

Navigating Tough Waters: Identifying and Overcoming International Challenges

Len Monheit, Executive Director,
New Hope Supply Network



Big Issues

In the news

By the numbers

Economics

Culture

Quality and supply (and safety)

Distribution / channels

Certification / standards / definitions

Region specific issues

The power of marketing

Other business considerations

Putting it all together





In the news...

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China moves to control quality of raw materials for dietary supplements

BEIJING, March 18 (Xinhua) -- China's State Food and Drug Administration (SFDA) required manufacturers of dietary supplements to tighten the control of raw materials in a circular issued on Friday.

Manufacturers are now required to review the qualifications of raw material suppliers and inspect the production of suppliers regularly, the SFDA said in the circular.

The suppliers must improve the quality control of raw materials and manufacturers should develop a detailed record of raw material purchases so that the sources of raw materials can be easily tracked, the document said.

The SFDA also asked its local branches to tighten the supervision of manufacturers who use expensive and rare extractions from animal and plants and imported raw materials.

Manufacturers that use substandard raw materials to produce dietary supplements will be seriously punished, the document said.

The SFDA pledged to publicize information on dietary supplements with health risks and stop its distribution.

The circular is part of the SFDA's efforts to regulate the industry of dietary supplements, which will last throughout the year.

Dietary supplements have become increasingly popular among Chinese consumers due to their awareness of health issues. But the quality of dietary supplements and the number of advertisements that exaggerate effects to mislead consumers has long troubled the industry.

Message

From: Organic Monitor [industrywatch@organicmonitor.com]
To: Organic Monitor
Cc:
Subject: What are Growth Openings in Asian Organic Market?

Email not displaying correctly? View it in your browser.

Organic Monitor

What are Growth Opportunities in Asian Organic Products Market?



Organic product sales are rising across Asia. Growing consumer spending power and concerns about food safety are driving market growth.

This new report by Organic Monitor finds that demand for organic foods is outpacing supply. Although the Asian region has over 3 million

Country Coverage

China

Japan

South Korea

Taiwan

Singapore

Malaysia

Thailand

India



Message

Reply
 Reply to All
 Forward
 Call
 Delete
 Move to Folder
 Create Rule
 Other Actions
 Block Sender
 Safe Lists
 Categorize
 Follow Up
 Mark as Unread
 Find
 Related
 Select
 Send to OneNote

From: Marc Ullman [marc@usulaw.com]
To: Monheit, Len
Cc:
Subject: Marc Ullman FYI Service/FDA: Gov't Shutdown Would Hamper Inspections



FDA will be 'severely' limited by shutdown

By Parija Kavilanz, senior writer April 8, 2011: 8:36 AM ET
 NEW YORK (CNNMoney) -- A government shutdown will severely restrict food and drug inspections, an official with the Food and Drug Administration warned Thursday.

"We will be pretty severely limited. We're hopeful that a resolution is reached before it comes to that," the official said.

The FDA, which is an agency within the Department of Health and Human Services, consists of nine centers and offices and employs 13,000 workers.

[Click Here for Complete Story](#)

Beware of unapproved radiation supplements

HEALTH NEWS

Consumer Reports Beware of unapproved radiation supplements

Mar 24, 2011 9:00 AM

Healthy Living

Conditions & Treatments

The U.S. Food and Drug Administration this week warned consumers to be wary of supplements and other products sold online and in retail stores that claim to treat or prevent the effects of radiation but are not FDA-approved for that purpose.

The FDA didn't specify which products might be making false claims. "These fraudulent products come in all varieties and could include dietary supplements, food items, or products purporting to be drugs, devices or vaccines," the FDA said.

It's an important warning for consumers who are considering taking dietary supplements during the reported shortage of potassium iodide, the FDA-approved drug that can help prevent radiation-induced thyroid cancer. [A true radiation emergency](#)



Message

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From: NPI Asia [npiasia@email.npinewsletters.com]
To: Monheit, Len
Cc:
Subject: Why demand in China; Vietnam regs

[What you need to know about probiotics](#)

There is perhaps no ingredient category more diverse than probiotics. Uncover insights about these beneficial bacteria in our Ingredient Intelligence Monograph probiotics report. Learn about regulations, new product launches, experts' top 4 probiotics forecasts for the year ahead, and more.

