

Omega-3 Fatty Acids: Short Course Chicago Aug 24/25 2009

Regulatory & Labeling Challenges for Omega-3 Products

Ian Newton
CERES Consulting
Ontario, Canada.
ian@ceresconsulting.com



Ceres Consulting

Copyright Ceres Consulting 2009

Milestones and Historical Perspective

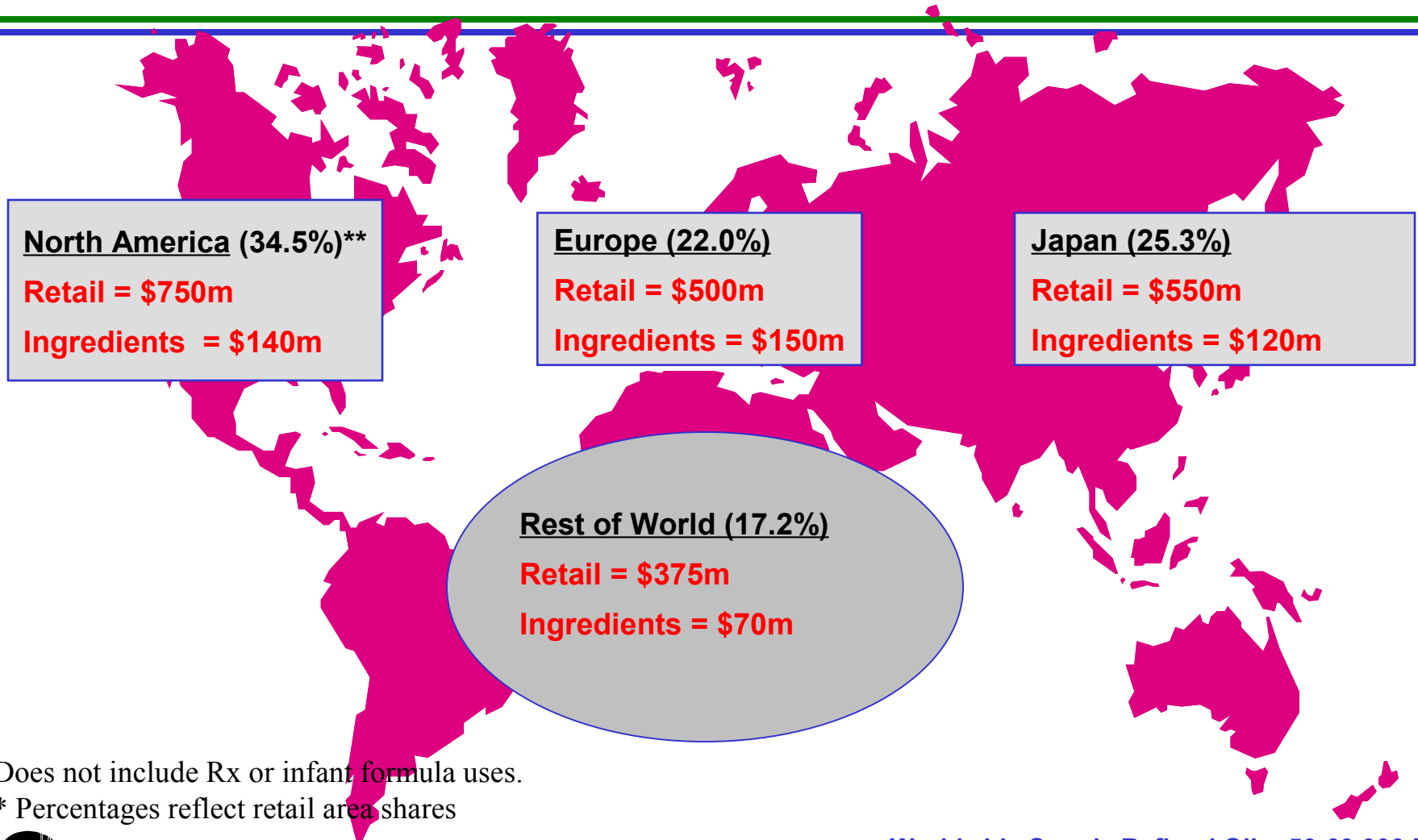
- 1780: Fish oil (CLO) taken for arthritis relief
- 1935: Prostaglandins (PG) discovered
- 1970: Eicosanoid, leucotriene, prostaglandin metabolism elucidated
- 1971: Prostaglandins recognized as causing bad inflammatory health effects
- 1971: Dyerberg & Bang showed diet high in LC lipids reduced heart disease
- 1982: Nobel prize awarded for PG discovery and role in human health
- Late 1980's: Growing scientific data on benefits of LCP for CVD
- Late 1980's-early 1990's: supplements of LCP launched for CVD and general health
- 1985-1990: Benefits of LCP shown for the developing embryo and infants
- Early-Mid 1990's: Large ingredient companies enter fish oil business and specialty refining commences. Investments made in research and marketing
- Early 2000's: Explosion in science papers on LCP, NGO recommendations and governments permit fortification, some RDA's developed



Current Fish Oil Ingredient and Supplement Retail Sales 2007

Total Retail Sales = \$2,100M (90% to Supplements/10% to Non-Supplement Markets/Foods)

Total Ingredient Sales = \$450-500M*



*Does not include Rx or infant formula uses.

