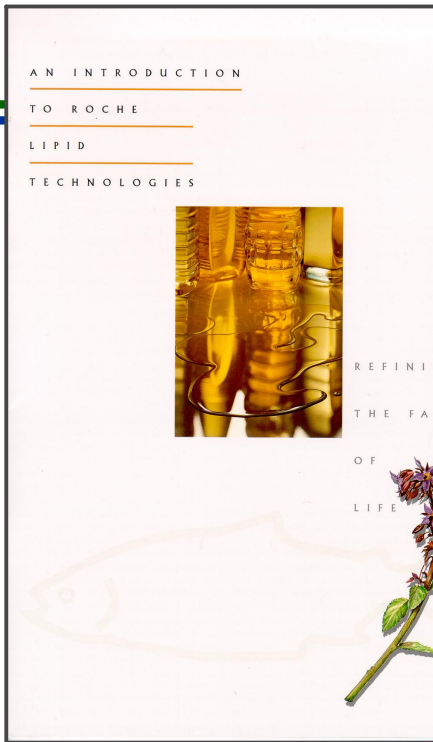
- Sponsor Speaker(s)
- Distribute Newsletters and Studies



[Ceres Consulting](#)



Scope of Available Literature (Roche/DSM)



PUFA NEWSLETTER

Polyunsaturated Fatty Acids in Nutrition and Disease Prevention

Growth & Development

- 2 Visual Function A Concern In HPA Children
- 3 Managing Fatty Acid Status Of Breast Milk
- 3 Better Stereopsis In The Older Child

Cardiovascular Disease

- 4 Fish Oil:LC-PUFA And The HRT Puzzle
- 5 Combination Therapy In Japanese Women
- 5 Fatty Fish Intake Benefits The Elderly

Inflammation

- 6 Clinical Value Of Correct LC-PUFA Balance
- 6 Collateral Use Of Omega 3 LC-PUFA In RA

Nutrition

- 7 Omega 3 LC-PUFA As Adjuvant In H. pylori Therapy

Cancer

- 8 A Fish-Rich Diet And Lung Cancer

PUFA Newsletter, Vol 5, No 1, March 2001

of rapid expansion in scientific unsaturated fatty acids (PUFA) in PUFA in particular. Both omega-3 were recognized as important nrienes, as well as precursor of rids known as eicosanoids, id in many important biological in body.¹¹ Recently it has been pical "Western" diet, which is omega-6 PUFA than in omega-3 optimal biological function.¹²

FATTY ACIDS IN THE EVOLUTION OF THE HUMAN DIET

For millions of years, prehistoric humans existed on a diet consisting primarily of fresh fruits, leafy vegetables and animals. This eating pattern, which remained virtually unchanged over this time, provided a 1:1 ratio of omega-6 to omega-3 PUFA, and included relatively large amounts of longer-chain versions of these fatty acids.¹³ The prehistoric diet, which has been termed the "Diet of Evolutionary Adaptedness," is thought to be reflective of the biochemical and physiological milieu in which humans evolved.¹⁴ Over the past 150 years, however, there have been significant changes in the composition of the food supply of Western societies, resulting in an increase in consumption of omega-6 PUFA and a decrease in intake of omega-3 PUFA. Today, the ratio of omega-6 to omega-3 PUFA in the typical North American diet is estimated to range from 10:1 to 25:1.^{15,16}

Changes in the composition of the food supply, including the shift in the omega-6 to omega-3 PUFA ratio, can be a source of a number of problems in the prevention method: for many frequently eaten foods, such as meats, eggs, fish, and oils.¹⁷ Food animals found in the wild fed upon naturally-occurring sources of both omega-3 and omega-6 PUFA. As a result, they were leaner and their body tissues had significantly higher amounts of omega-3 PUFA.¹⁸ Today, however, our food animals are commercially raised on feeds that are high in omega-6 and lack omega-3 PUFA.¹⁹ As a result, meat and other animal products, such as eggs, contain less omega-3 PUFA. Fish raised through the practice of aquaculture also contain less omega-3 PUFA because they don't have access to marine foods that are a source of these fatty acids. Since a significant amount of fat in the modern Western diet comes from beef and dairy products, there is a greater concentration of omega-6 than omega-3 PUFA in our body tissues.

In addition, the industrial revolution introduced vegetable oil technology and popularized the use of cooking oils derived from sunflowers, safflowers, peanuts, and corn—all rich sources of the omega-6 PUFA, linoleic acid.²⁰ Of critical importance for infants, during the latter half of this century these vegetable oils have become the primary source of essential fats in infant formula. In contrast to human milk, typical vegetable oil-based formulas sold in the United States do not contain docosahexaenoic acid (DHA), an essential omega-3 PUFA.²¹

Fat Intake and Incidence of Coronary Heart Disease*

*Herman, J. and, et al., PhD, is the Acting Scientific Director of the Internal Research Department of the National Institutes of Health. He is also Chief of the National Institute of Environmental Health Sciences. He is also Chief of the National Institute of Environmental Health Sciences. He is also Chief of the National Institute of Environmental Health Sciences. He is also Chief of the National Institute of Environmental Health Sciences.

