



# INSIDER<sup>®</sup>

**Webinar June 2010**

**The Latest Consumer Trends in Fish Oil.**

**Science and Regulatory Review**

**Ian Newton**



**Ceres Consulting**



# Presentation Overview

- Long Chain Omega-3's and Science
- Recommendations
  - Government
  - NGO's
  - Health professional Associations
  - RDI's
- Health Claims
- Other Issues



# 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

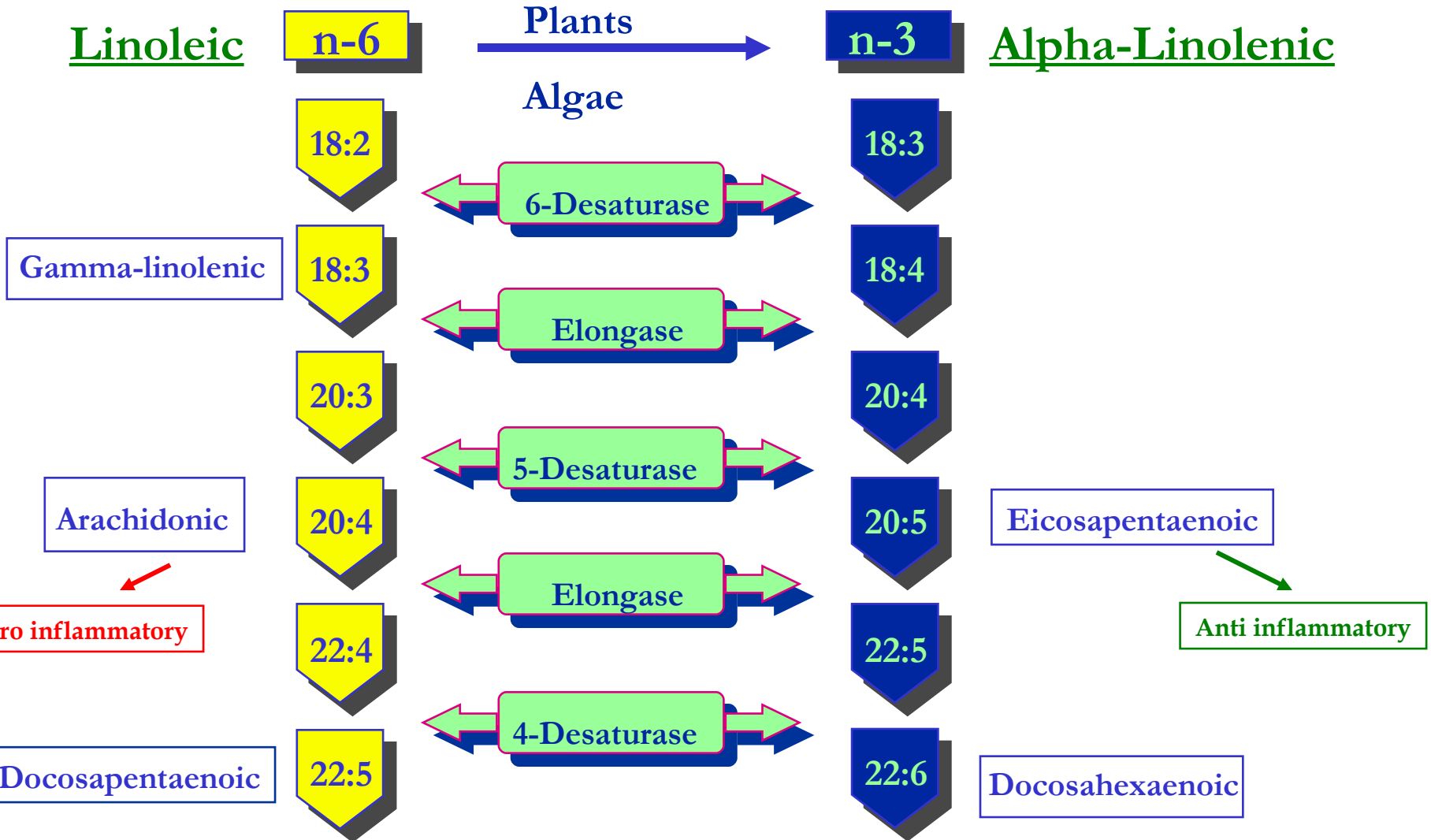


# Omega-3's: Large & Growing Science Base

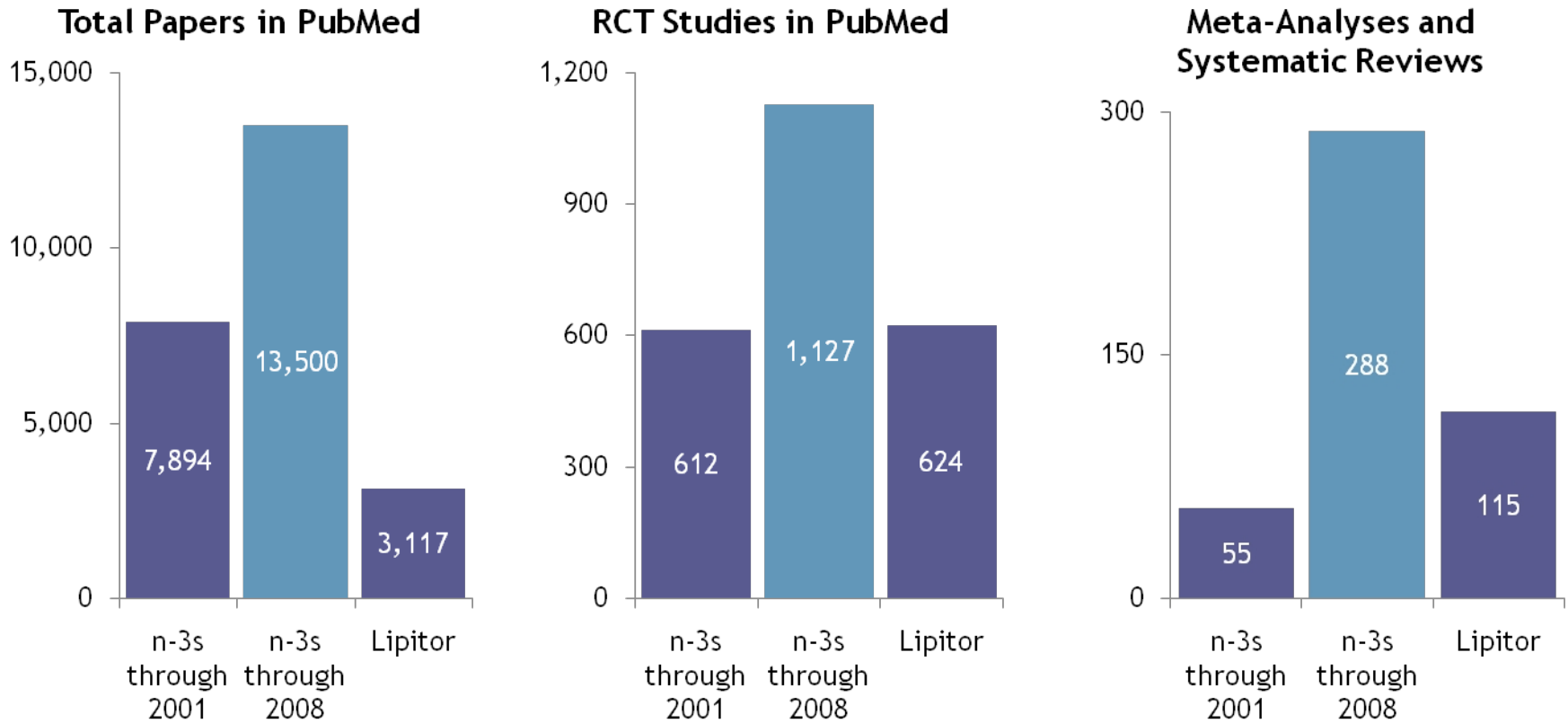
- 16,000 published papers
- Several critical meta analyses show health benefits, particularly CVD
- Excellent rationale based on the science and the human inflammatory response
- Brain and eye function with a well documented need for DHA and possibly EPA
- Other inflammatory based diseases
- IOM Reviews
- AHRQ Reports 3/2004 confirm the science
- Very long history of use
- Gene signaling by omega-3's a new frontier for research