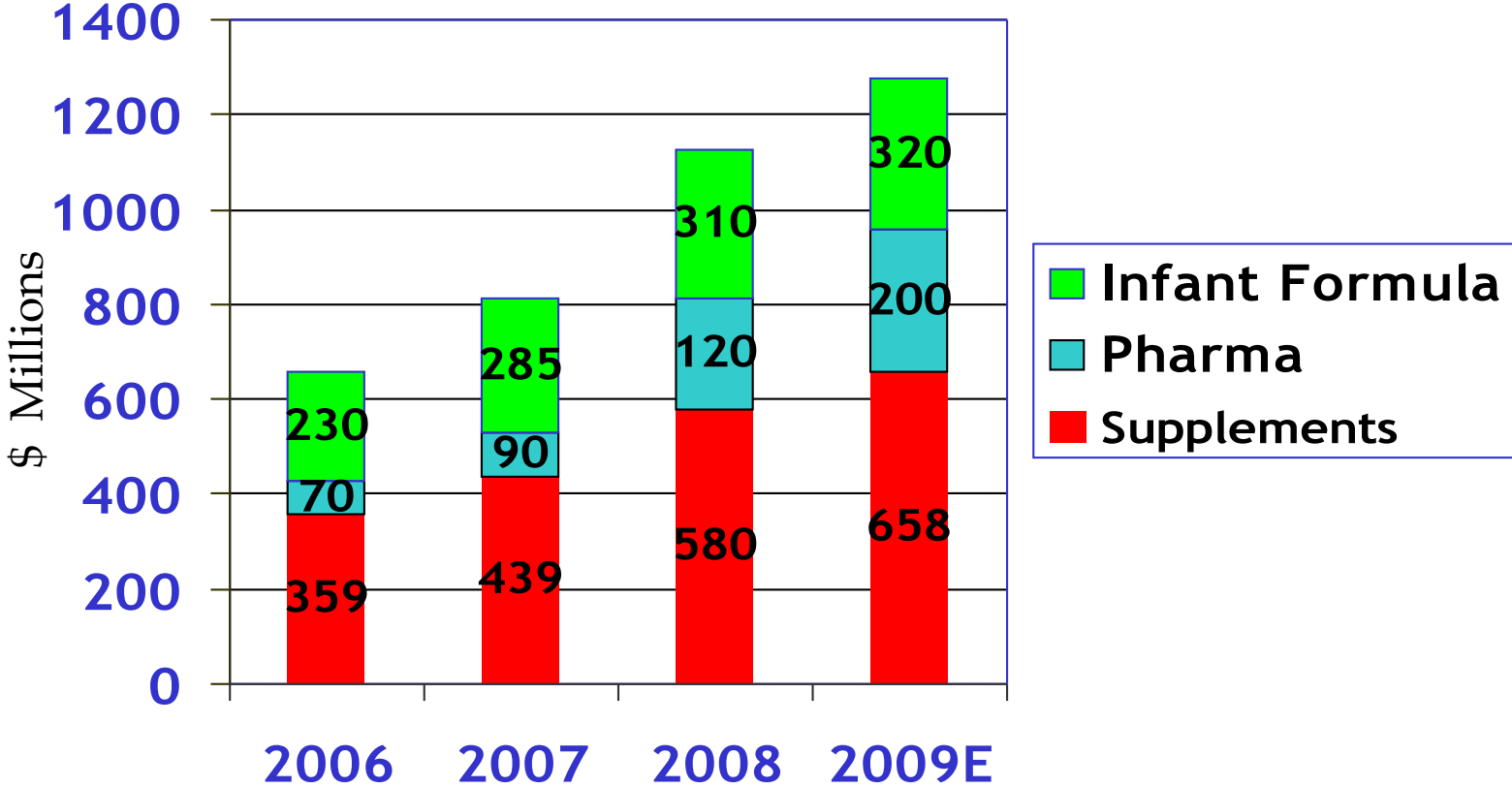
** Percentages reflect retail area shares



Global Sales Estimates of Bulk Omega-3 LCP Oils:

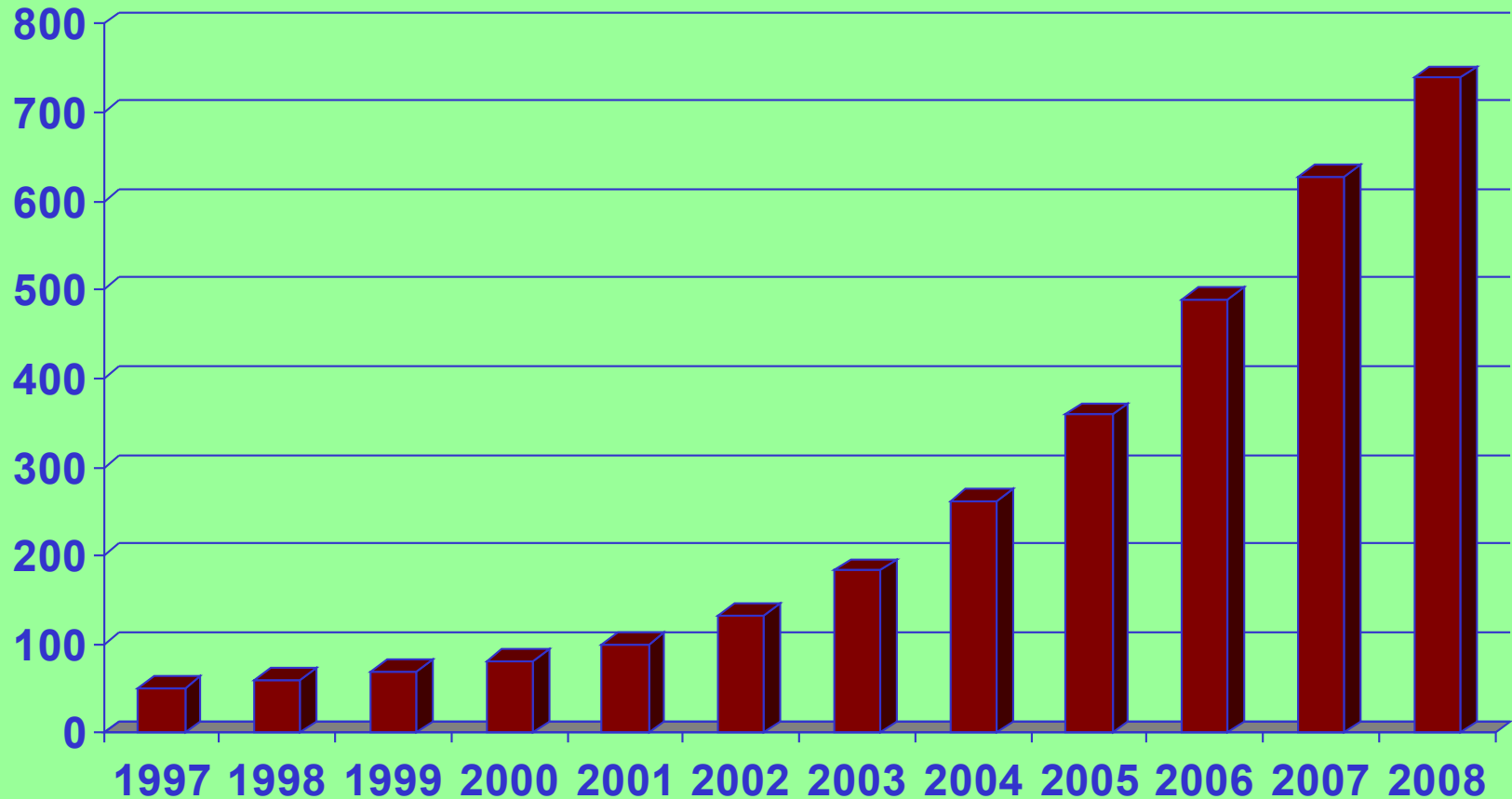
Major Sectors

2006-2009 (Millions Dollars)



US Retail Fish Oil Supplement Sales

1997-2008 (\$ millions)



Key Issues Exist for Omega-3's

- Government recommendations (RDA's) not widespread
- Health Claims- few available, US and UK
- TG not recognized as major CVD factor
- Health professional support slowly building
- Quality of raw materials: safety, supply
- Consumer awareness/confusion (EPA,DHA, ALA, good fat)
- Plant oils vs. fish oils
- Too many health benefits, confuses consumers
- Taste/stability (Raw Material and food forms)
- Food companies slow to fortify (cost, no RDI)
- Safety (unfounded)