8 pages

Backgrounder

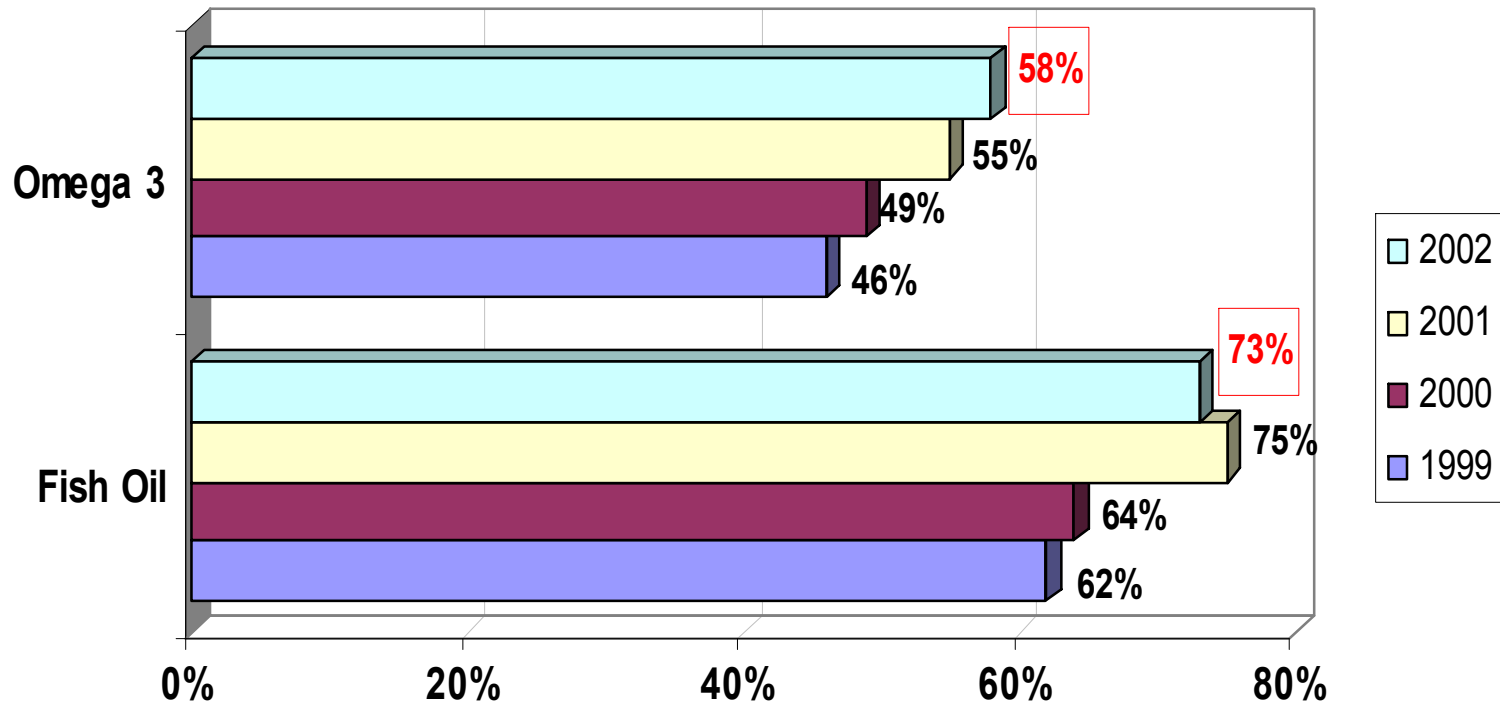
VOLUME 3, NUMBER 1
JANUARY 1999

Introduction to Polyunsaturated Fatty Acids

Reviewed by Norman Salem, Jr., PhD¹

8 pages

LC-PUFA Consumer Awareness



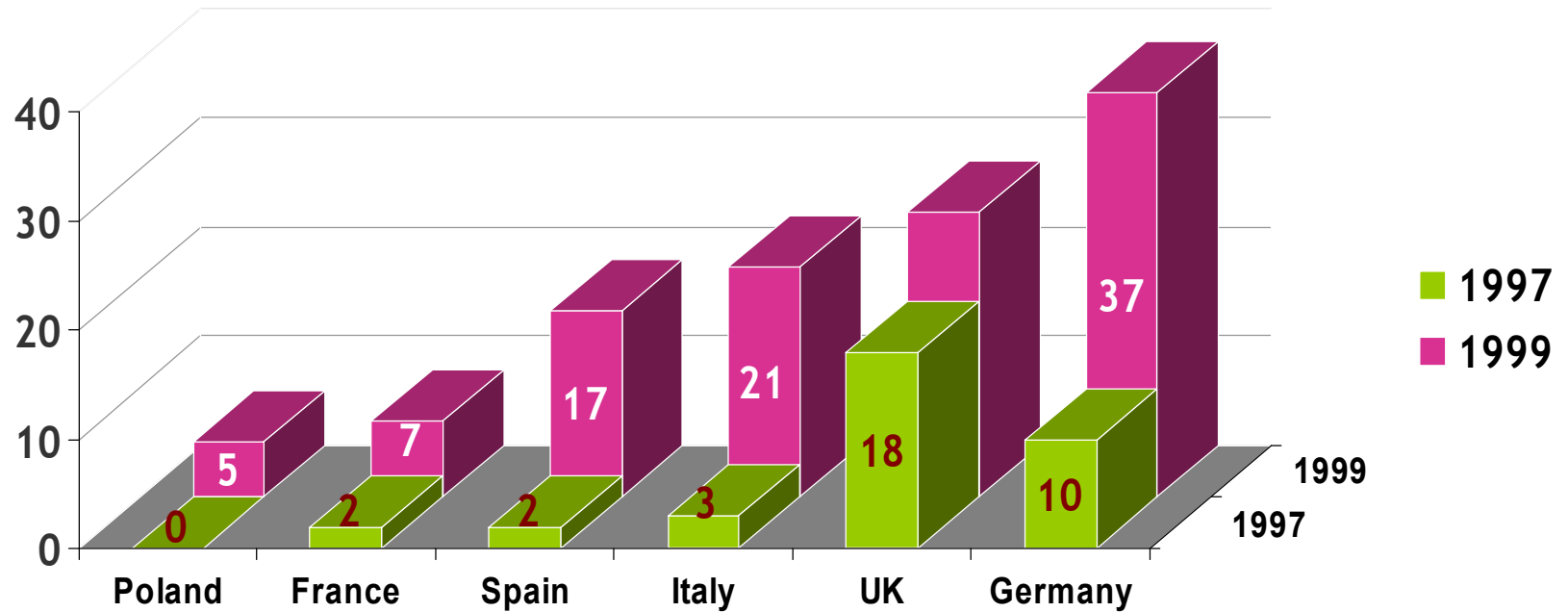
Demographics of Consumer Awareness (2002)

74% female vs 56% male. 75% ages 35 to 65+. 80% incomes >\$50K
80% West Coast; 76% East Coast; 74% South
84% college grads and 72% some college education

