Future Research Needs and Industry Incentives for Health & Nutrition Research

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Cargill, Inc.
“Medicine today focuses on suppressing the symptoms of disease. A truly preventive medicine, capable of tackling degenerative diseases like arthritis and Alzheimer’s, will be based on diet supplements, not drugs.”

Paul Clayton, Nutrition the new medicine. Prospect Magazine, June 2003
IFT Expert Report on Functional Foods

Functional Foods: Opportunities and Challenges

While food has long been used to improve health, our knowledge of the relationship between food components and health has now been used to improve food. Strictly speaking, all food is functional, in that it provides energy and nutrients necessary for survival. But the term “functional food” conveys that this notion can extend beyond mere survival.

Food and nutrition science has moved from identifying and correcting nutritional deficiencies to designing foods that promote optimal health and reduce the risk of disease.

This report explores the role of functional foods in disease prevention and public health. It examines the scientific evidence for the health benefits of functional foods and the regulatory challenges associated with their development.

The report highlights the importance of functional foods in public health and the need for regulatory frameworks that support their development.

The report also discusses the role of functional foods in addressing chronic diseases and the need for continued research and innovation in this field.

IFT Expert Report

Founded in 1939, the Institute of Food Technologists is an international not-for-profit scientific society with 26,000 members working in food science, technology, and related professions in the food industry, academia, and government. As the society for food science and technology, IFT serves science to the public discussion of food issues.
Important Considerations Regarding Functional Foods

- Safety
- Efficacy
- Ethics
- Legal considerations
- Research
- Regulatory impediments/incentives
Hill’s Criteria

- Strength of association
- Consistency of the observed association
- Specificity of the association
- Temporal relationship of the observed association
- Dose response
- Biological plausibility
- Coherence of the evidence
Identified Research Areas

The IFT Functional Food panel identified the following areas for research focus:

- Identification of nutrients and bioactives
## Evidence For Bioactives Reducing Risk of CVD

<table>
<thead>
<tr>
<th>Bioactive</th>
<th>Food(s)</th>
<th>Evidence</th>
<th>Strength of Evidence</th>
<th>Health Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterol/Stanol</td>
<td>Spreads, OJ, yogurt</td>
<td>Clinical</td>
<td>Very Strong</td>
<td>NLEA</td>
</tr>
<tr>
<td>Soluble Fiber</td>
<td>Psyllium, Oat Products</td>
<td>Clinical</td>
<td>Very Strong</td>
<td>NLEA</td>
</tr>
<tr>
<td>Soy Protein</td>
<td>Beverages, tofu, etc</td>
<td>Clinical</td>
<td>Very Strong</td>
<td>NLEA</td>
</tr>
<tr>
<td>Omega-3 Fatty Acids</td>
<td>Fish &amp; supplements</td>
<td>Clinical</td>
<td>Strong to Moderate</td>
<td>QHC for CVD</td>
</tr>
</tbody>
</table>

Evidence For Bioactives Without Approved Health Claims

<table>
<thead>
<tr>
<th>Bioactive</th>
<th>Food(s)</th>
<th>Evidence</th>
<th>Health Benefit</th>
<th>Strength of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proanthocyanidins</td>
<td>Cranberry Juice</td>
<td>Clinical/Epi</td>
<td>Reduced UTI</td>
<td>Moderate</td>
</tr>
<tr>
<td>Lycopene</td>
<td>Tomato products</td>
<td>Epi, in vitro, in vivo</td>
<td>Reduced Prostate Cancer Risk</td>
<td>Moderate</td>
</tr>
<tr>
<td>Resveratrol</td>
<td>Grape Juice, red wine</td>
<td>Epi, in vitro, in vivo</td>
<td>Reduced platelet aggregation</td>
<td>Moderate to Strong</td>
</tr>
<tr>
<td>Lutein/Zeaxanthin</td>
<td>Spinach, Kale, etc.</td>
<td>Epi and in vivo</td>
<td>Reduce risk of AMD</td>
<td>Moderate</td>
</tr>
<tr>
<td>MUFA</td>
<td>Tree Nuts</td>
<td>Clinical Trial</td>
<td>Reduced risk of CHD</td>
<td>Moderate QHC</td>
</tr>
</tbody>
</table>

The IFT Functional Food panel identified the following areas for research focus:

- Identification of nutrients and bioactives
- Identification of biomarkers
- Food delivery vehicles
Consumer Options
Supplements vs. Foods