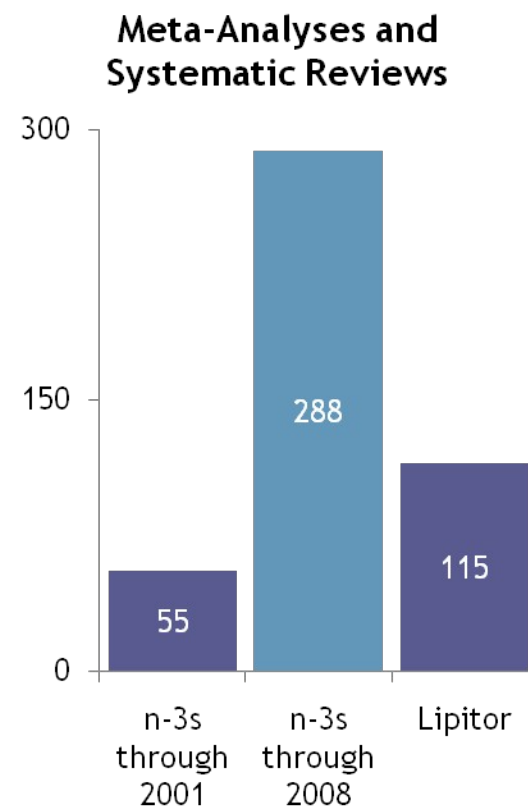
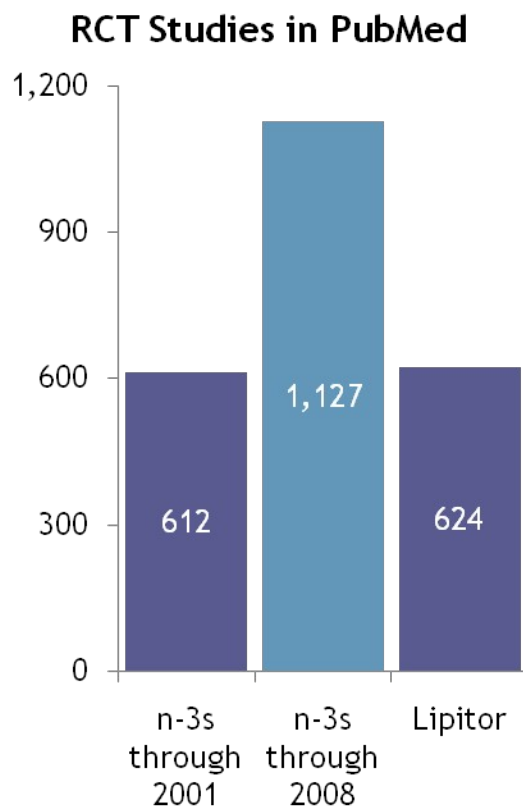
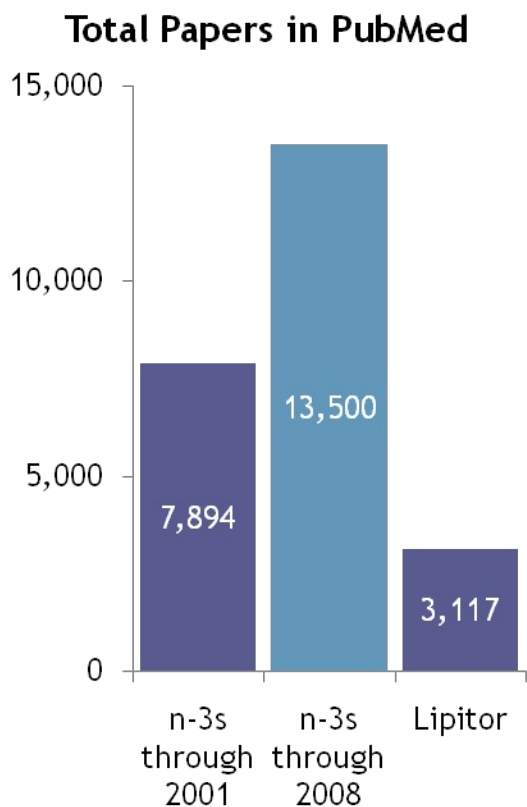


Key Regulatory Issues for Omega-3's

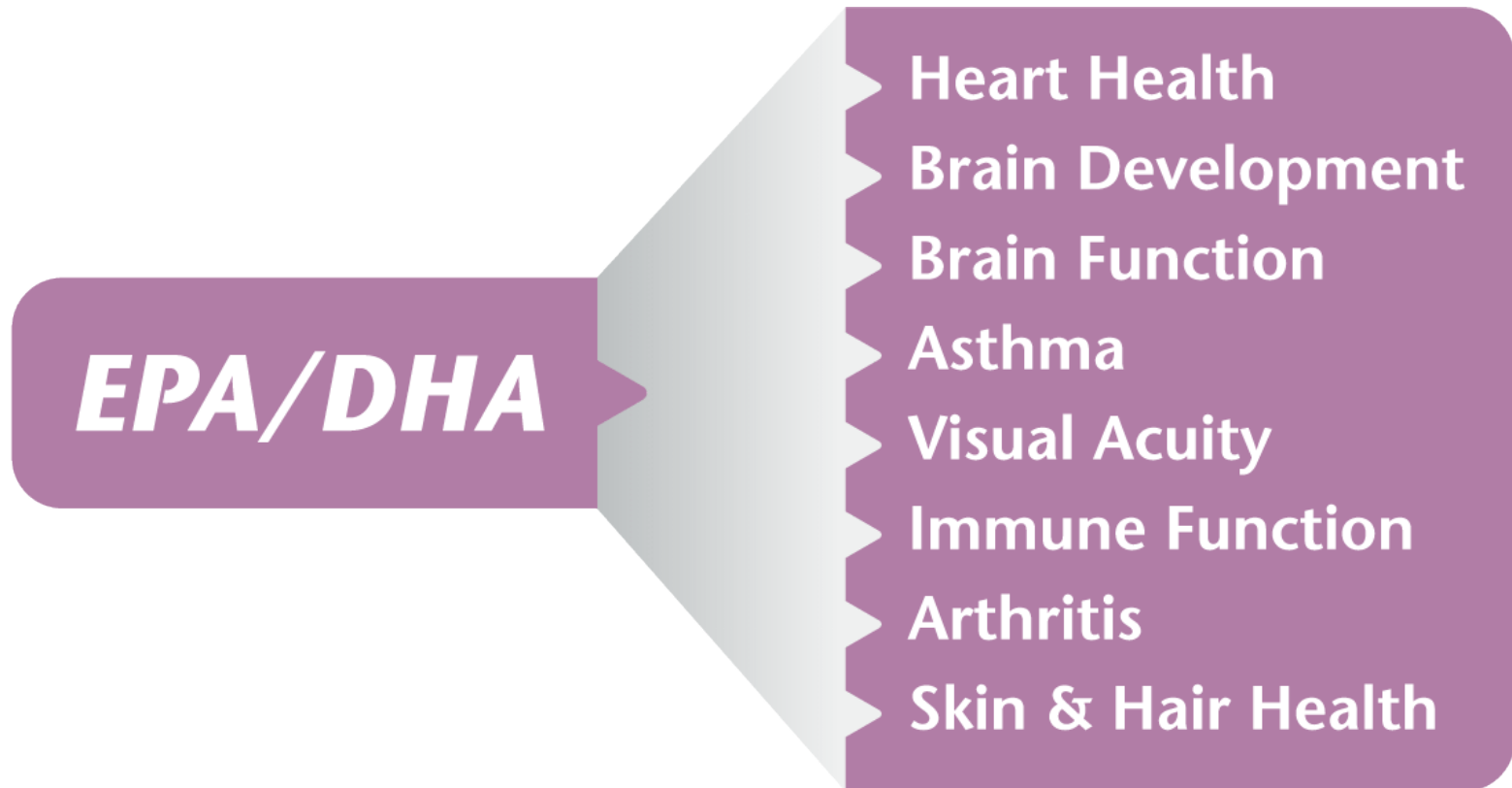
- RDA's, RDI's
- Health Claims- few available, US and UK
- Government Recommendations/Guidelines
- Quality standards/monographs
- EU Hygiene Rules for foreign produced oils
- European Food Safety Agency (EFSA) Health Claims process/rules
- Infant formula ingredient requirements Indonesia
- Global standards for human use (CODEX)