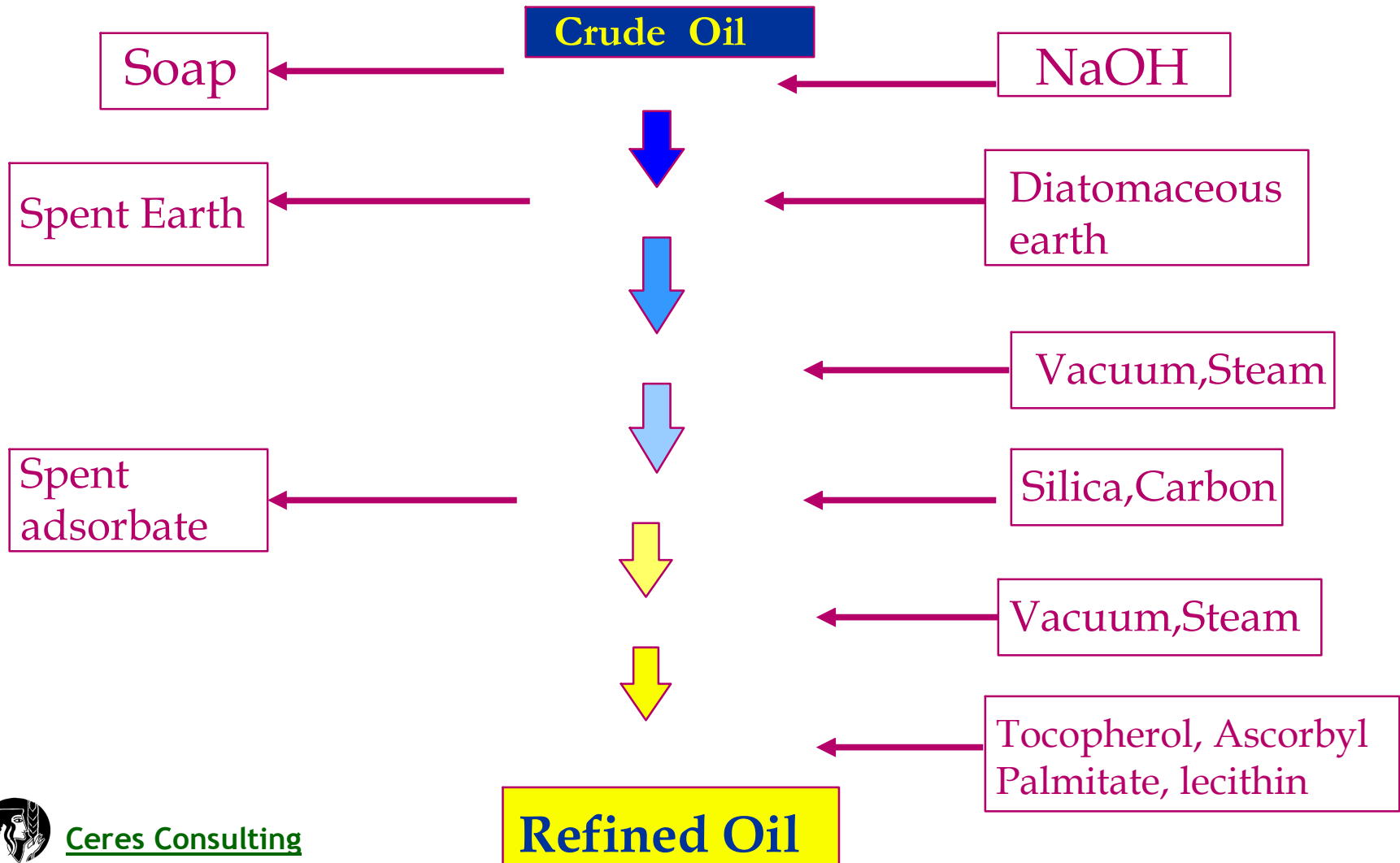


Awareness Study Europe

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



PRODUCTION PROCESS OF ROPUFA OMEGA-3 OILS



Formulation of lipophilic actives

I. Preparation of Solutions

Fat Soluble Active
Ingredient + Stabilizers

Matrix (Gelatin) +
Sugar + Water

Emulsification

II. Preparation of Emulsion

O/W Emulsion

Spray drying

Powder Catch

III. Drying of Emulsion

Solid SD Form

Solid PC Form