# LC PUFA Metabolism



# Published Papers on Omega-3 PUFA's

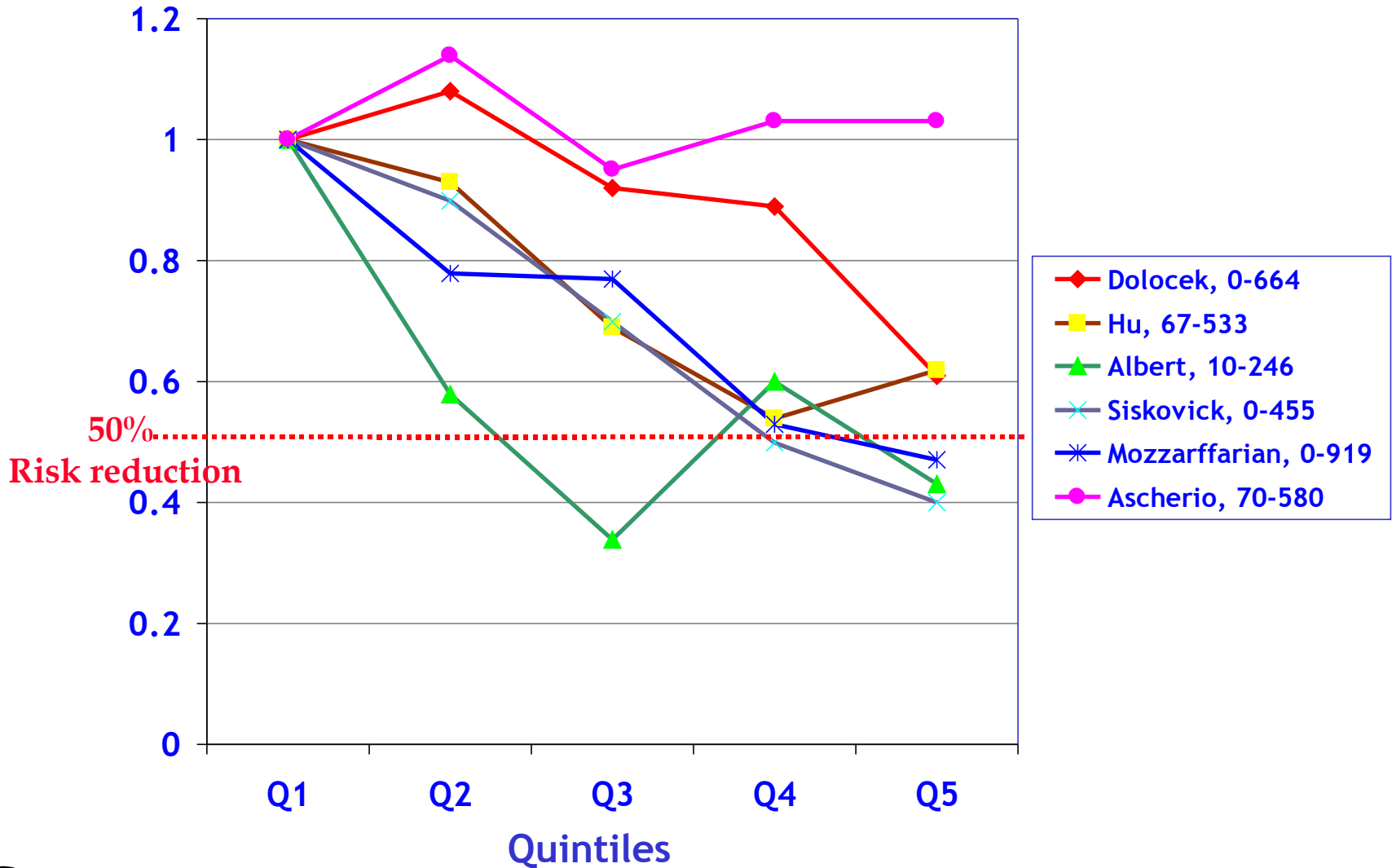


# Clinical Conditions with Involvement of Omega-3 EPA/DHA

- **High blood pressure**
- **High Triglycerides**
- **Infant mental & visual development**
- **Secondary CVD**
- **Primary CVD**
- **Rheumatoid Arthritis**
- **Angina pectoris**
- Asthma
- Inflammatory diseases (e.g. GI tract)
- Eczema
- Degenerative neurologic disorders, dementia
- Depression
- Bipolar disorder
- Crohn's disease
- Bone health
- Macular degeneration



# Relative Risk Odds for Six LC Omega-3 Trials at Varying Dietary Intakes EPA/DHA per day.





# US Dept Human Health Services; AHRQ Report (Mar.2004)

- **Report on Effects of Omega-3 Fatty Acids on Cardiovascular Disease**

*“Overall, the evidence from the primary and secondary prevention studies supports the hypothesis that consumption of omega-3 fatty acids (EPA, DHA, ALA), fish, and fish oil reduces all-cause mortality and various CVD outcomes such as sudden death, cardiac death (coronary or MI death), and MI, although the evidence is strongest for fish or fish oil”*

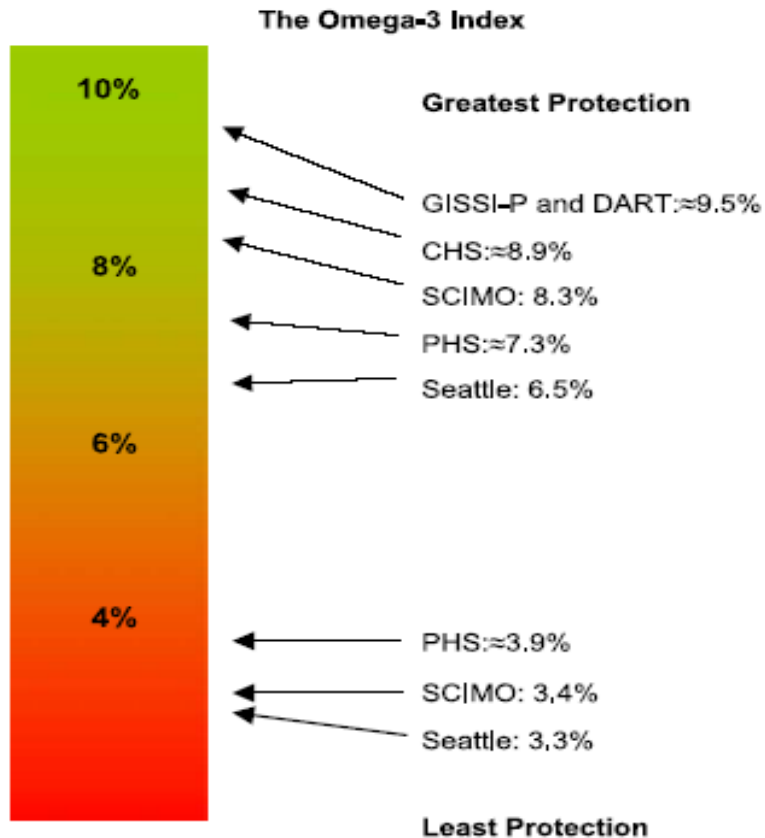


# EPA/DHA Support Healthy Cardiovascular Function

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



# 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



# Low EPA/DHA Intake Kills 84,000 Americans: More Dangerous than Alcohol or Trans fats!!

New study by the National Institute of Health explored preventable causes of death in the USA, found tobacco and high blood pressure kill more Americans than any other factors, but also found low intakes of EPA and DHA are responsible for 84,000 deaths per year.

Importantly, of all the risk factors explored in the study, except for those related to PUFAs, are recognized by the US government as dangerous.

The inclusion of low omega-3 intakes in this study could help the recognition of the role EPA and DHA play in reducing mortality risk in the general population.