Published Papers on Omega-3 PUFA's



Omega-3's EPA/DHA Benefits



EPA/DHA Support Healthy Cardiovascular Function

Paper	Implication
Mayo Clinic Proceedings (2008)	Asserts that the general population should aim for 500mg/day to reduce cardiovascular disease risk
American Dietetic Association (2007)	Asserts that AIs are low and that science supports that Americans should consume 500mg/day
Dietary Guidelines Advisory Committee Report (2005)	Recommends population consume two servings of fish per week, based on a 496mg/day intake recommendation
AHRQ Report on Omega-3s and Cardiovascular Disease (2004)	Reviewed evidence through 2004 and established that omega-3 consumption reduces CVD risk
GISSI Study (1999)	Established that EPA/DHA help prevent CVD-related deaths



DHA & EPA Support Cardiovascular Health in Children and Adults

- Favorable effects on blood lipid profile
 - Reduced triglycerides (fasting and following a meal)
 - Increased HDL (good cholesterol)
 - Improved LDL particle size
- Modest reductions in blood pressure (higher doses)
 - Improved arterial compliance
 - Anti-thrombotic effects
- Cardiac rhythm
 - Stabilizes heart rhythm
 - Lowers heart rate

FDA Qualified Health Claim

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



Normal Adult Cognitive Function

- Strong data from a **US cohort** (n=3718) supports a relationship between decreased cognitive decline and fish intake
 - 10% slower decline among subjects reporting 1 fish meal per week (about 80 mg); 13% slower with 2 fish meals per week

Morris et al. Arch Neurol, 2005, 62:1-5.

- Data from **EU cohorts** suggest a relationship between DHA and cognitive function
 - Whalley and coworkers studied 364 non-demented elderly from a cohort of 2000 studied for childhood IQ
 - Plasma DHA significant predictor of IQ at age 64

Kalmijn et al. Neurology, 2004, 62:275-80.

Whalley et al. AJCN, 2004, 80:1650-7.



RDI on the Way!? August 2009 Paper

Recommended Daily Dose for Omega-3 May Be on the Way New Analysis May Pave the Way for Greater Acceptance of Fish Oil Nutrient

By PEGGY PECK and DAN CHILDS

ABC News Medical Unit in Collaboration with **MedPage Today**

STATE-OF-THE-ART PAPER

Omega-3 Polyunsaturated Fatty Acids and Cardiovascular Diseases

Carl J. Lavie, MD*,*, Richard V. Milani, MD*, Mandeep R. Mehra, MD and Hector O. Ventura, MD*

* Department of Cardiovascular Diseases, Ochsner Medical Center, New Orleans, Louisiana

Division of Cardiovascular Diseases, University of Maryland School of Medicine, Baltimore, Maryland

Manuscript received February 5, 2009; accepted February 25, 2009.