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

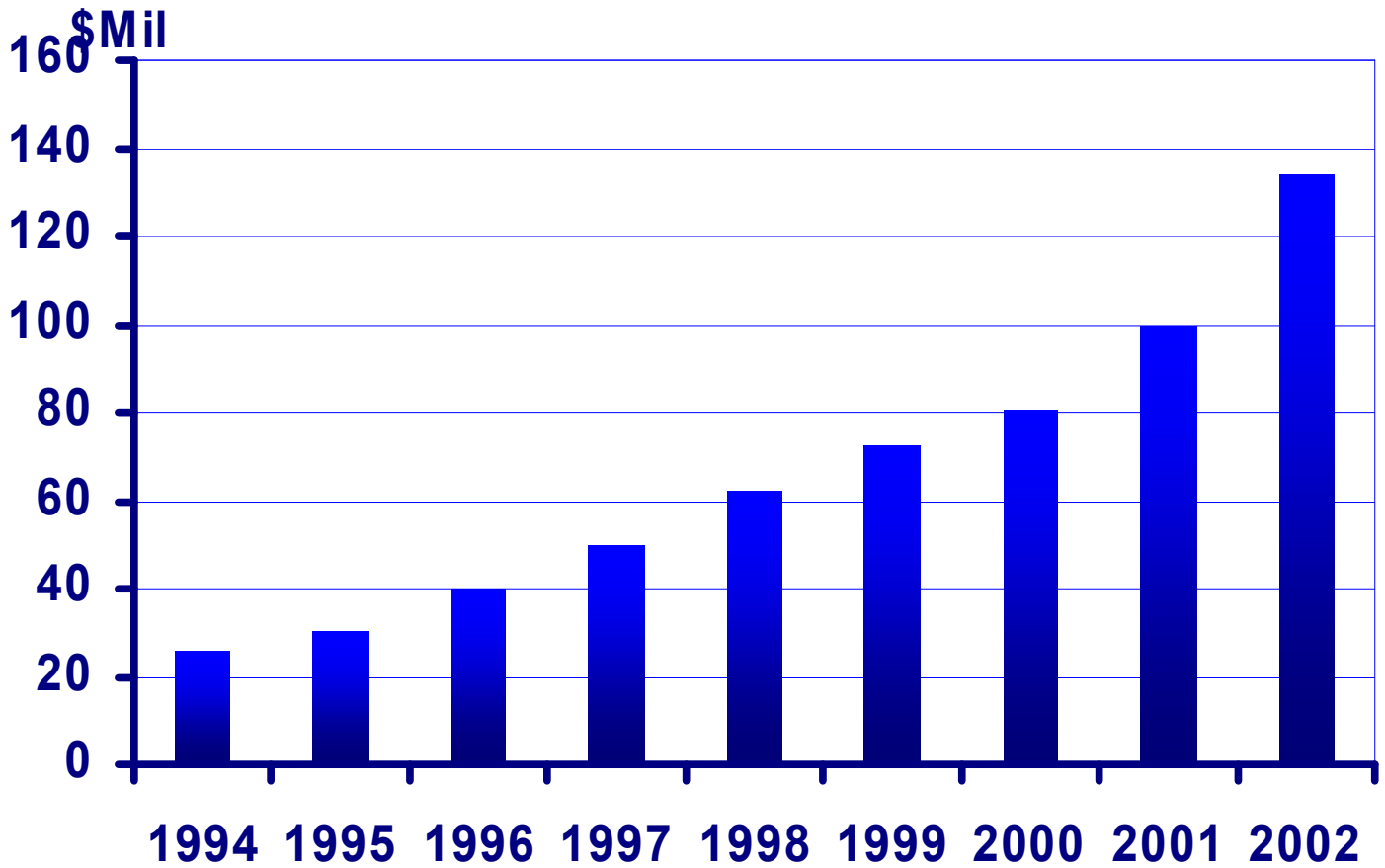


n-3 LC-PUFA Food Fortification: Fish Oil in Cow's Milk

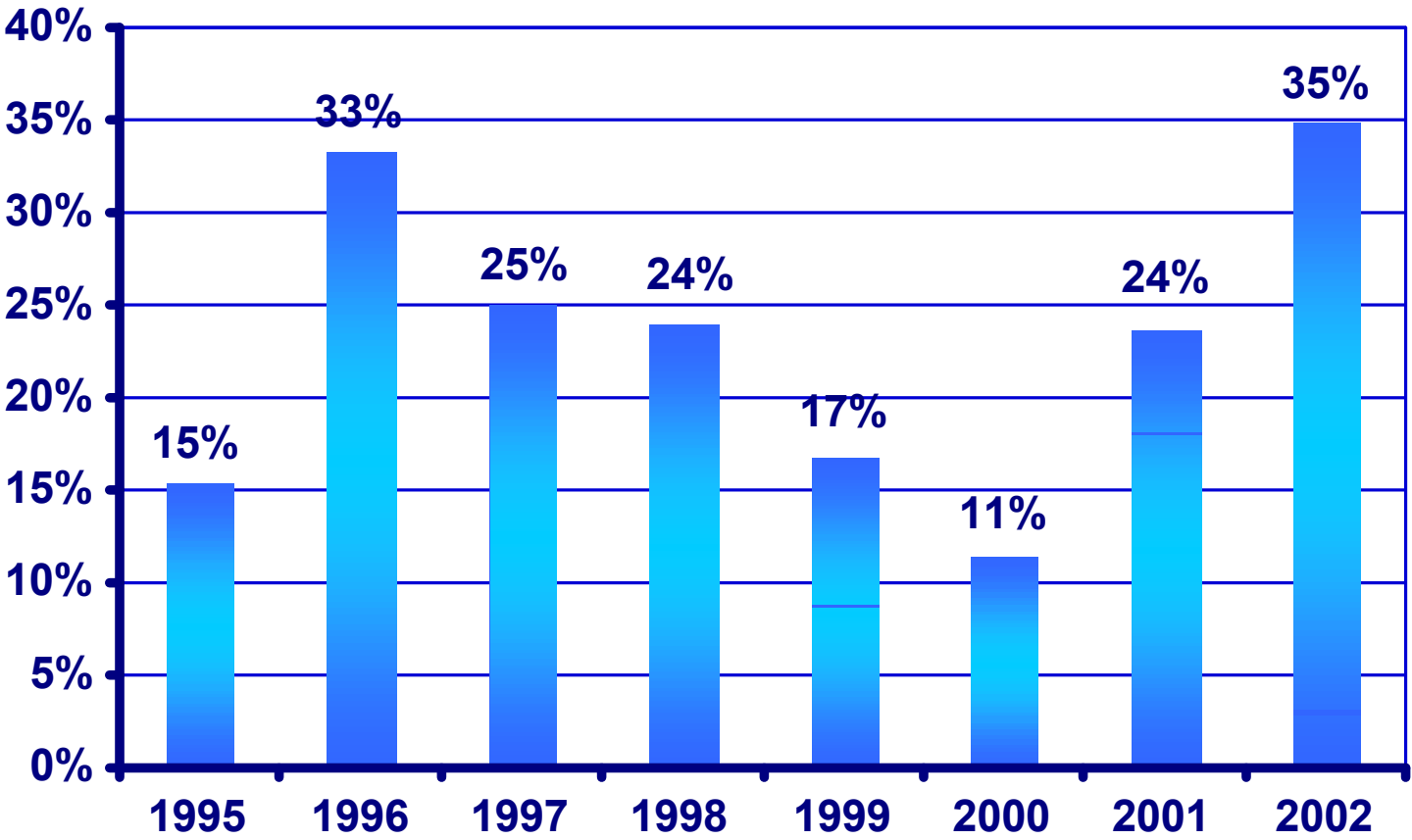
- Open label trial of **0.3 g EPA + DHA** in milk
 - Eight subjects received 500 mL part skim milk per day
 - Fortified with ROPUFA '30' Food Oil
- After three weeks, **triglycerides decreased 12%** and **HDL-C increased 21%** from baseline (p<0.05)
- Conducted in Italy with Parmalat Plus Omega 3®