NPI ASIA NEWS

[EAS appoints regulatory adviser for Asia](#)

International food policy consultancy EAS has appointed Evon Chan as a regional regulatory affairs adviser to utilize her expertise in food and nutritional product marketing across the Asian region.
[Press release](#)

[Enzymotec to supply krill oil in India](#)

Enzymotec Ltd has signed a long term contract to supply its Krill Oil to one of the biggest pharmaceutical companies in India, Lupin Limited.
[Press release](#)

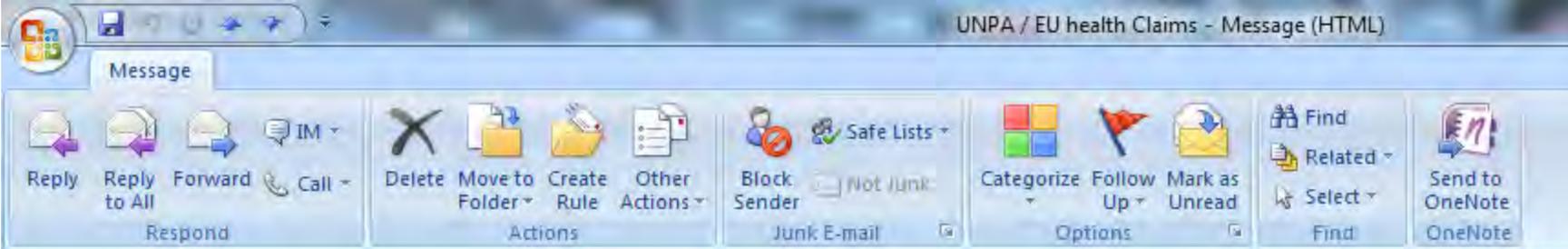
BUSINESS

[Demand for whey protein growing in China](#)

The demand for whey especially high value added whey products is growing constantly thanks to the rapid development of China's economy and higher requirement for food nutrition and especially for baby formula.
[Press release](#)

REGULATORY

[Health supplement regulation in Vietnam](#)



You forwarded this message on 4/8/2011 3:49 PM.
This message was sent with High importance.

From: Harry Rice [harry@unpa.com]
To: UNPA COLLEAGUES
Cc:
Subject: UNPA / EU health Claims

Dear Colleagues-

The European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies (NDA) has published Article 13 (general function) health claims proposed for use on food products. The 442 claims assessed relate to health oxidative damage to body cells, contribution to either cognitive or bowel function; and maintenance of normal blood ch future decisions of the European Commission and EU Member States which are responsible for the authorization of the claims remain to be finalized by the June 2011 deadline.

Claims evaluated with a favorable outcome include the relation between: walnuts and improved function of blood vess olive oil on LDL cholesterol; and the relation between caffeine and alertness and caffeine and increased physical end claims based on the replacement of certain nutrients were supported by sufficient scientific evidence including: the re lower the increase of blood glucose levels after meals; the replacement of saturated fatty acids with mono- and polyun cholesterol levels; as well as the role of a range of sugar replacers (e.g. xylitol or sorbitol) in maintaining tooth mineraliz levels after meals.

As for previous evaluations, many of the unfavourable opinions in this series were linked to the poor quality of the info included, for instance: the inability to identify the specific substance on which the claim is based; the lack of evidence maintenance or improvement of body functions; or the lack of precision regarding the health claim being made. In add current legal framework.

EFSA and its scientific experts are pursuing dialogue with stakeholders to further explain their work and to provide app applications. Following consultations carried out in 2010, EFSA will launch three additional on-line consultations later 1) bone, joint and oral health 2) oxidative damage and cardiovascular health, and 3) satiety, weight management and b

Opinions from all four series can be viewed on [EFSA's website](#). Please let me know if you have any questions.



ERNA

eHPM

PRESS RELEASE

Fundamental reappraisal of claims process needed, says industry

11 April 2011

The European Commission should undertake a discussion of the specific limitations of nutritional research and reappraise the claims evaluation process, rejecting claims based on EFSA opinions, three industry associations have said.

Commenting jointly on the fourth batch of claims opinions published by the Food Safety Authority (EFSA) last week, European associations EHPM, EBF and ERNA said that continued reliance in the assessment process on criteria that are often unfeasible and inappropriate for the majority of claims, is contributing to a growing number of negative EFSA opinions.