Am Coll Cardiol, 2009; 54:585-594, doi:10.1016/j.jacc.2009.02.084

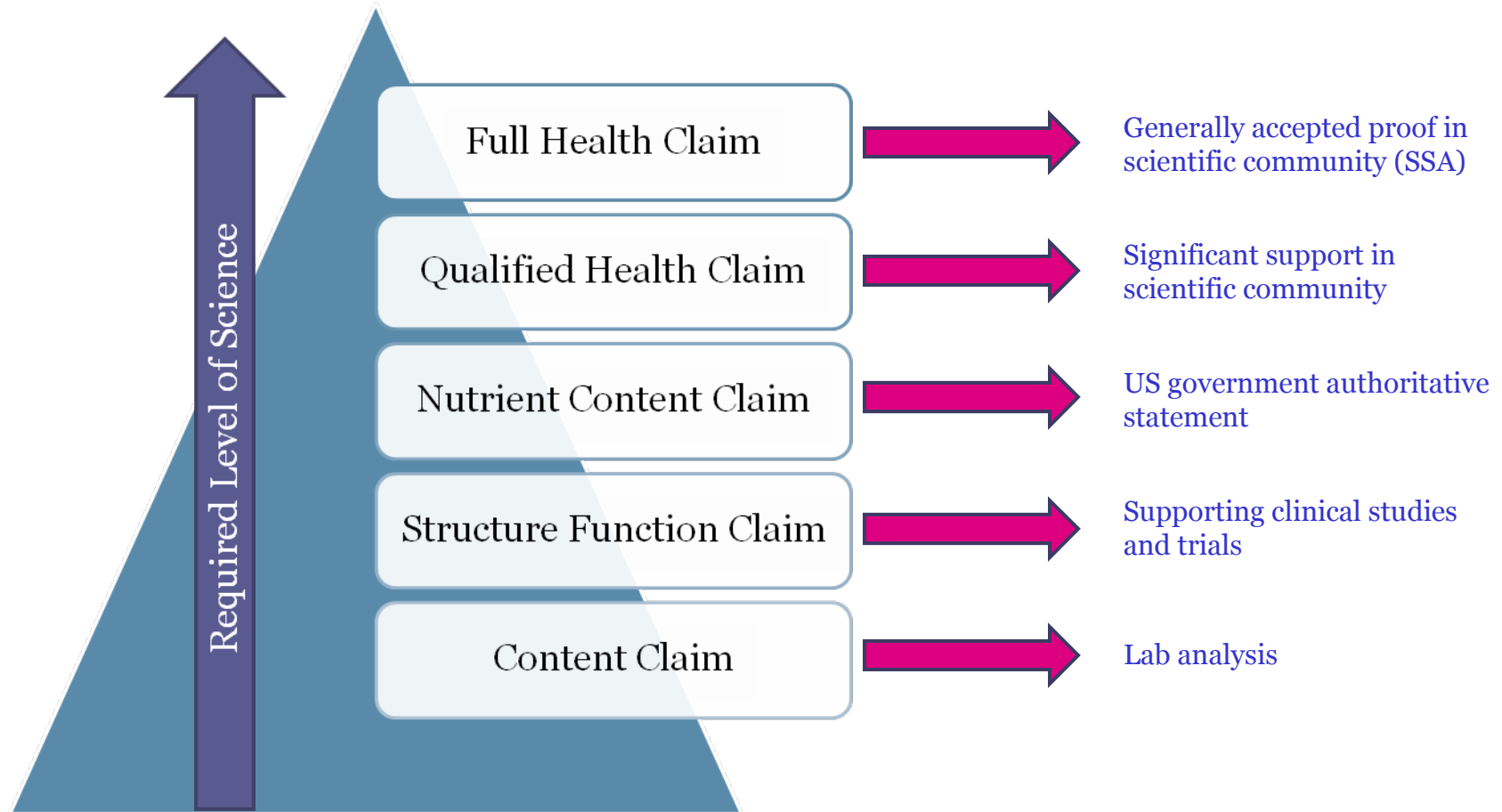
© 2009 by the American College of Cardiology Foundation



Current US Claims for EPA/DHA Omega-3 fatty Acids



The level of science behind each claim is different



There are currently four types of claims available in USA for Long Chain Omega-3's

Claim Types	Examples
Full Health Claim	Not Available
Qualified Health Claim	<i>"Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [name of food] provides [x] grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat and cholesterol content.]"</i>
Nutrient Content Claim	<i>"Excellent Source of EPA & DHA Omega-3s" "Rich in EPA & DHA Omega-3s"</i>
Structure Function Claim	<i>"Supports a Healthy Heart"</i>
Content Claims	<i>"Contains 30mg of EPA & DHA Omega-3s"</i>



The FDA is proposing to disallow nutrient content claims on EPA and DHA products

- FDA feels it can act on the claims now through rulemaking, rather than an assessment of notifications filed to date
- FDA believes no authoritative statement has been made establishing an intake level for omega-3s, thus there is no basis to make a nutrient content claim

FDA states specific requirements for an authoritative statement to be accepted

- Must come from a recognized scientific body of the US government
- Must set a nutrient level on which nutrient content claims can be based
- Accepted nutrient levels include; Recommended Daily Allowances (RDAs), Estimated Safe Intakes (ESIs) and Adequate Intakes (AIs)
- An AI is the average daily intake by generally healthy people that is assumed to be adequate



Omega-3 / DHA & EPA Recommendations

- Institute of Medicine (IOM) - US (2002/2005)
- Dietary Guidelines for Americans (USDA Food Guide Pyramid) (2005)
- PeriLip Consensus Conference - EU (2005)
- American Heart Association (2002/2006/2007)
- Food Standards Agency - UK (2004)
- Child Health Foundation (2001)
- International Society for the Study of Fats and Lipids (ISSFAL) (1999)
- World Health Organization (1994/2003)
- British Nutrition Foundation (1992/2000)

FDA issued a qualified health claim for Omega-3 fatty acids (2004)

- “Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease.”