Specialty Supplement Sales: Fish Oil



Annual Growth in Sales: Fish Oil



Margarines

Ontdek nu...
Découvrez maintenant...
info: zie binnenin / voir à l'intérieur

Gezond smeren - Tartiner sain

Vitelma
Progress

01.04.2002
L. 1513

verrijkt met
enrichi d'
OMEGA 3

Omega 3 draagt bij tot de goede werking van hart en bloedvaten
Les Oméga 3 contribuent au bon
fonctionnement du système cardio-vasculaire

Ontdek nu...
info: zie binnenin

Vitelma



Milks

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

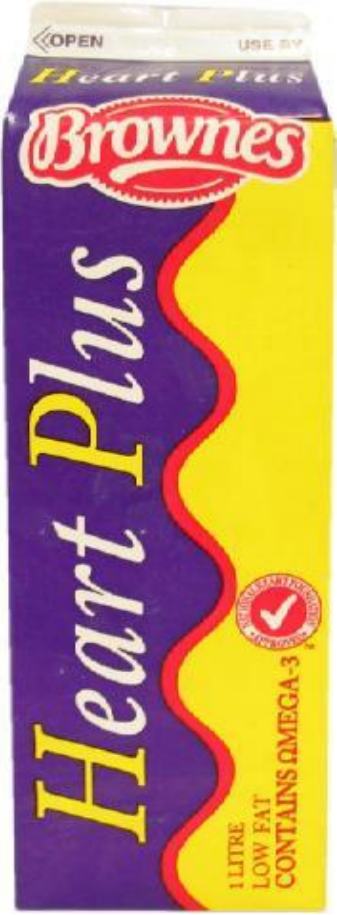
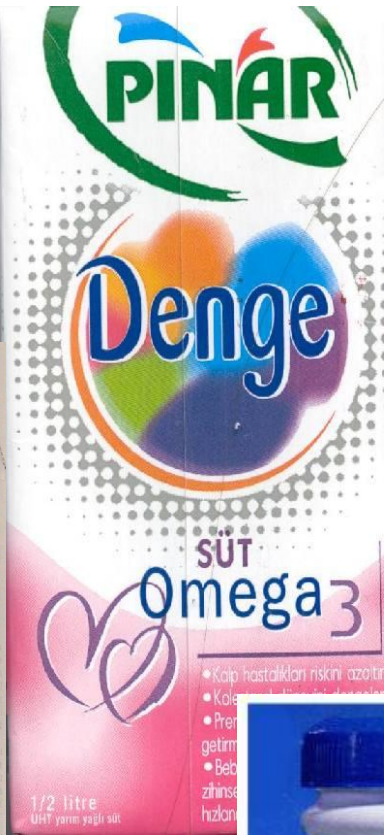
VALOR NUTRICIONAL

	100 ml	200 ml
ENERGÉTICO		
Energía	48	100
Proteína	3,27	100
Grasa	0,2	0,4
Carbón	0,2	0,4
Carbohidratos	2,5	5
Azúcares	0,5	1
Almidón	0,2	0,4
Almidón	0,2	0,4
VITAMINAS Y MINERALES		
Calcio	100	200
Proteína D ₂	0,2	0,4
Vitamina A	0,05 CNU	0,1 CNU
Vitamina B ₁	0,05 CNU	0,1 CNU
Vitamina B ₂	0,05 CNU	0,1 CNU
Vitamina B ₆	0,05 CNU	0,1 CNU
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Vitamina D ₃	0,05 CNU	0,1 CNU
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Vitamina K ₉₈	0,05 CNU	0,1 CNU
Vitamina K ₉₉	0,05 CNU	0,1 CNU
Vitamina K ₁₀₀	0,05 CNU	0,1 CNU



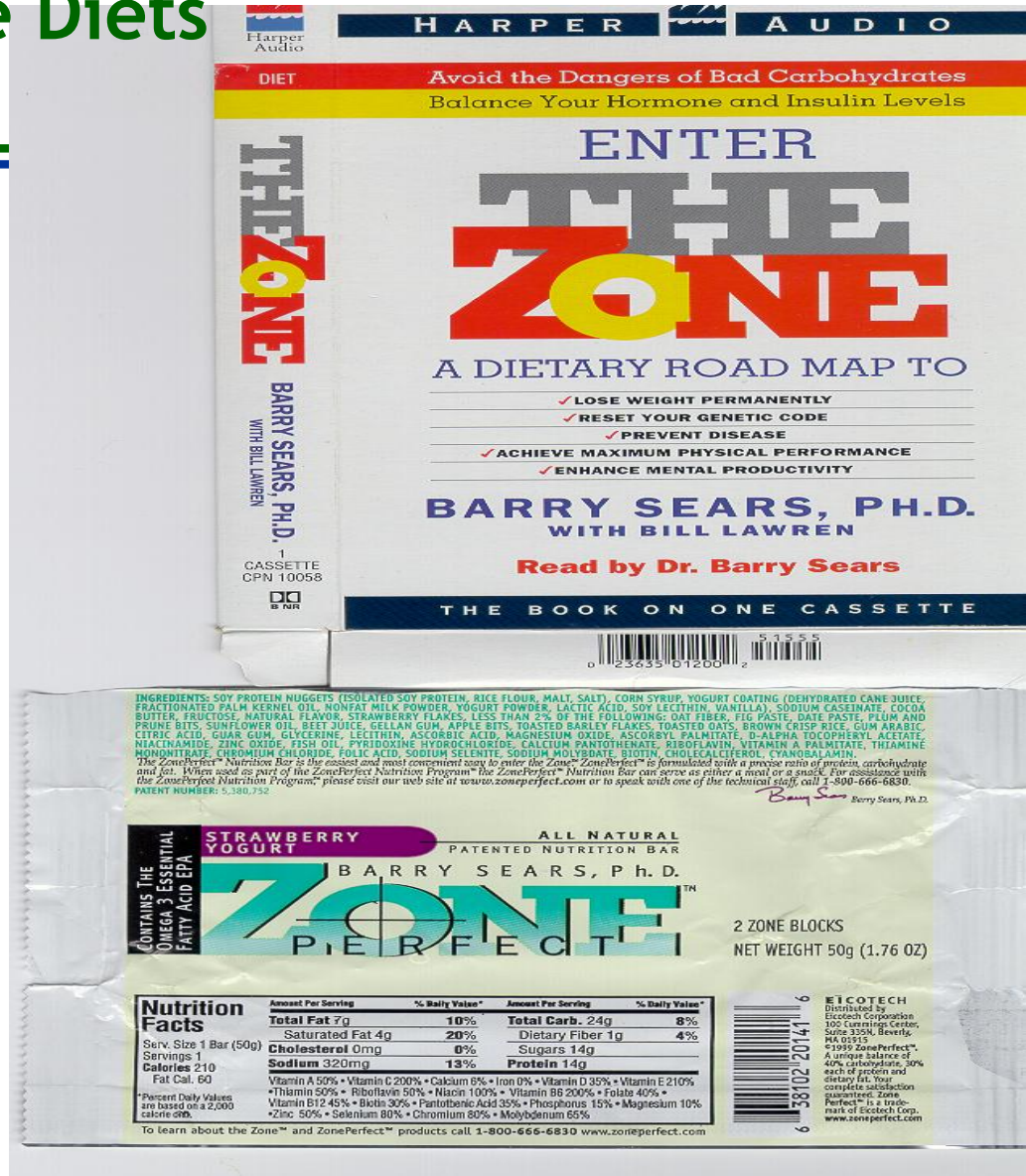
IL LATTE DEL CUORE INTEGRATO CON OMEGA 3