Negative opinions

Taurine – fatigue / performance

ATP – energy / fatigue

L-arginine – maintenance of muscle mass / performance

Caffeine – fat mass loss / body weight loss and oxidation

Caffeine + EGCG – oxidation and body weight loss

Colostrum – immune support

Copper – tiredness and fatigue

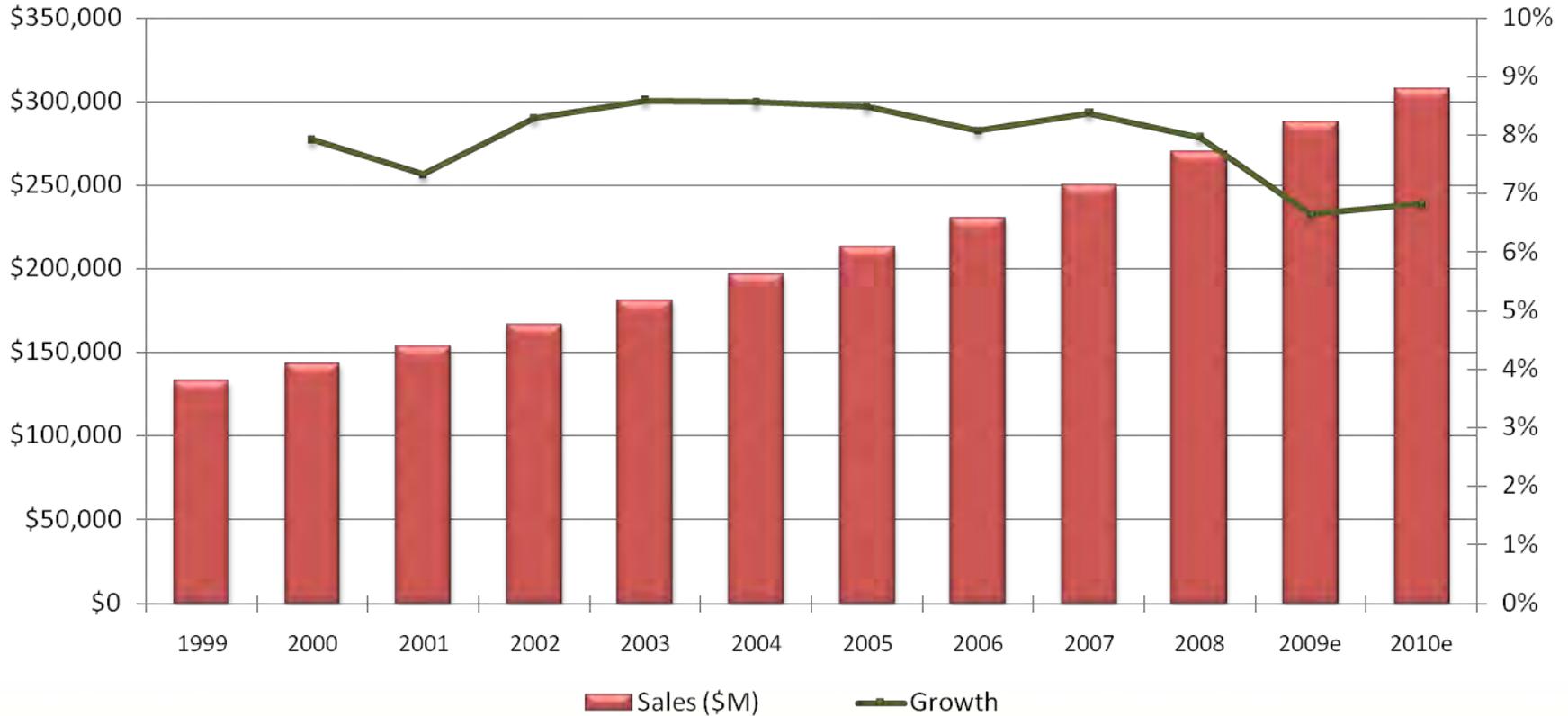
L-Carnosine – power / performance etc





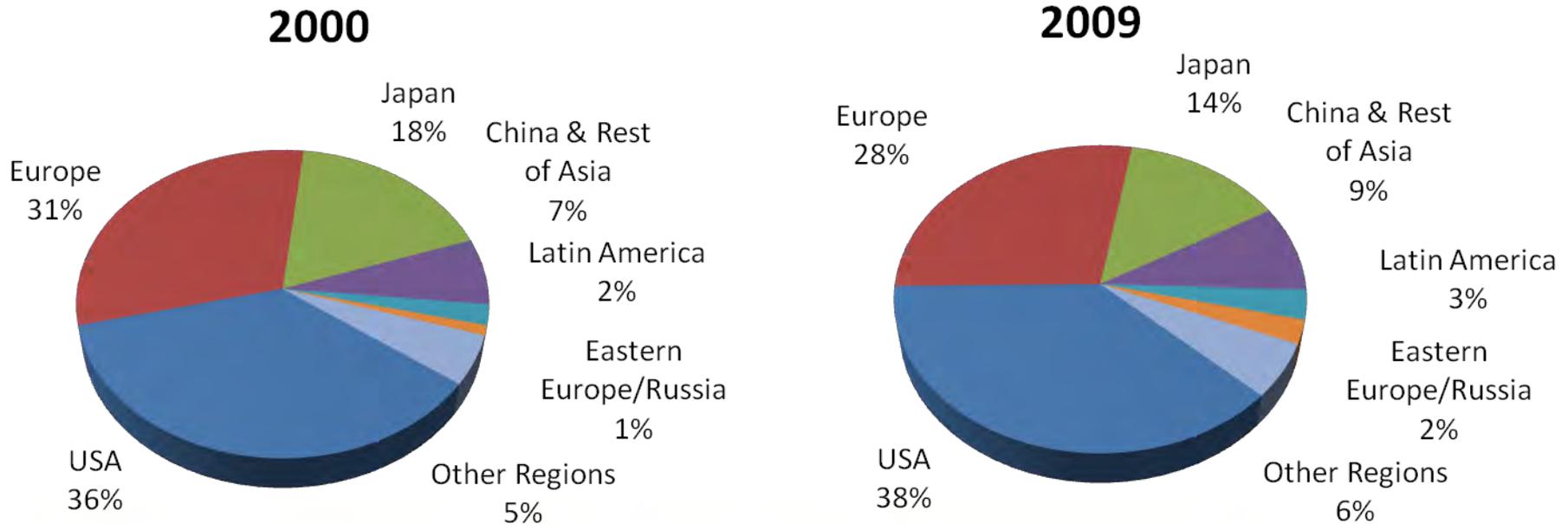
By the numbers...