# DHA Essential for Fetus and Newborn

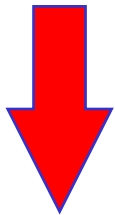
- Human milk contains DHA
- DHA passes through placenta and is accreted in brain and eye
- Intellectual performance, psychomotor development and visual function are better in breast-fed babies
- DHA supplementation improves development of formula-fed infants



# Nutritional flow chart of brain DHA

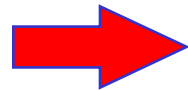
## Optimal Development

Diet Rich in  
n-3 PUFA



Breast Milk  
rich in DHA

Formula  
rich in DHA



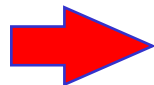
Mother



Fetus



Fetal Brain



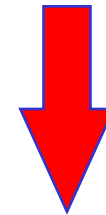
Infant



Infant Brain

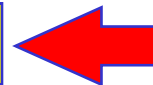
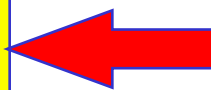
## Suboptimal Development

Diet poor in  
n-3 PUFA

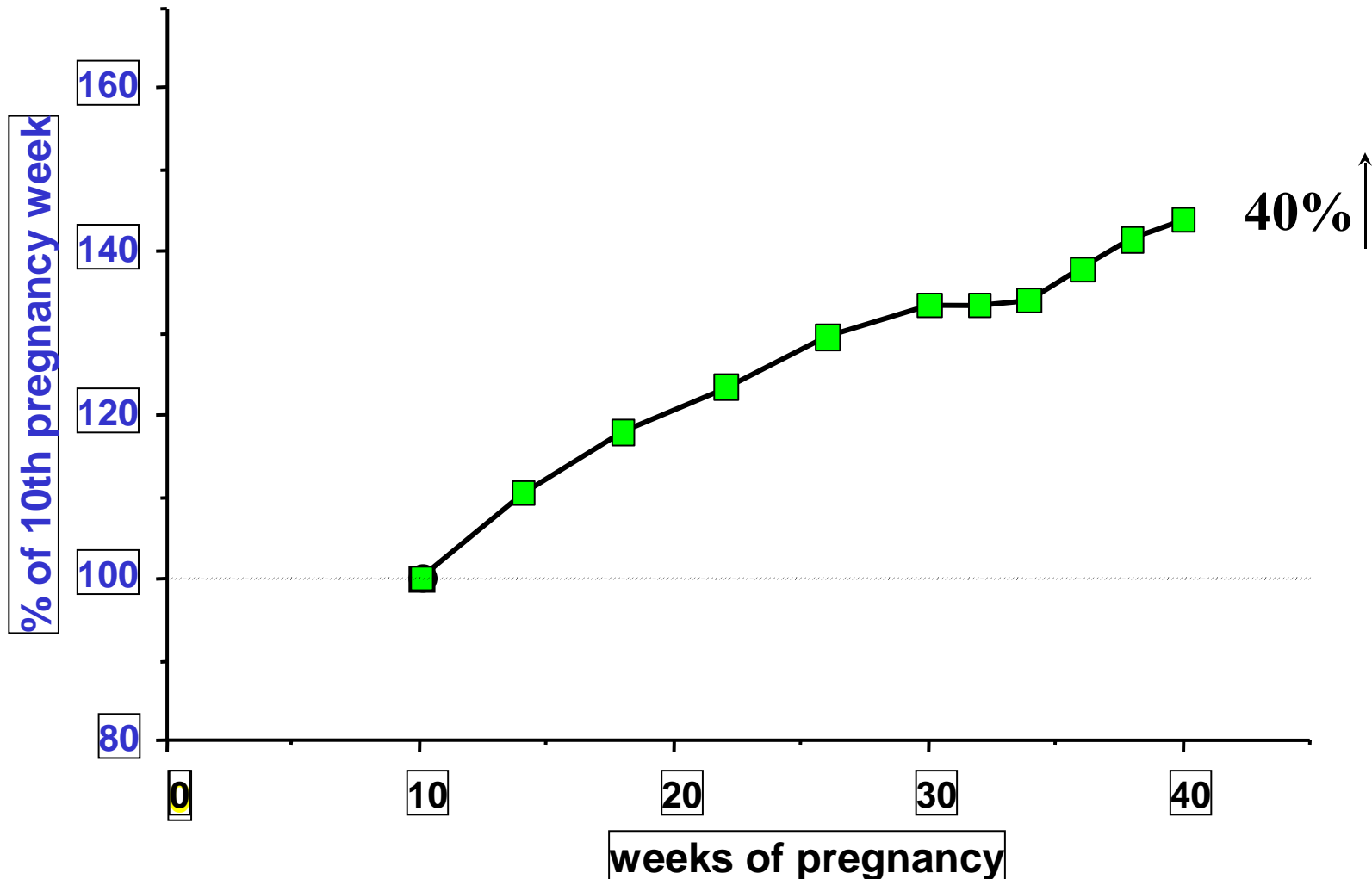


Breast milk  
poor in DHA

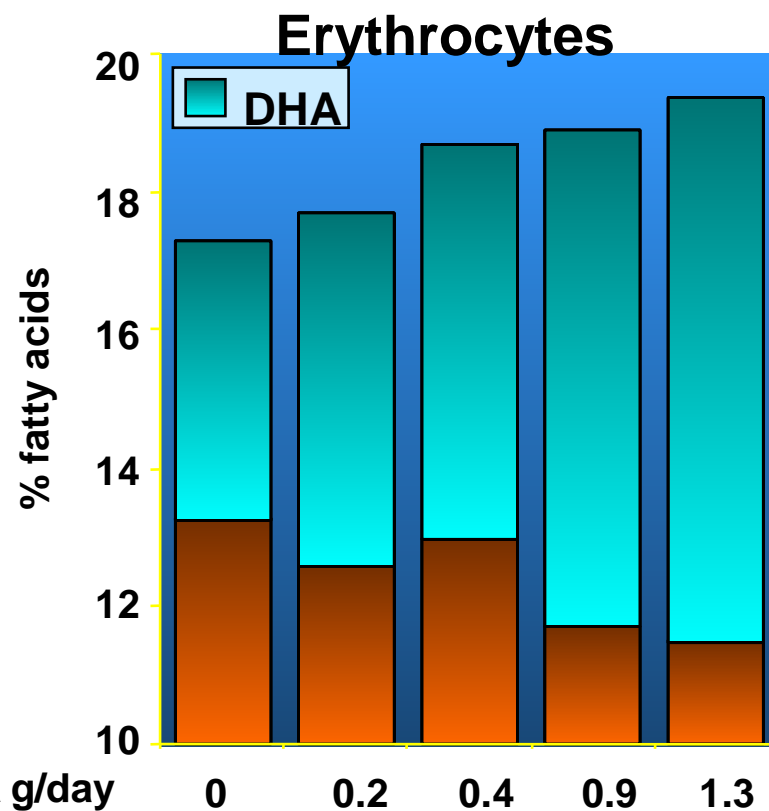
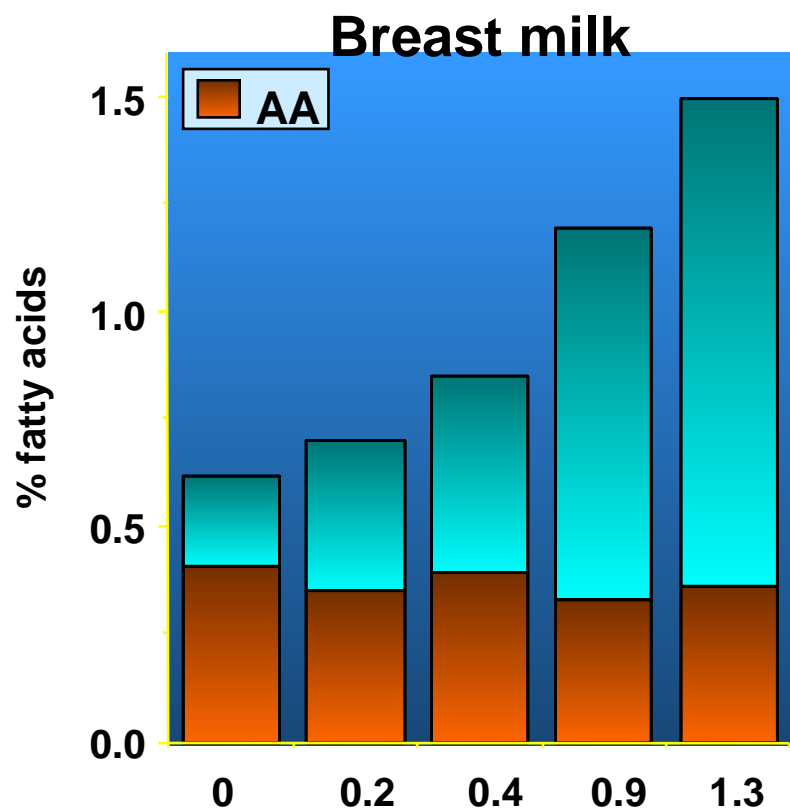
Formula  
poor in DHA