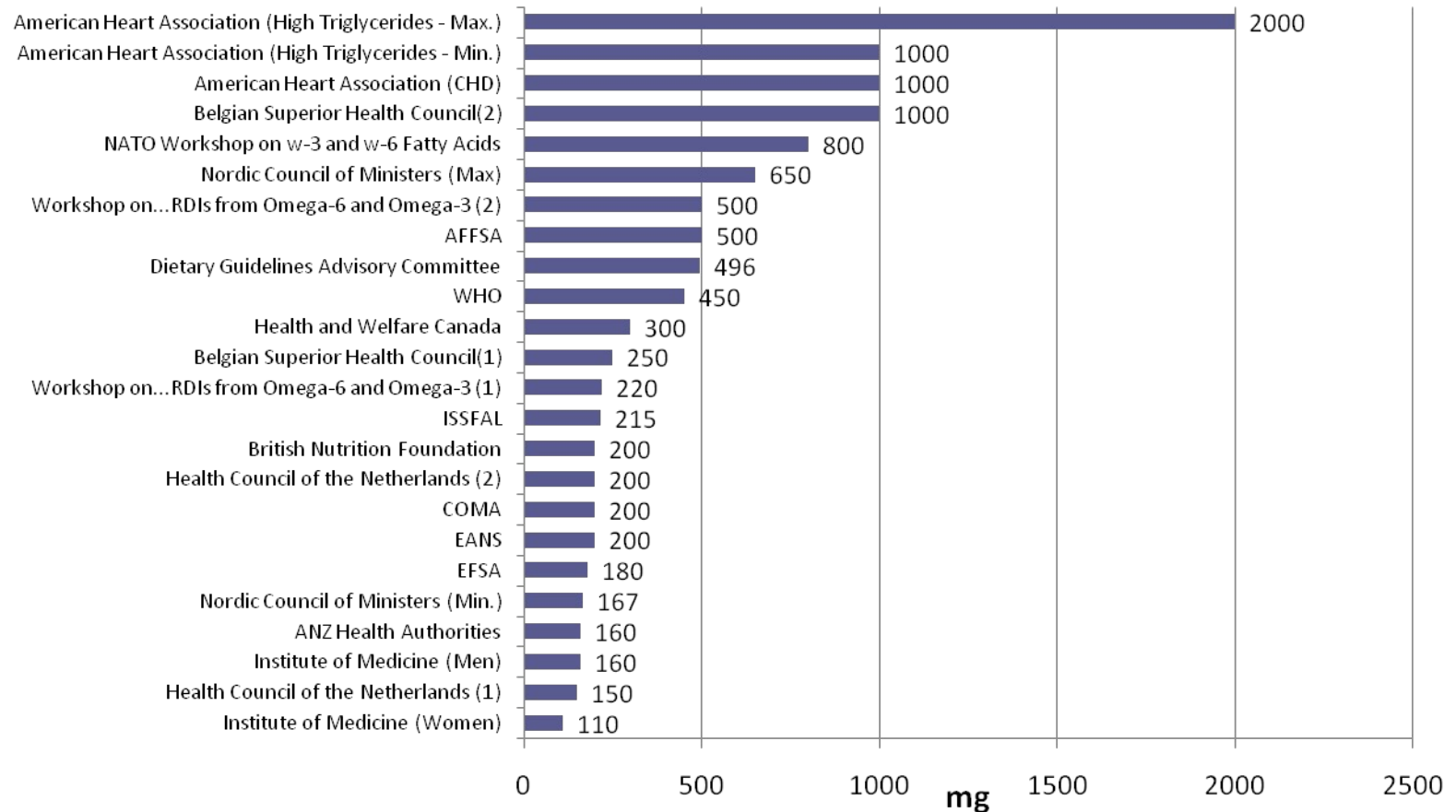
IOM Macronutrient Report (2005)

- AI (calculated) for DHA and/or EPA 160 mg for good health
- AMDR advises consumption of 133-267 mg/day DHA (and/or EPA) to reduce risk of cardiovascular disease