Global Nutrition Industry: 2000-2010e

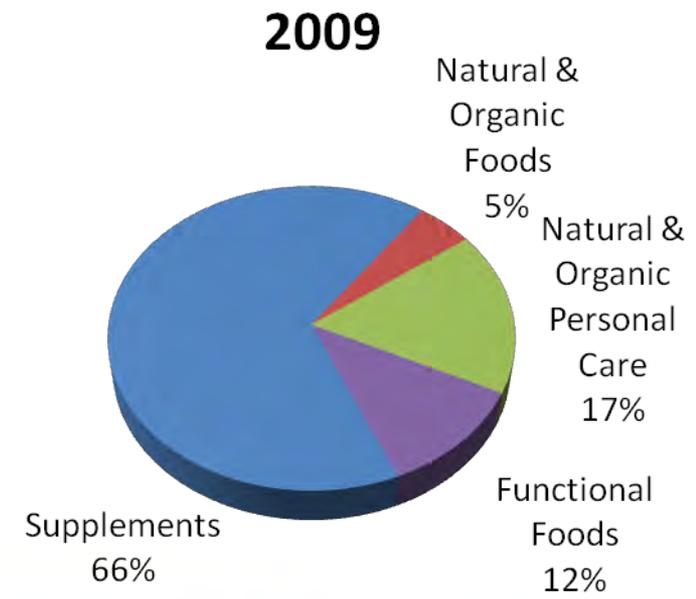
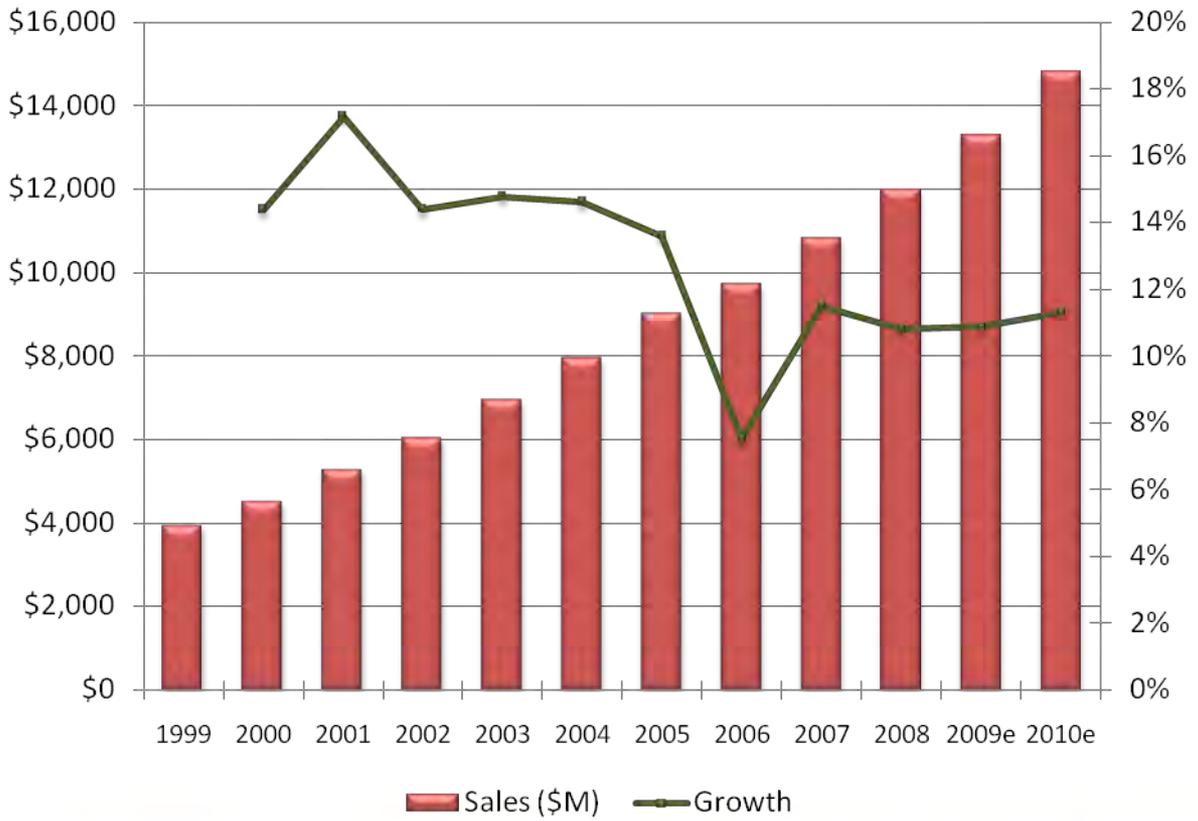
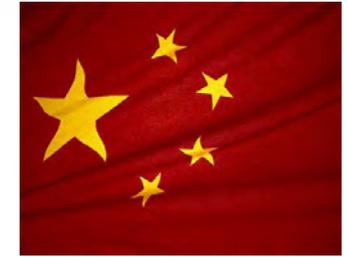