# The essential fatty acid content of plasma phospholipids increases 140% during pregnancy (n=110)

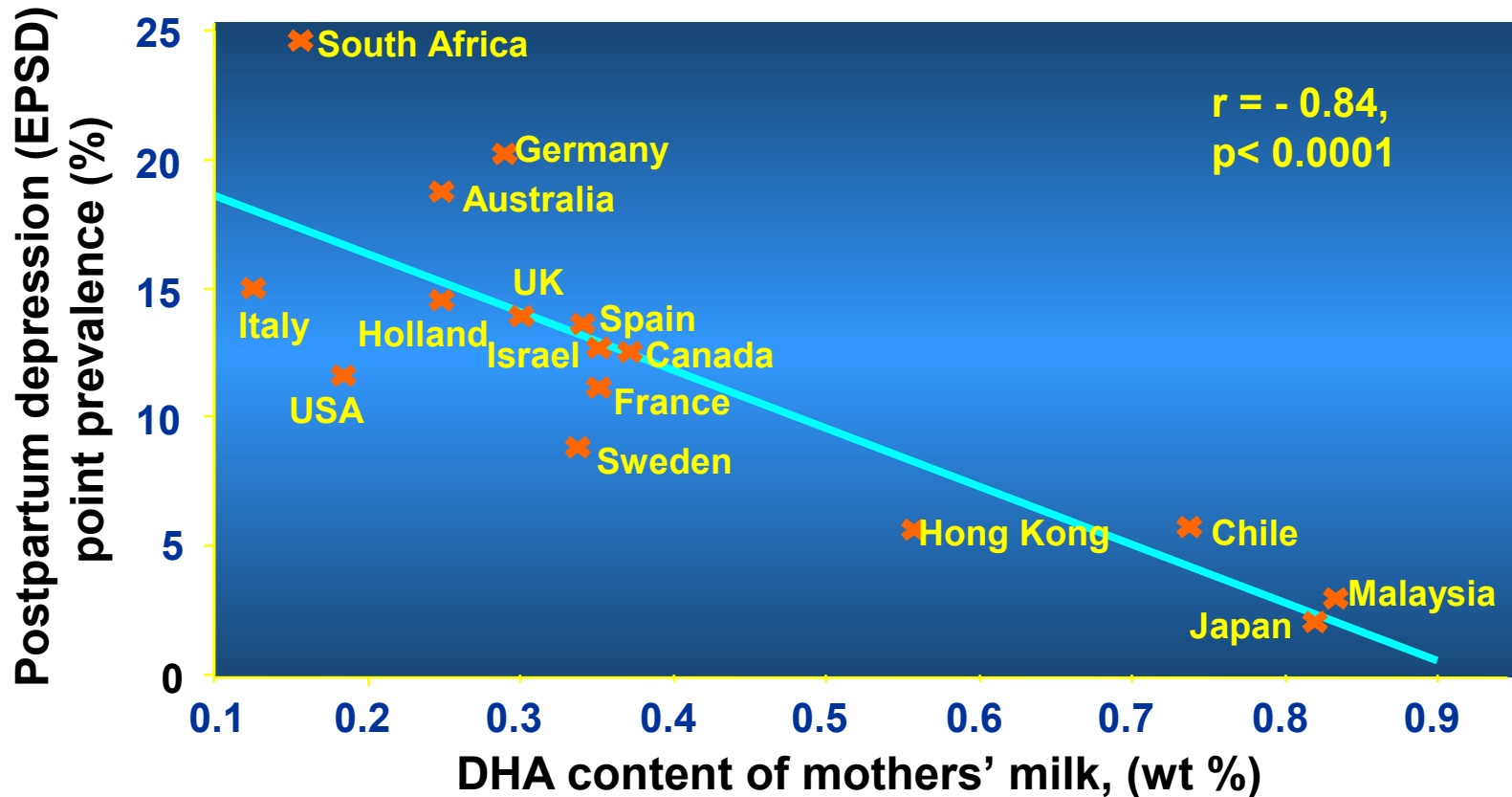


# DHA supplementation of lactating mothers increases the DHA content of their milk (Makrides, 1997)





# Prevalence of postpartum depression is associated with maternal DHA status



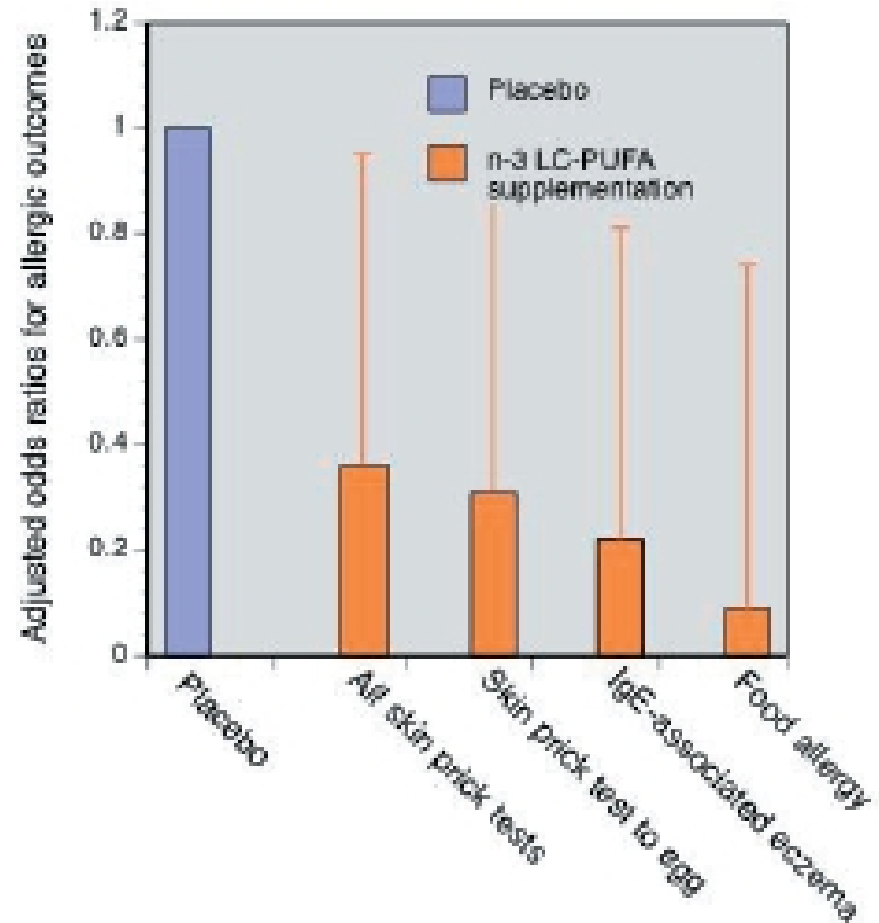
# Other Disease Conditions

- Bone Mineral Density
- Immune Function
- Crohn's Disease
- Vision & Macular Degeneration
- Eczema & Asthma
- Diabetes
- Weight loss



# EPA/DHA During Pregnancy May Improve Infants Allergy Response

Consumption of 3.0 g/day LCP in last half of pregnancy reduced the incidence of skin sensitization (eczema) and food allergies in first year of life.