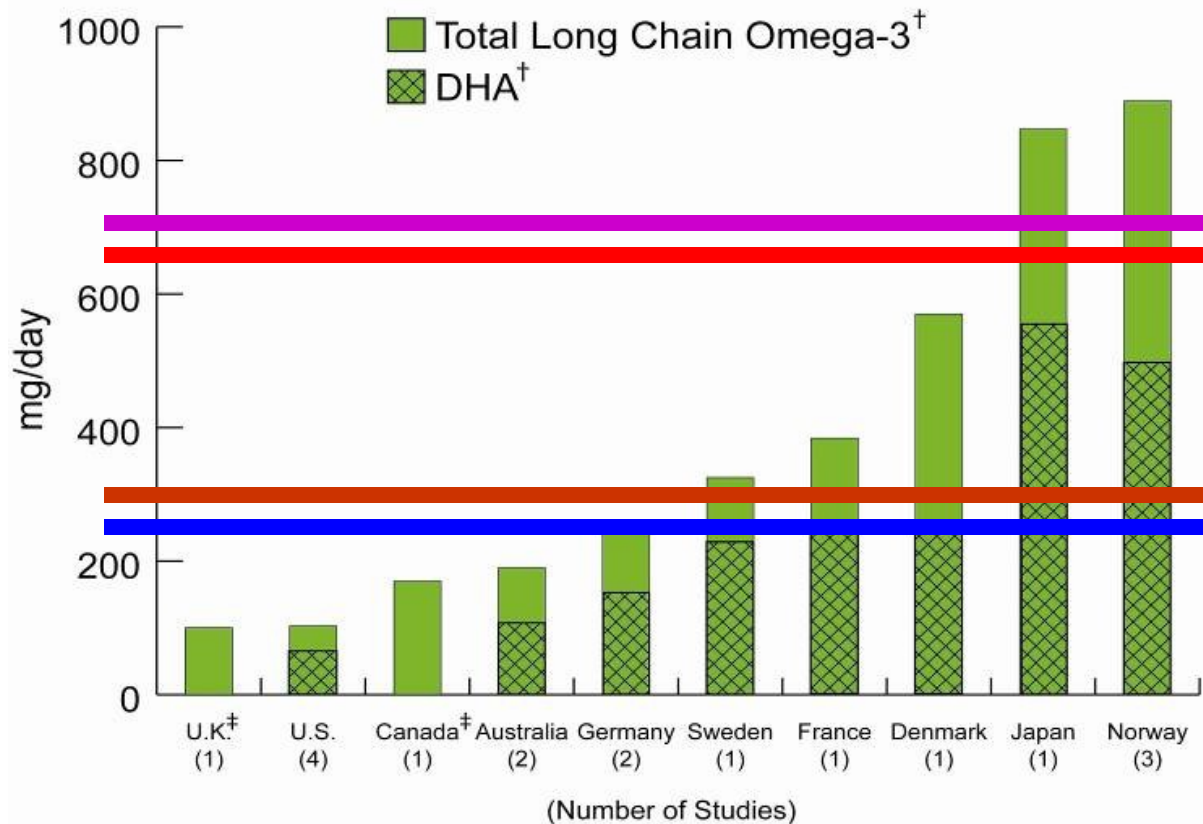
Numerous health bodies have set intake recommendations

Daily EPA/DHA Intake Recommendations from Global Health Bodies



Current Global Adult Intakes versus Recommendations of Long-Chain Omega-3s

Intake:



† weighted means
‡ DHA data not available

Recommendations:

LC n-3
ADA (2007)
ISSFAL (2004)
WHO/FAO (2003)
France (2001)
UK (2003)
Netherlands (2006)
Canada (2005)
Australia (2005)

DHA alone
France (2001)



Quality & Safety

GOED Omega-3 Monograph

TESTS

<i>Acid value.</i>	Maximum 3 mg KOH/g; AOCS Official Method Cd 3d-63
<i>Peroxide value.</i>	Maximum 5 meq/kg; AOCS Official Method Cd 8-53
<i>Anisidine value.</i>	Maximum 20; AOCS Official Method Cd 18-90
<i>TOTOX.</i>	Maximum 26 (result of calculation, (2 x PV) + AV)
<i>PCDDs and PCDFs.</i>	Maximum 2 pg WHO-PCDD/F-TEQ/g
<i>PCBs.</i>	Total PCBs should be expressed on a weight/weight basis and should include IUPAC congeners 28, 52, 101, 118, 138, 153 and 180 Maximum: 0.09 mg/kg
<i>Dioxin- like PCBs</i>	Maximum 3 pg WHO -TEQ/g (maximum for Dioxin and Furans remains at 2pg/g).
<i>Heavy Metals.</i>	
Lead (Pb):	Less than 0.1 mg/kg
Cadmium (Cd):	Less than 0.1 mg/kg
Mercury (Hg):	Less than 0.1 mg/kg
In-organic Arsenic (As):	Less than 0.1 mg/kg



EU Food Hygiene Regulations

- Proposed EU food hygiene rules would have created problems for fish oil imports to EU
- GOED working with regulators now have fish processors approved, utilizing agreed processing times and rancidity levels. Generally all boats and fleet licensed
- Tuna oil from Taiwan going to Japan OK since refining in Japan meets regs.
- Majority of oil is from Chile and Peru



EFSA Health Claims Proposals

- Several well documented Article 14 claims (Health Claims) for LCP sent to Panel for ruling on vision, cognitive, CVD, pregnancy.
- Several submissions rejected due to incomplete dossiers
- 3 submissions for LCP for visual acuity already approved
- Like many other nutrient submissions the standards for allowing claims set VERY high and similar to drug requirements, requiring multiple DBPCT trials.
- Many nutrient claims to date have been rejected on this basis and there is considerable discussion as to whether organizations should continue to fight for claims. Some companies have withdrawn submissions
- No Article 13 claims (s/f claims) yet reviewed, and may appear in fall 2009



Infant Formula Issues

- Indonesian Infant Formula Ingredient Review
 - Initially only LCP's permitted algal oils
 - Following academic and corporate submissions algal, fungal and fish oil now possible IF they meet stringent standards
 - The proposed standards are derived from a variety of documents and require discussion with authorities
 - Likely changes will occur but the standards will high
- CODEX Standards for fish oils in human use.
 - Submission from Swiss delegation
 - Not all countries delegates are supporting
 - Monograph will be developed at some point
 - CODEX moves exceedingly slow