Bioactive

Foods Permit A Variety of Delivery Forms

COLA
Identified Research Areas

The IFT Functional Food panel identified the following areas for research focus:

- Identification of nutrients and bioactives
- Identification of biomarkers
- Food delivery vehicles
- Food composition and dietary intake data bases
- Nutrigenomics and function of bioactives
**Effect of β-Sitosterol In Patients With Benign Prostate Enlargement**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta-sitosterol</td>
<td>Beta-sitosterol</td>
<td>Beta-sitosterol</td>
<td>Beta-sitosterol</td>
</tr>
<tr>
<td># Patients</td>
<td>177</td>
<td>200</td>
<td>519</td>
</tr>
<tr>
<td>Daily Dose</td>
<td>130 mg</td>
<td>60 mg</td>
<td>NA</td>
</tr>
<tr>
<td>IPSS</td>
<td>-5.4</td>
<td>-5.3</td>
<td>-4.9</td>
</tr>
<tr>
<td>QMax (ml/sec)</td>
<td>+4.5</td>
<td>+5.3</td>
<td>+3.9</td>
</tr>
<tr>
<td>PVR (ml)</td>
<td>-33.5</td>
<td>35.4</td>
<td>28.6</td>
</tr>
</tbody>
</table>

IPSS=International Prostate Symptom Score; QMax=max. urinary flow rate; PVR= Post-void residual volume

Blood Levels of Long-chain n-3 Fatty Acids and Risk of Sudden Death

(Physicians Health Study Data - 378 participants)

Multivariate model corrected for all known contributing factors, i.e., smoking, aspirin, trans FA, etc

From: Albert et al, NEJM 346:1113, 2005
Value of Omega-3 Blood Levels Compared To Traditional Risk factors

(Physicians Health Study Data - 22,071 participants)

From Albert et al, Circulation 105:2595, 2002 and NEJM 346:1113, 2005
## Effects of Omega-3 Fatty Acids on Mortality

**GISSI – Prevenzione Trial**

<table>
<thead>
<tr>
<th>Deaths</th>
<th>Omega-3</th>
<th>Control</th>
<th>Rel. Risk</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Includes ± Vitamin E and n-3 FA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Patients</td>
<td>5666</td>
<td>5668</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>472</td>
<td>545</td>
<td>0.86</td>
<td>-13</td>
</tr>
<tr>
<td>CV</td>
<td>291</td>
<td>348</td>
<td>0.83</td>
<td>-16</td>
</tr>
<tr>
<td>Sudden</td>
<td>122</td>
<td>164</td>
<td>0.74</td>
<td>-26</td>
</tr>
<tr>
<td><strong>n-3 fatty acid groups only</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Patients</td>
<td>2876</td>
<td>2828</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>236</td>
<td>293</td>
<td>0.80</td>
<td>-20</td>
</tr>
<tr>
<td>CV</td>
<td>136</td>
<td>193</td>
<td>0.70</td>
<td>-30</td>
</tr>
<tr>
<td>Sudden</td>
<td>55</td>
<td>99</td>
<td>0.55</td>
<td>-45</td>
</tr>
</tbody>
</table>

*Lancet 354:447-455, 1999*
Serum LDL-C Levels Over Time In Stable Statin Users

*No test spread was consumed between Week 8 & Week 14.

Am J Cardiol 2000; 86: 46-52
Hypothetical Cost Model

From Kanter, M., personal communication
The IFT Functional Food panel identified the following areas for research focus:

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- Identification of biomarkers
- Food delivery vehicles
- Food composition and dietary intake data bases
- Nutrigenomics and function of bioactives
- Incentives for industry research and development
US Food Expenditures – Percent of Disposable Income

\[ \Delta = -1.2\% \text{ per year} \]
Retail Food Sales ($Billions)

$300
$350
$400
$450
$500

1992
1994
1996
1998
2000
2002

$300
$350
$400
$450
$500

\( \Delta = +2.75\% \text{ /year} \)
Per Capita Retail Food Sales
1992 - 2003

Sales per capita
+1.59% per year
Per Capita Retail Food Sales
1992 - 2003

Sales per capita
+1.59% per year

Sales per capita adjusted for CPI
-0.88% per year
Consumers of tomorrow

“Mass Customization”

Will the Science Community & the Food Industry be ready?

“Here’s my sequence…”

Personalized Foods