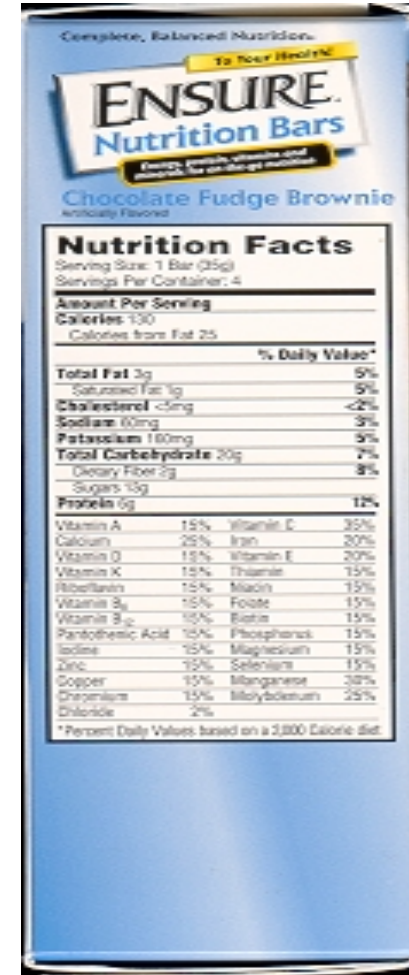
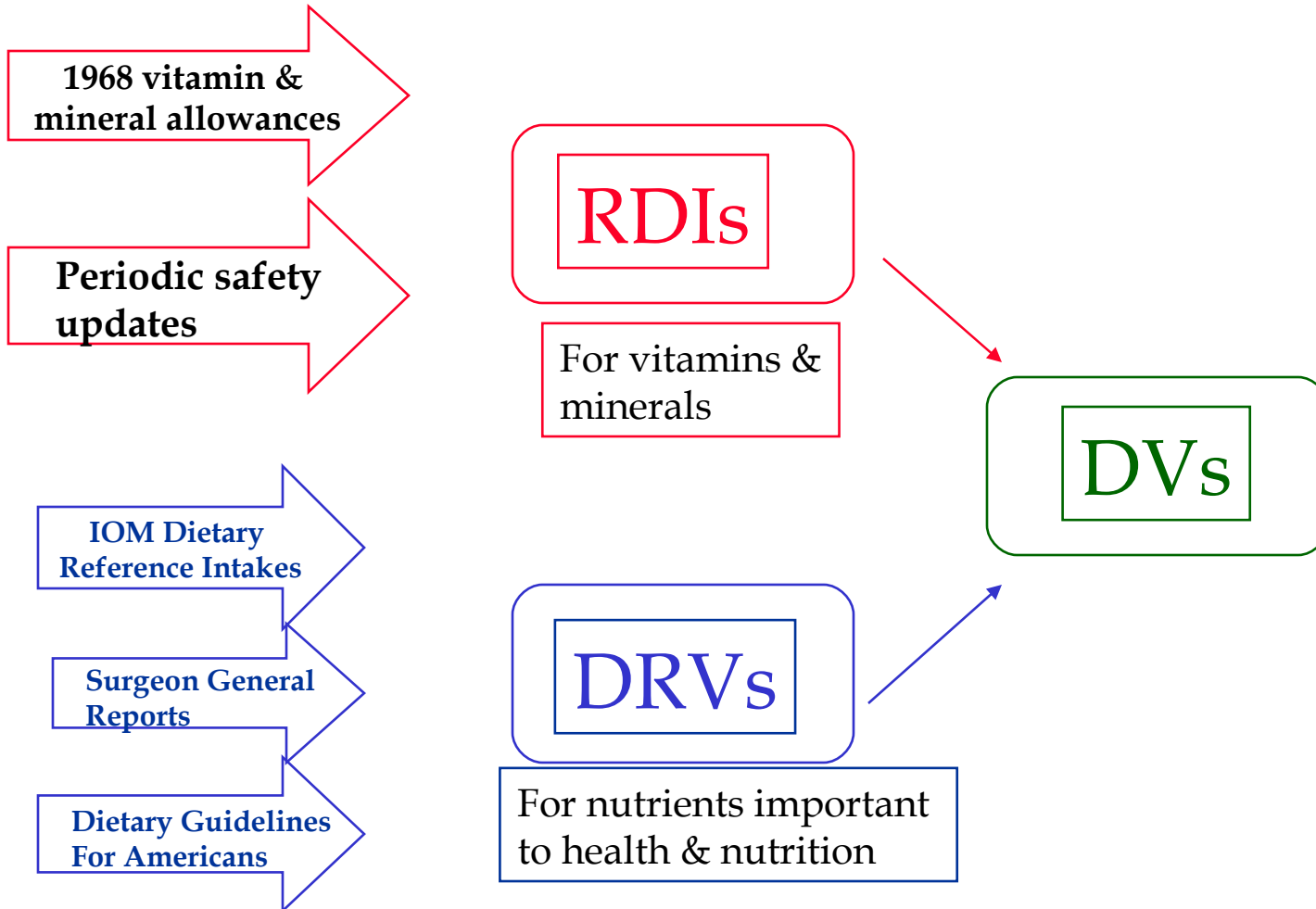


# Key Regulatory Issues for Omega-3's

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



# Daily Value Process



# 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)**

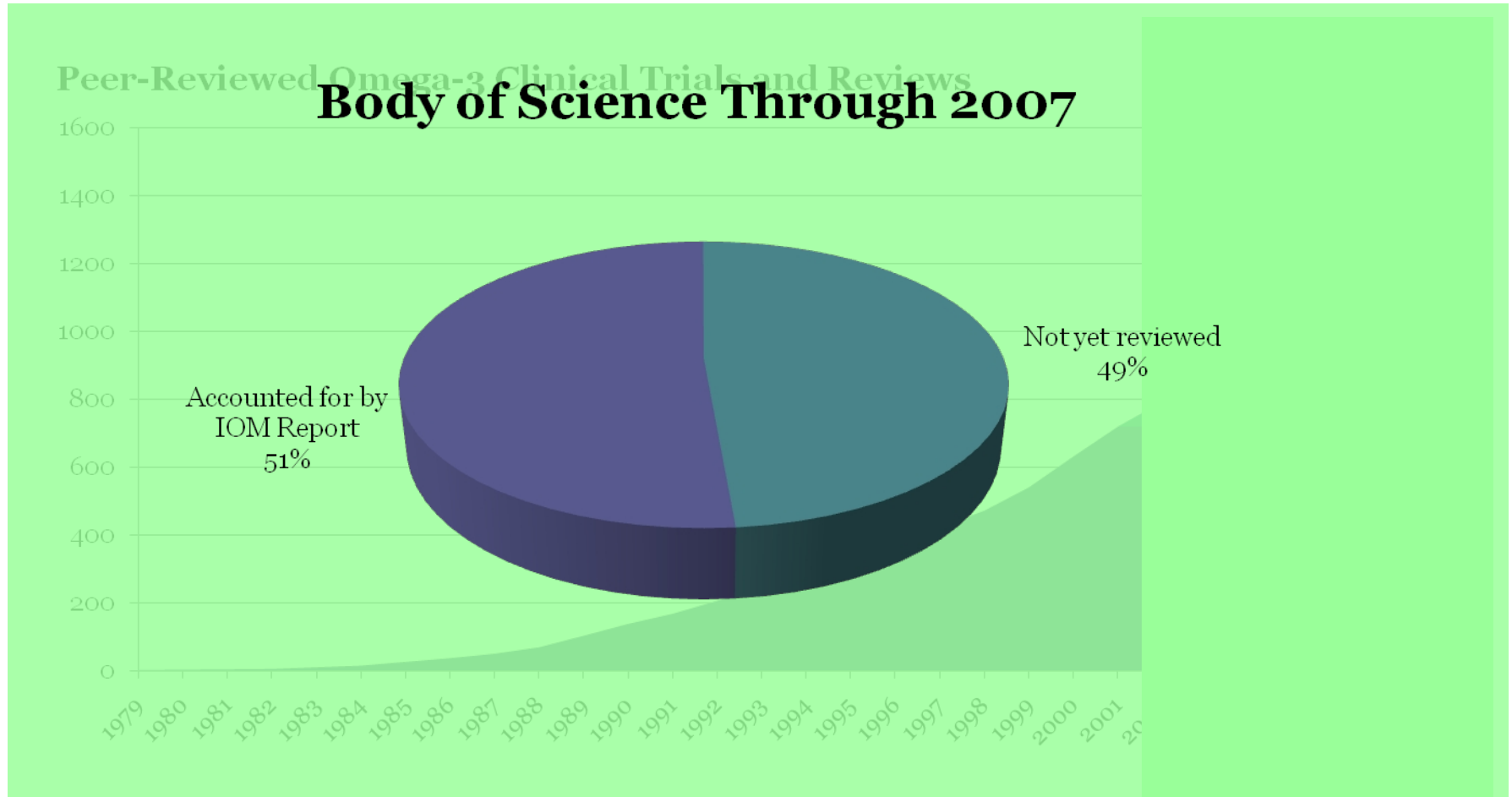
- “Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease.”