LATTE PARZIALMENTE SCREMATO



Dr. Barry Sears - Zone Diets

Snack & Meal Bars: More About Weight Management



High Concentrated/ Extra Strength Fish Oil (EE)

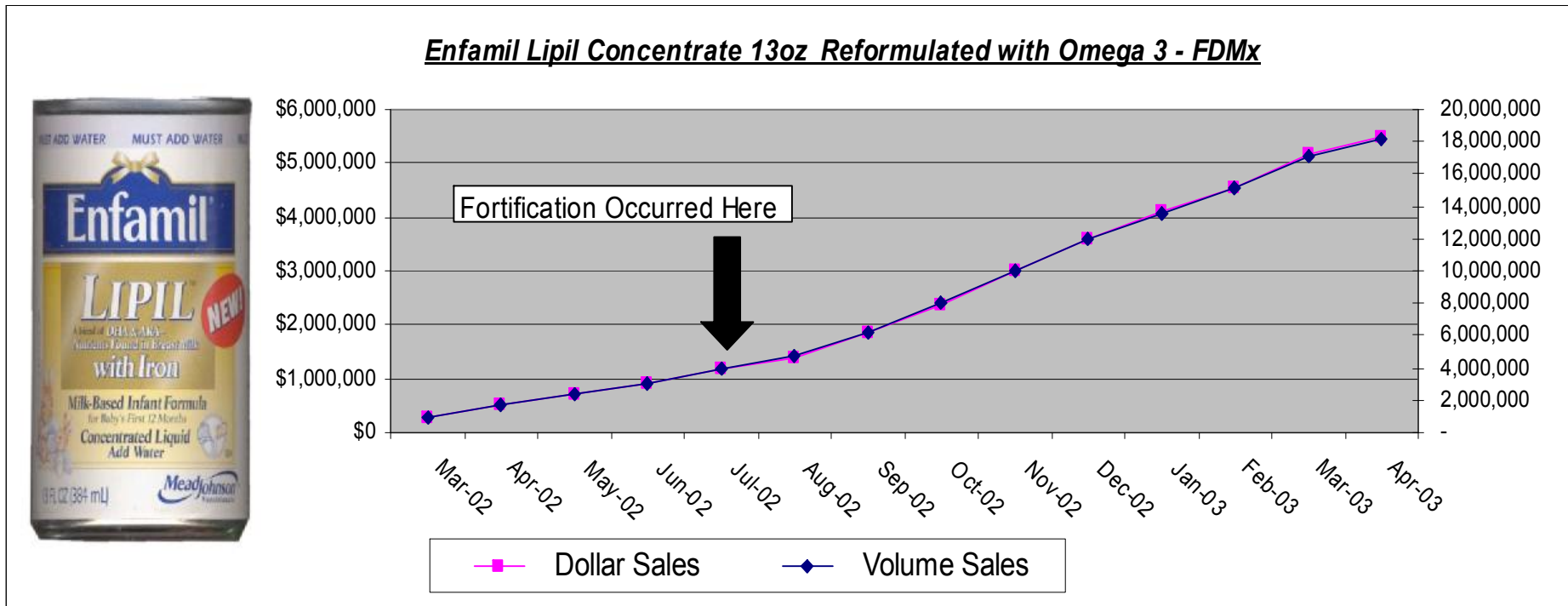
Zone Diet
Now Embraces
Ethyl Esters



Sears' Lab introduces nutrition bars
with long-chain omega-3:
83 mg per serving in 3 delicious flavors



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



Indulge - Adult Chocolate Meal Replacement

- **Satisfy with chocolate**
- **Balanced nutrition**
- **Drink to better health**

This is not the typical chalky meal replacement liquid. This is real chocolate low-fat milk now as an excellent source of 13 vitamins plus minerals already in milk like calcium, magnesium and phosphorous. The beverage is enhanced with LC-omega-3 often lacking in adult diets.