Why Go Global?

Global Nutrition Industry: 2000 vs. 2009

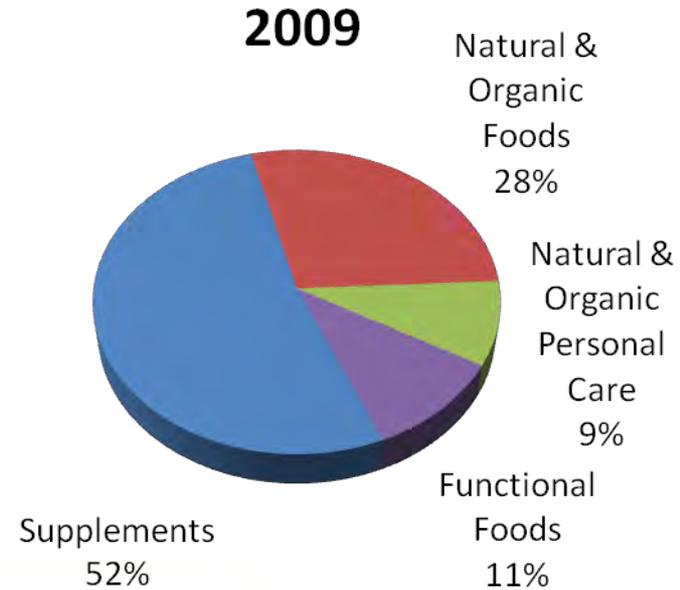
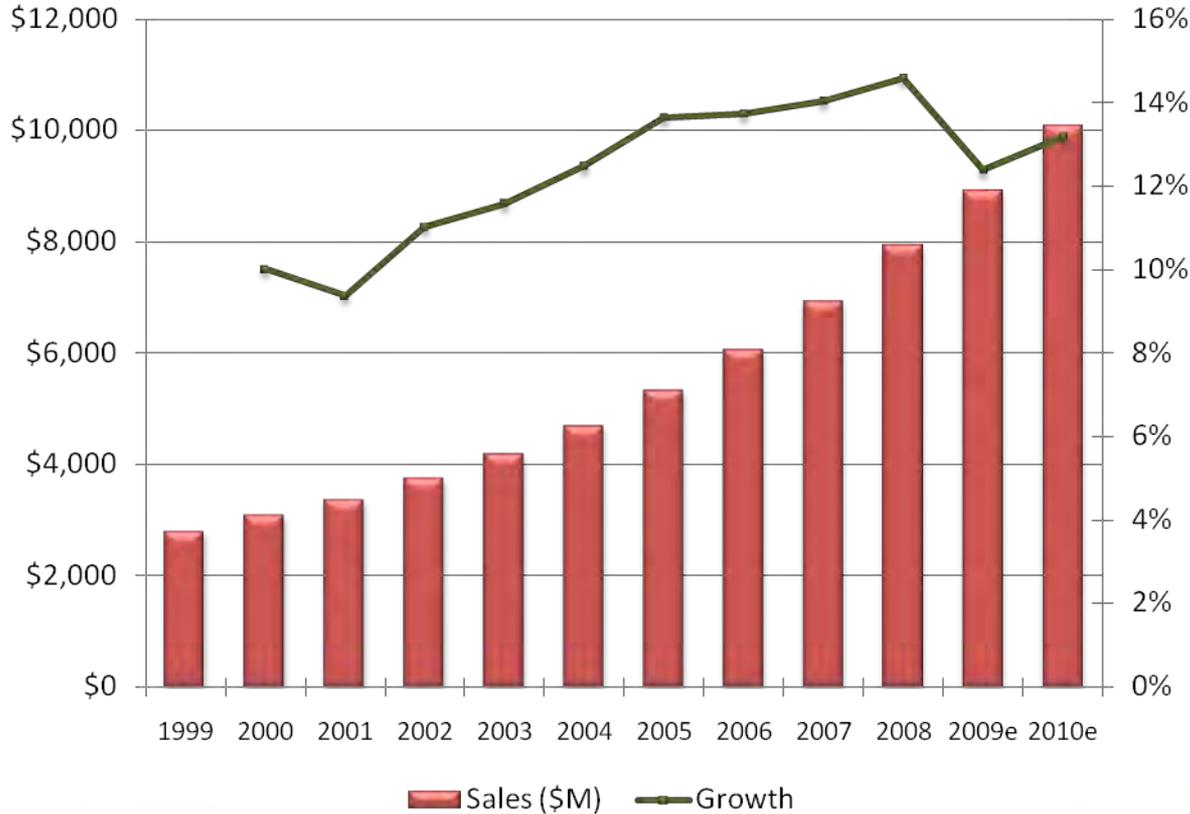