**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



A significant part of the body of science for omega-3s has never been accounted for



# US 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

### 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

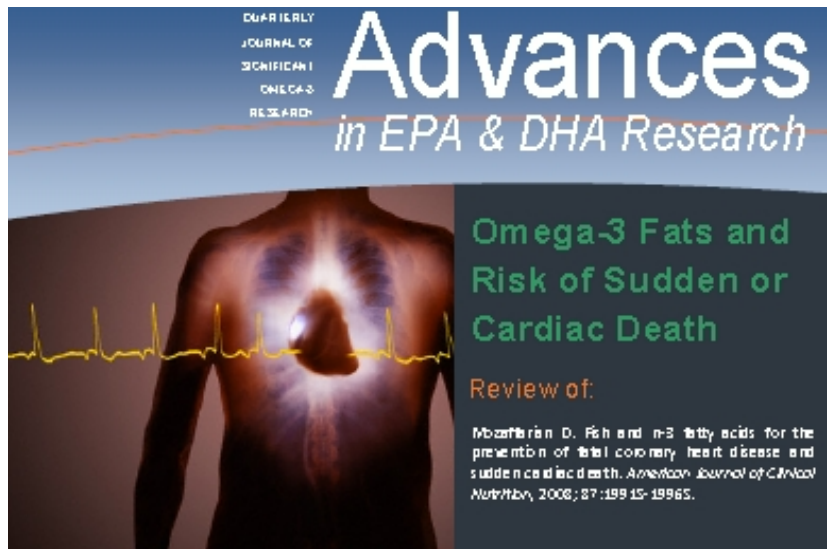
Division of Cardiovascular Diseases, University of Maryland School of Medicine, Baltimore, Maryland

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

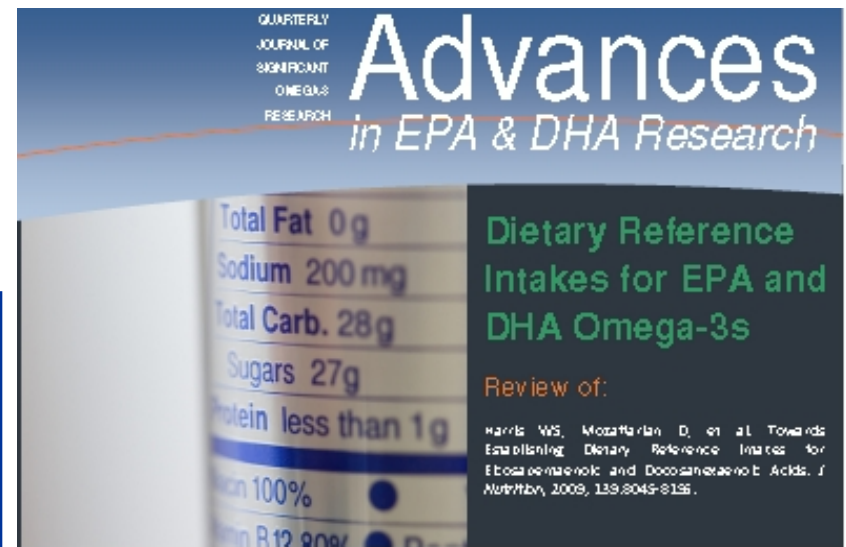




# Omega-3 Research Reviews- Cardiovascular Disease.



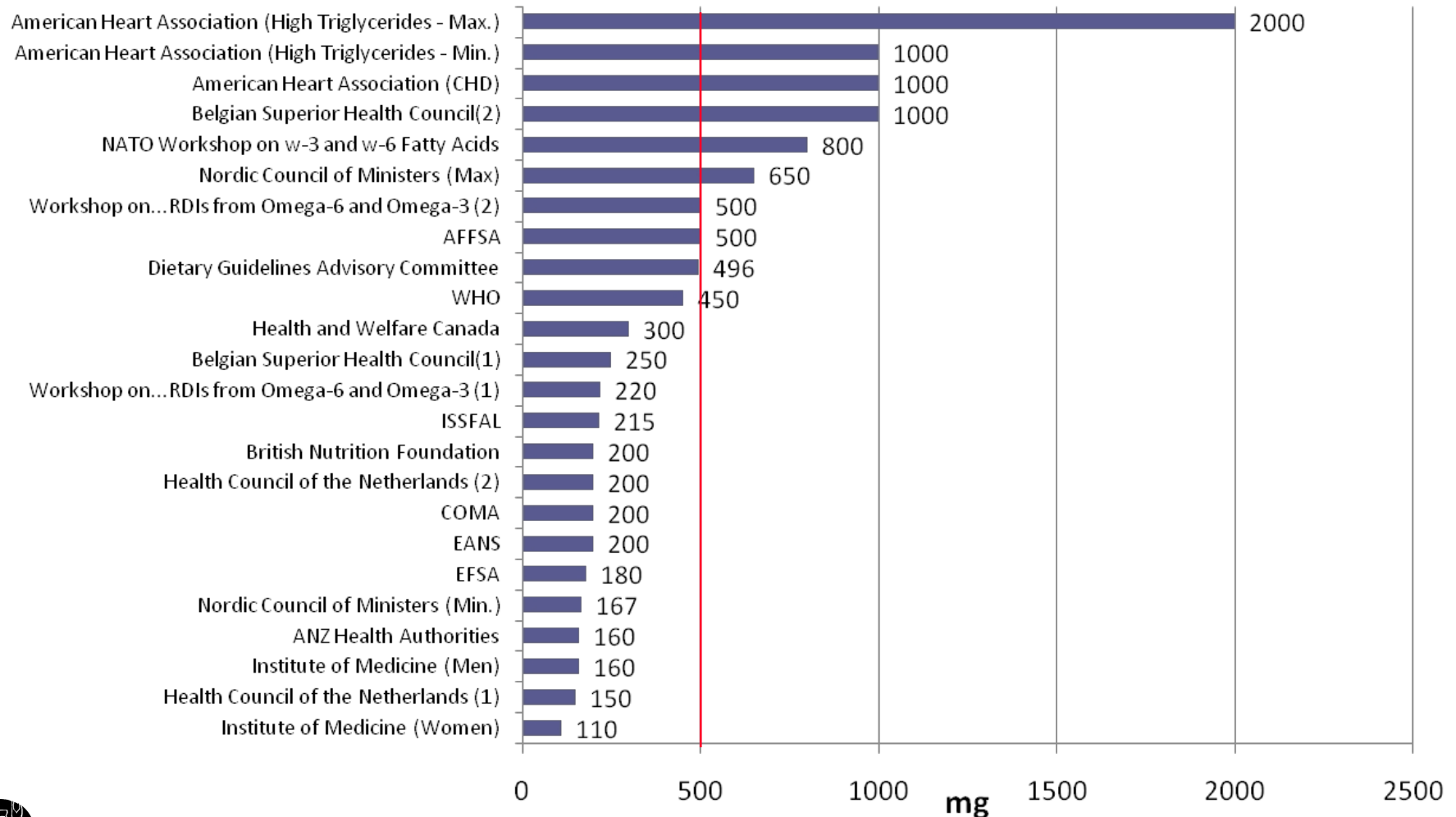
Consistent findings indicate a 36% reduction in risk of sudden cardiac death from modest consumption of EPA/DHA (250-500mgm/day).  
Mozaffarian D. AJCN 2008.



There is a strong and compelling argument for establishing a 250-500 mg/day RDI for EPA/DHA.