**Delicious
Nutrition**
Indulgent taste
LC-omega-3
rich in calcium and
13 vitamins



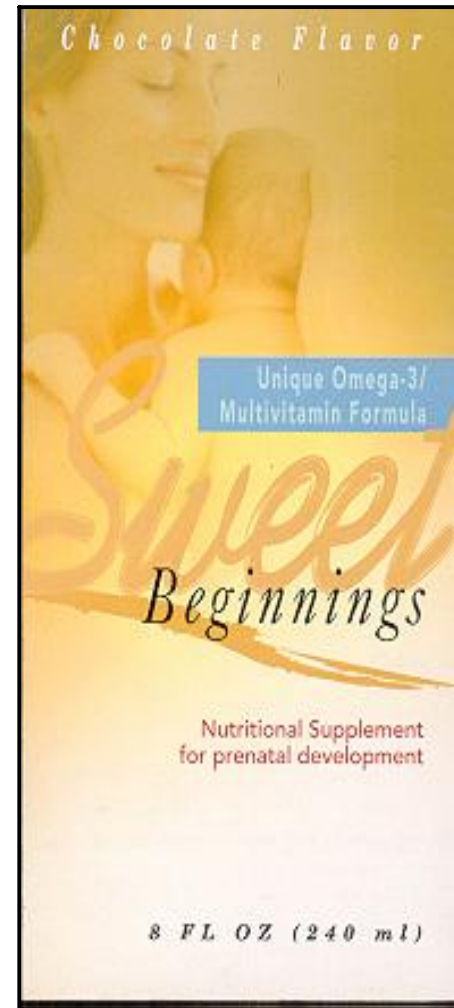
Cosmetic / Wellness / Prevention



Ceres Consulting

Maternal Health Concept **Sweet Beginnings**

**A delicious Chocolate Beverage
with an
Omega -3 PUFA &
Calcium Blend
for Maternal Health!!!**



Continuing Global Launch of New Products - Processed Fish



Nutrition

Per 100g: energy 790kJ, 11.8g protein, 6.9g fat, 0.8g of which saturates, 2g of which polyunsaturates, 0.6g omega-3, 490mg alpha linolenic acid (ALA), 40mg eicosapentaenoic acid (EPA), 100mg docosahexaenoic acid (DHA), 4g monosaturated fat, 19.7g carbohydrates, 2.3g of which sugar, 333mg sodium

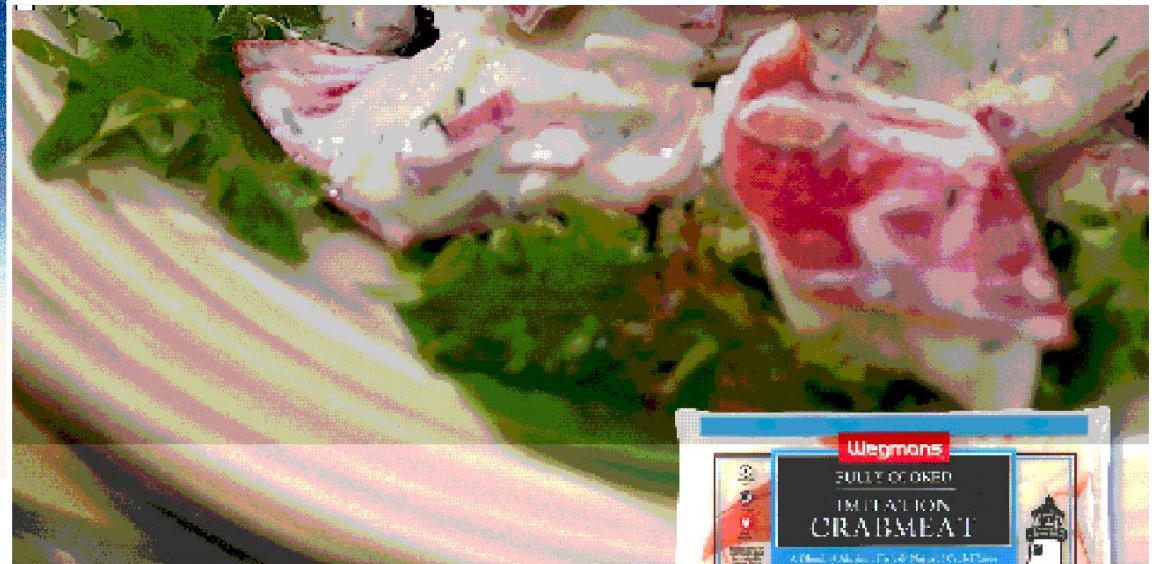
Company: JR Simplot Company

Country: Australia

Launch: Mar-2003



Supermarket Brand Starts Value-Added Seafood



Specialty
Foodservice Value-
Added Seafood

A Heart-Healthy Catch

Our delicious
imitation crabmeat
now has omega-3s



Ceres Consulting

Diversity in Value-Added Seafood

1000MG OMEGA-3'S
MEGA OMEGA![™]
PER SERVING



Long-chain omega-3 in liquid egg substitute product in Canada & U.S.



CANADA
20
PRODUCT OF CANADA

PASTEURIZED AND
HOMOGENIZED
KEEP REFRIGERATED
500 mL IS EQUIVALENT
IN VOLUME TO
10 LARGE EGGS



NATUREGG

OMEGA PRO™

LOW IN FAT & 80% LESS CHOLESTEROL*

SEE
RECIPE
INSIDE

LIQUID EGG PRODUCT



- Made With Real Egg White & Whole Egg
- Source of Omega-3 Polyunsaturates and Protein

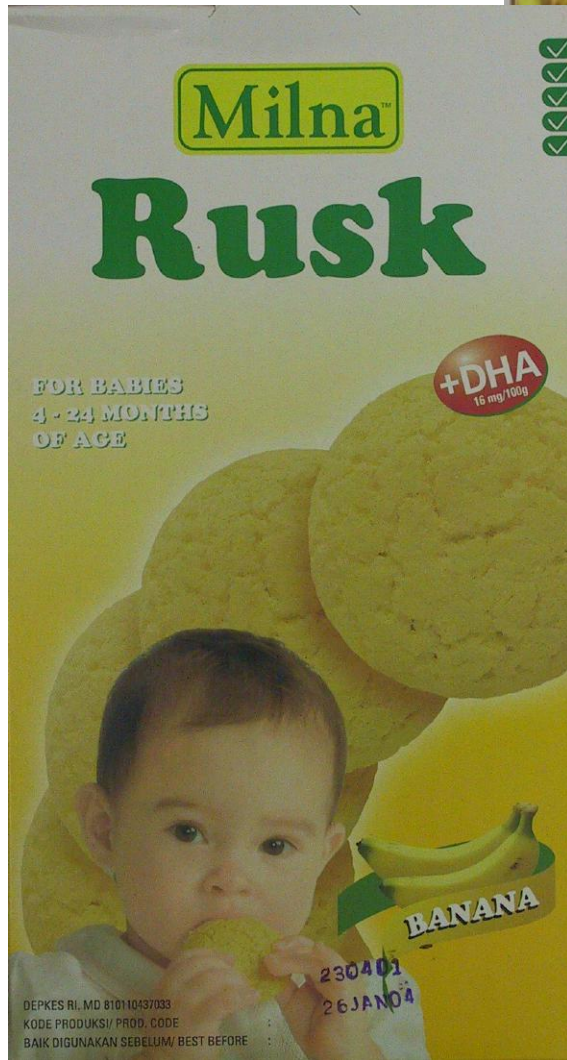
* COMPARED TO 50g WHOLE EGG

500 mL (500 g)



† See bottom panel.