China: What's Really Happening?



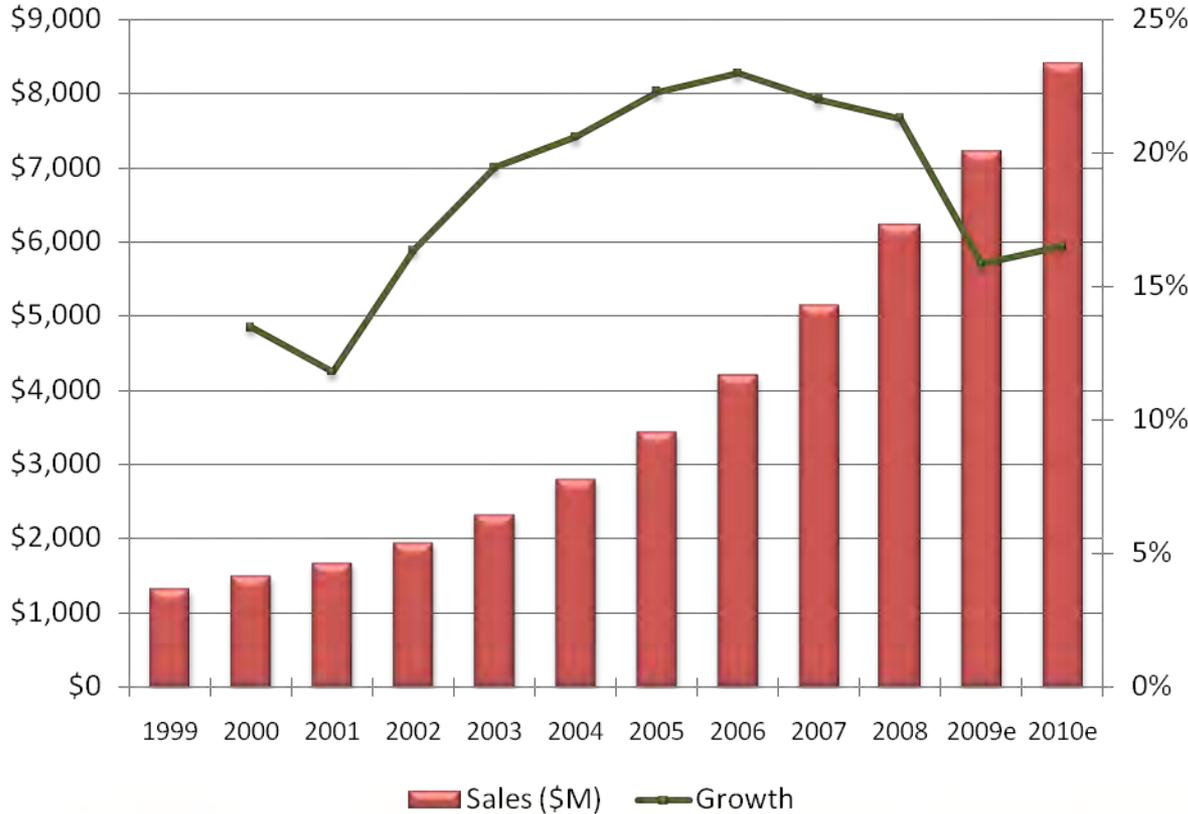
(U.S. Consumer Sales, \$ million)

Is Latin America Really Attractive?