# 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

## Recommendations:

### LC n-3

ADA (2007)

ISSFAL (2004)

WHO/FAO (2003)

France (2001)

UK (2003)

Netherlands (2006)

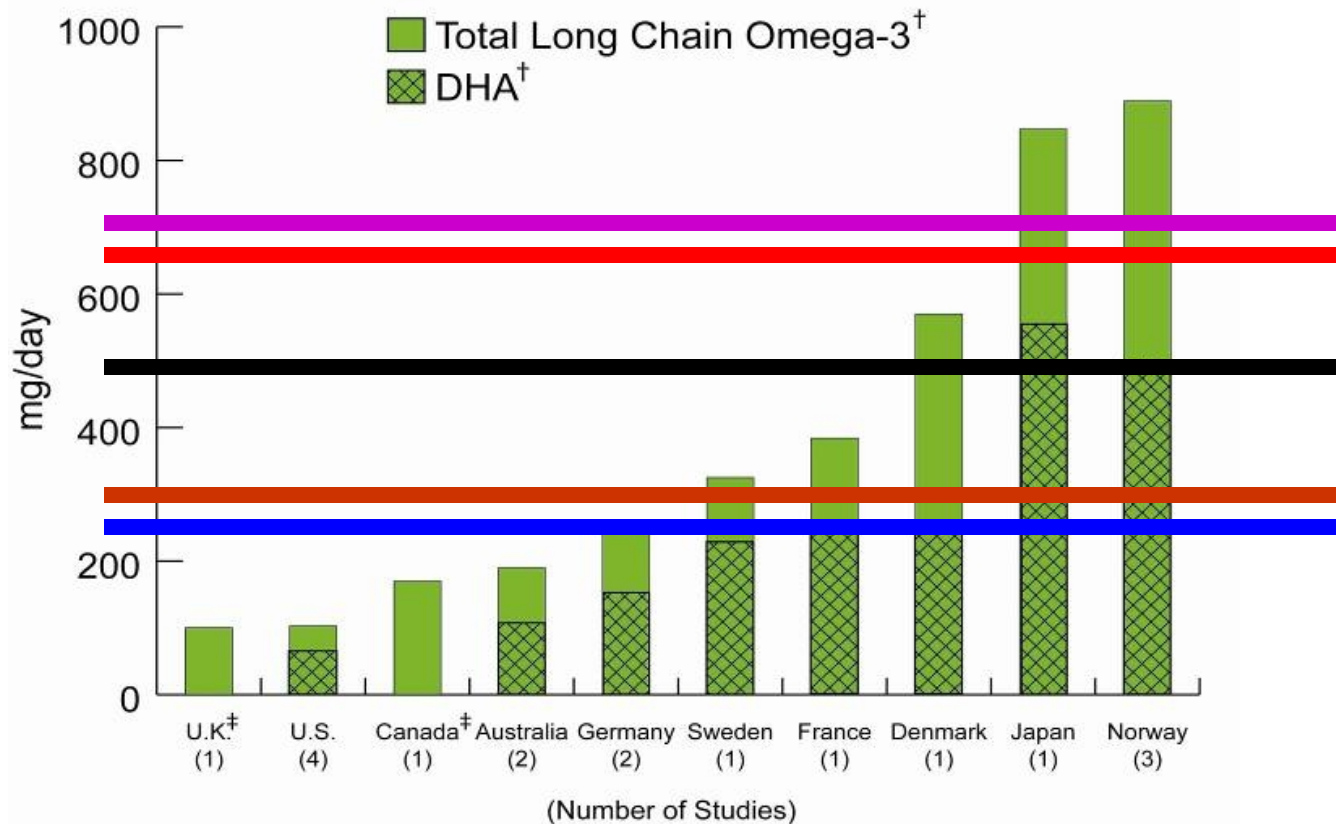
AHA (2002-7)

Canada (2005)

Australia (2005)

EFSA (2010)

## Intake:



# Place to Obtain Reputable Scientific Publications on Omega-3 EPA/DHA

## Omega-3 Learning Center-Purdue University



**OMEGA-3**  
LEARNING  
*for HEALTH & MEDICINE*

Fact Sheet

National Institutes of Health (NIH)  
National Library of Medicine Medline



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# 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 &amp; DHA Omega-3s" "Rich in EPA &amp; DHA Omega-3s"</i>
Structure Function Claim	<i>"Supports a Healthy Heart"</i>
Content Claims	<i>"Contains 30mg of EPA &amp; DHA Omega-3s"</i>



# EFSA Health Claims

- Several well documented Article 14 claims (Health Claims) for LCP sent to Panel for ruling: claims for vision and brain development are or will likely be approved
- Many submissions by organizations rejected due to incomplete dossiers
- 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 those organizations should continue to fight for claims. Some companies have withdrawn submissions
- EFSA LCP Article 13.1 claims (s/f claims) two approved:  
for maintaining normal TG levels; maintenance of normal BP.



# Recent paper highlights flax oil superior to fish oil as a source of n-3' s

## Actual results:

- Low levels of fish oil intake led to higher serum levels of long-chain n-3's than high intakes of flaxseed oil
- Fish oil led to higher serum levels of DHA, flaxseed oil did not
- The increase in serum long-chain n-3 levels was uniform for fish oils, but increases from flax oil were much more variable

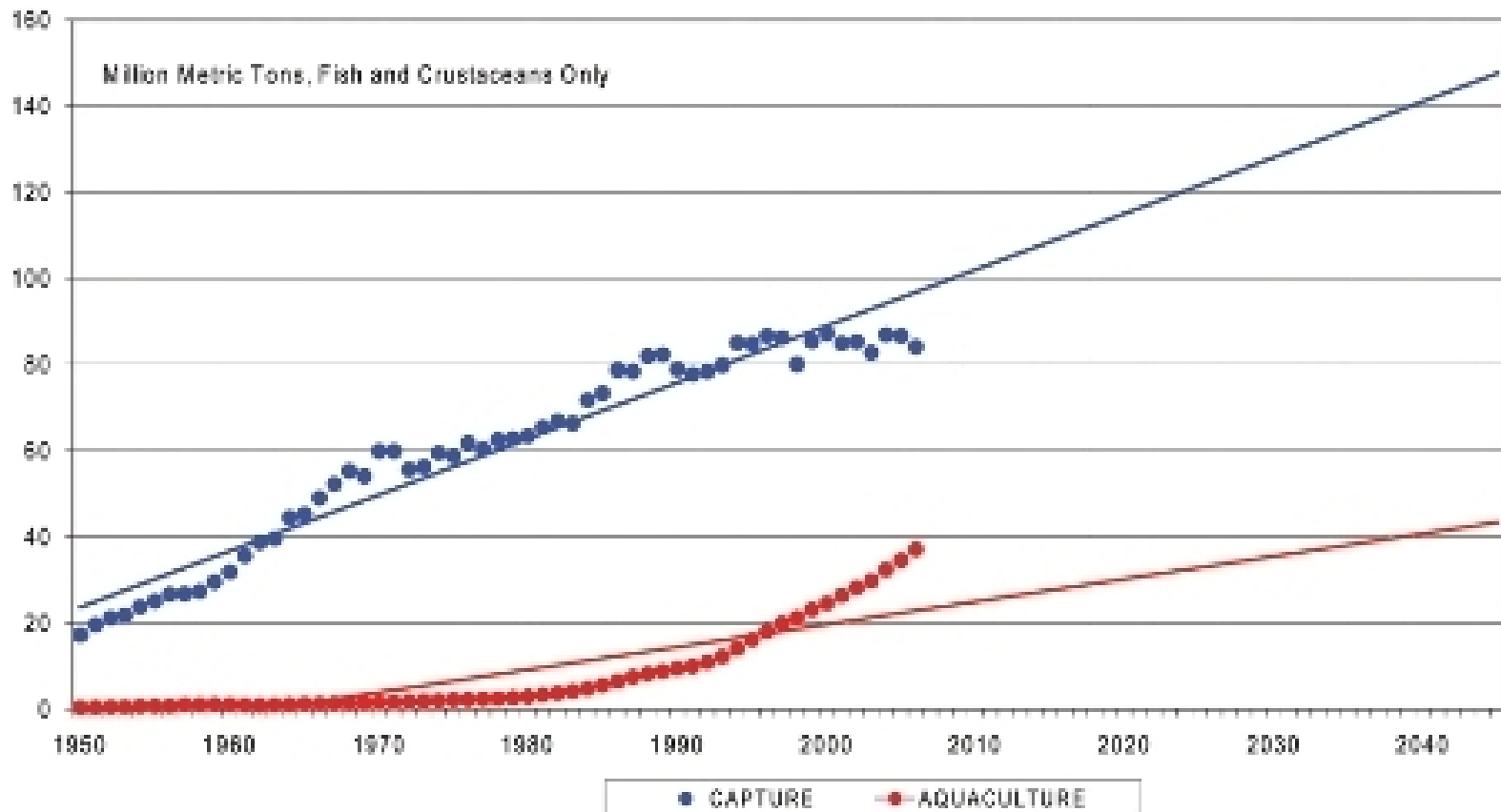
**NUTRA**  
ingredients.com | europe

Breaking News on Supplements &  
Nutrition - Europe  
Dietary ALA sufficient to raise  
omega-3 levels, says study