Biscuits



Cookies



Drinks/Other



Isabel's
**Hearty
and
Healthy
Soups**

SPANISH POTATO SOUP
JUST HEAT AND SERVE



NET WT. 12 OZ.
(340 g)



Enriched with Omega 3.
A Heart Healthy Product



Omega-3 Battle Looming

- Differences between omega-3 and EPA/DHA and ALA
- Conversion around 5-10% of ALA to EPA
- Data for CVD not nearly as strong as for EPA/DHA

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's Dairy Oh! Omega-3 fortified

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.

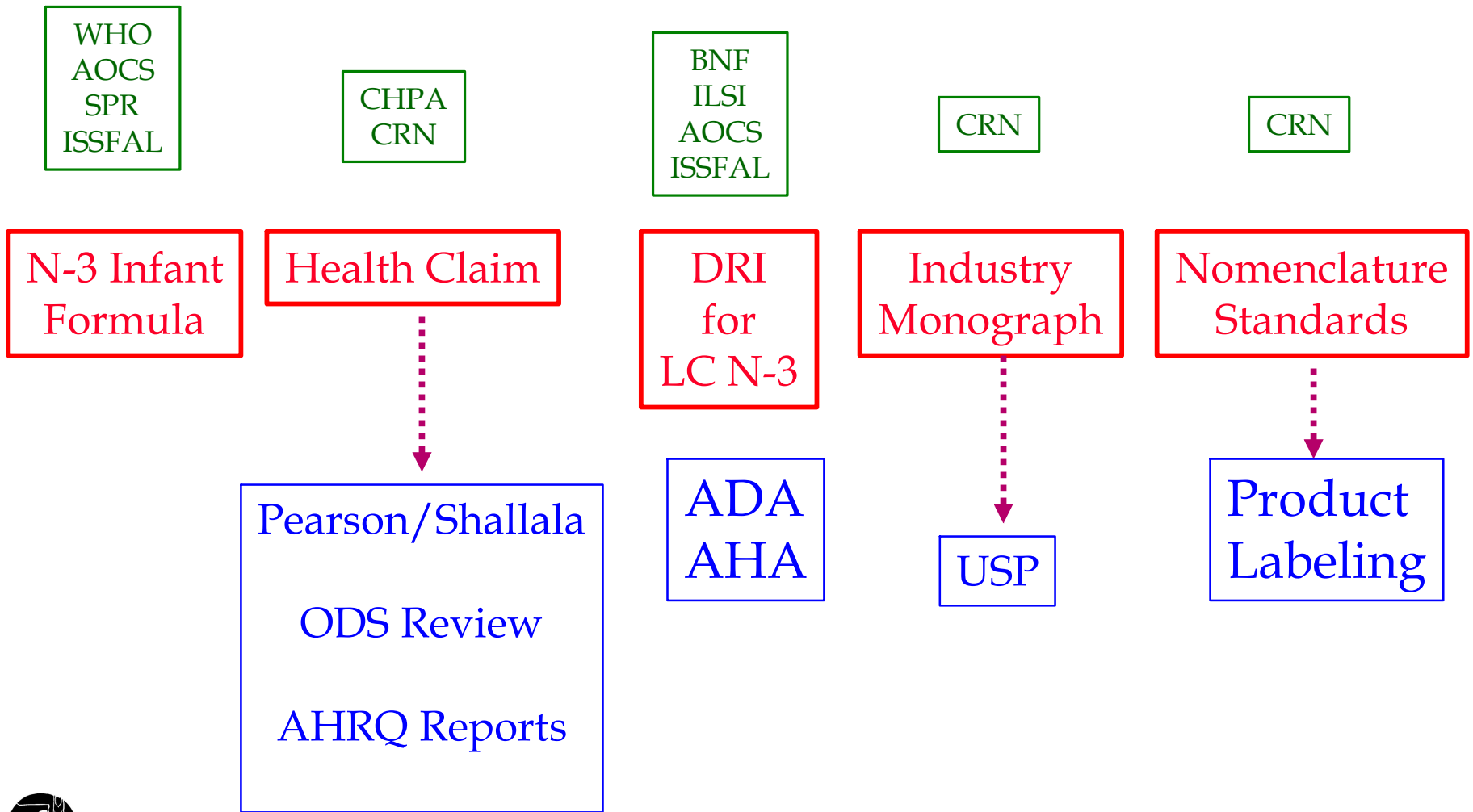
COMMENT: Some will argue that this will be a poor test from which to draw conclusions, since the Neilson product provides only 20mg of DHA per 250ml serving compared to 125mg per 250ml serve for most DHA-fortified milks. However, it is questionable whether time-pressed consumers will notice or



The milk on the left is fortified with fish-source



Milestones



Trends in Fish Oil

- **Consumer:** High attention and awareness to omega-3 fatty acids; "Strong, positive science is driving sales.... Not a day goes by that's not about proof, whether its cardio, vision, inflammation or maternal health."
- **Manufacturer:** No dominant manufacturer or brand
- **Raw Material Supply:** Leaders include Lodders Croklaan, Ocean Nutrition, Pronova and DSM. Food applications generating a lot of interest: Food suppliers DSM, Omega Protein, ONC, Clover and BASF focus on 'taste and smell'
- **Science:** Numerous studies and reports on multiple health concerns; Omega-3 is in line for a food health claim under FDA's Consumer Health Information initiative;



Thank You