# Global Fisheries- Capture vs Aquaculture

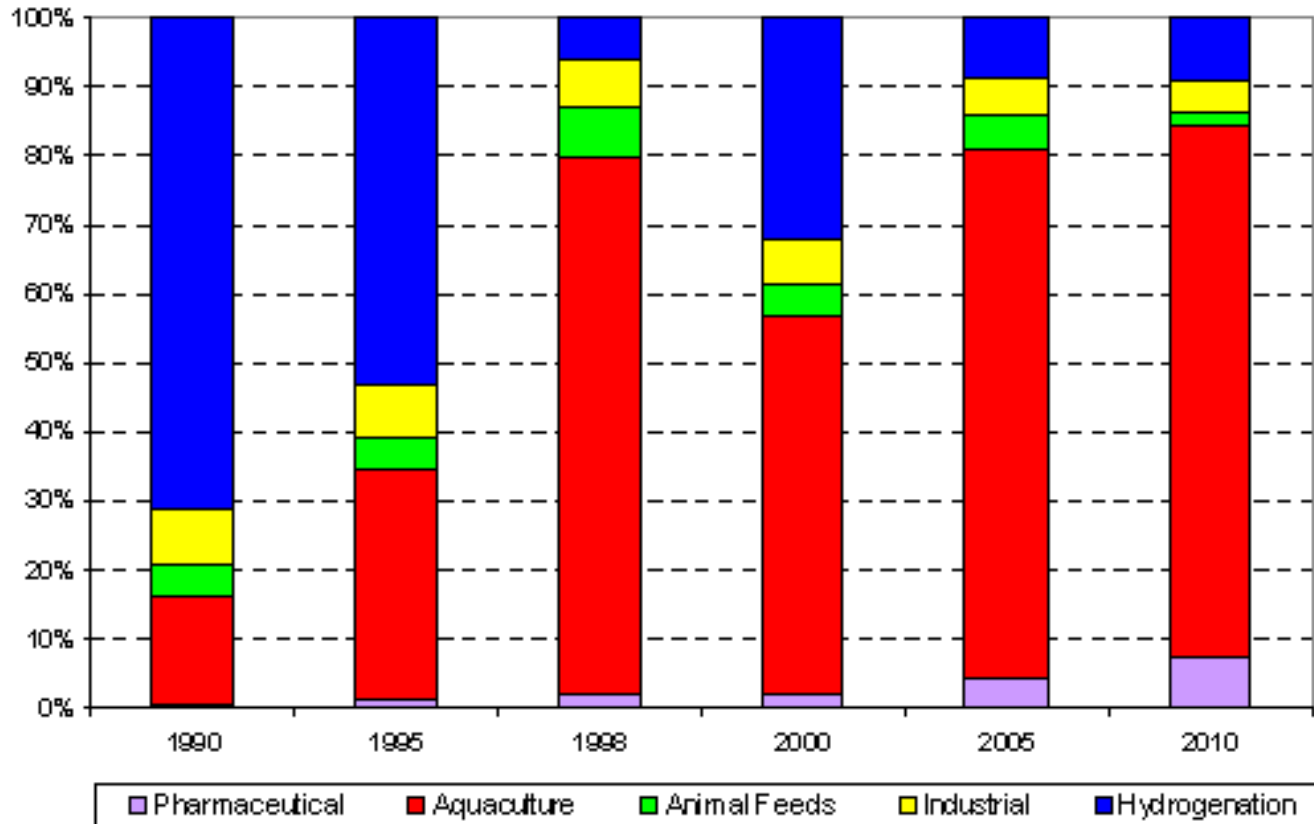
GLOBAL FISHERIES CAPTURE VS. AQUACULTURE PRODUCTION





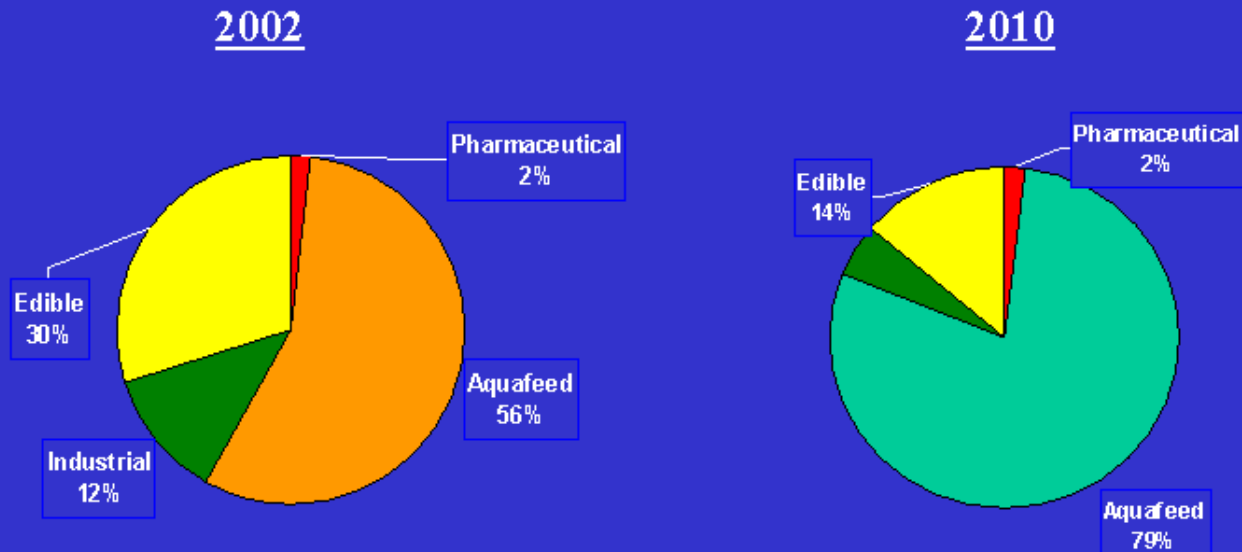
# Use of Fish Oil 1990-2010 (~1.2 million tons)

CHANGE IN THE MARKET STRUCTURE OF FISH OIL



# Fish Stocks: Fish Oil Use 2002-2010

## SUMMARY OF FISH OIL USE FOR THE PERIOD 2002 AND 2010



September 2002



# Quality & Safety

## GOED Omega-3 Monograph

### TESTS

**Acid value.** Maximum 3 mg KOH/g; AOCS Official Method Cd 3d-63

**Peroxide value.** Maximum 5 meq/kg; AOCS Official Method Cd 8-53

**Anisidine value.** Maximum 20; AOCS Official Method Cd 18-90

**TOTOX.** Maximum 26 (result of calculation,  $(2 \times PV) + AV$ )

**PCDDs and PCDFs.** Maximum 2 pg WHO-PCDD/F-TEQ/g

**PCBs.** 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

**Dioxin- like PCBs** Maximum 3 pg WHO -TEQ/g (maximum for Dioxin and Furans remains at 2pg/g).

### Heavy Metals.

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

Only GOED Members sign affidavits that their product meet or exceed the Monograph.



# Key Issues/Success Drivers for Omega-3's

- Government recommendations (US RDI)
- Health Claims- few available, US and UK
- TG not recognized as major CVD factor
- Health professional support
- Consumer awareness/confusion (EPA, and ALA, good fats, plant oils vs fish oils)
- Too many health benefits, confuses consumers
- Quality of raw materials: safety, supply
- Taste/stability (RM and food forms)
- Food companies slow to fortify
- Safety (unfounded)



# Thank you:

Ian Newton,  
Ceres Consulting

[ian@ceresconsulting.com](mailto:ian@ceresconsulting.com)  
[www.ceresconsulting.com](http://www.ceresconsulting.com)