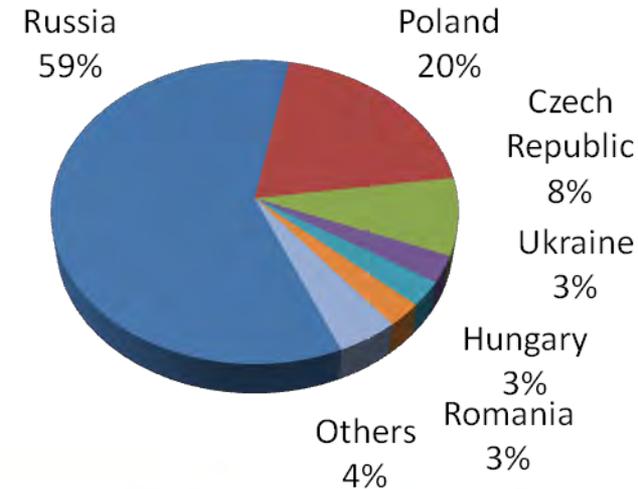


(U.S. Consumer Sales, \$ million)

Can Foreign Firms Make it in EE?

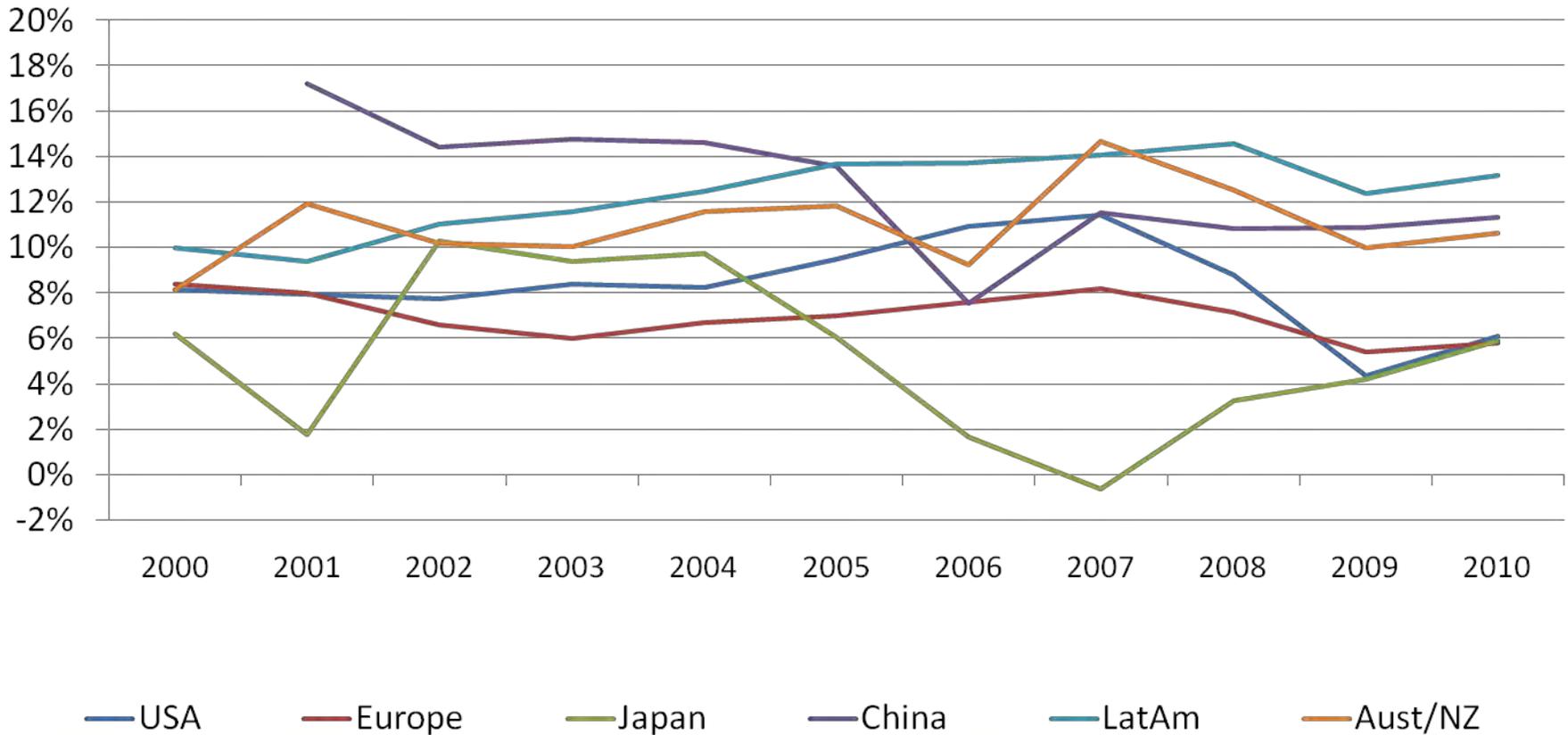


2009 Supplements



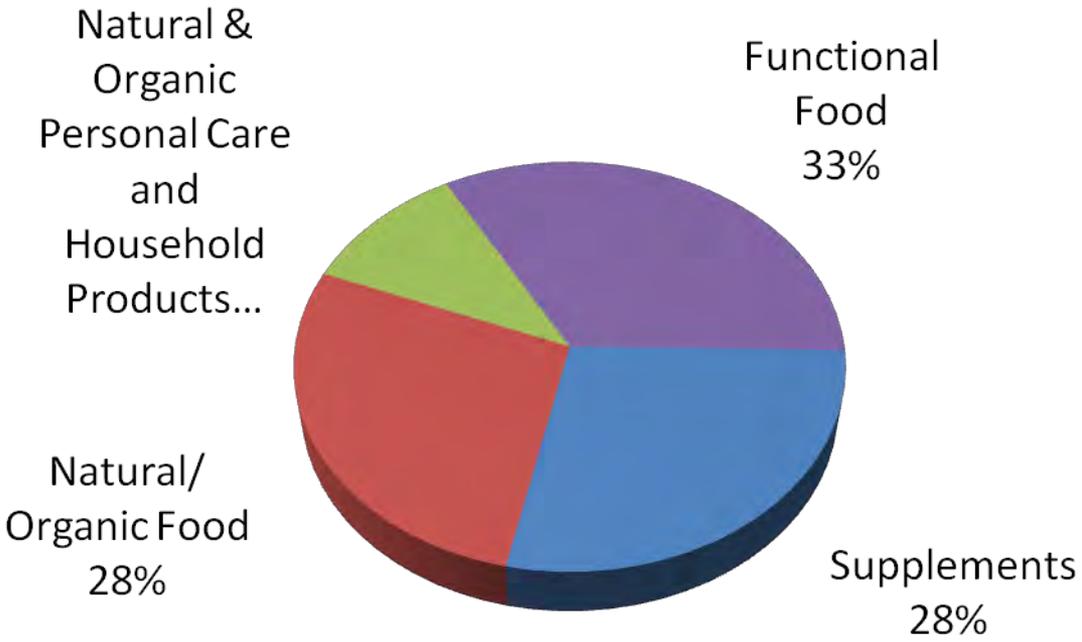
(U.S. Consumer Sales, \$ million)

Global Nutrition Growth Comparison



(U.S. Consumer Sales, \$ million)

Global Nutrition by Category



Economics

Global recession shifts trade balances
Trading issues: A business friendly environment?
The power of emerging (emerged) economies
Access to capital



March 2011... Japan: The world's third-largest economy faced one of its worst natural disasters ever. The damage caused by the earthquake and tsunami are estimated at around \$300 billion.

A recovery in the Euro-zone and the U.S. could help improve trade prospects for Asian economies in the coming months.

Will Europe really work?

Will global growth continue?
Two economies (45% and 5% since 2005)



Culture

Alliances and trading blocks
East versus west...or not
Knowledge on the ground is key
What categories are hot based on culture?
Is there ongoing anti-China momentum?
Entrepreneurial power?



Supply and quality issues

Export of regulation (EU, ASEAN, US)

Changing of regulations

Safety concerns - legislation

Changes at FDA

Agencies asked to do more with less

Adulteration

Supply chain management

Third party certification

Vendor qualification

Analytical testing and C of A's

US: NDI: ODI

Is the GRAS greener?



GMP and related issues

More and more....

Your firm failed to conduct at least one appropriate test or examination to verify the identity of a dietary ingredient, prior to its use, as required by 21 CFR 111.75(a)(1)(i).

Specifically, your firm uses Thiamine HCl, Riboflavin Phosphate, Pyridoxine HCl, Cyanocobalamin, Ascorbic Acid, Folic Acid, Niacinamide, D-Biotin, and Calcium D-Pantothenate dietary ingredients in your xxx Liquid Dietary Supplement product, but you firm do not perform an identity test or examination on any of these dietary ingredients used in this dietary supplement.



Distribution and Channels

Knowledge on the ground
Know your channel options
Geographical differences
Evolving markets and relationships



Certification and Standards

3rd party quality
Natural
Organic
Kosher
Halal
Regional decisions



Region Specific Issues

General regional issues

ASEAN

Emerging Asia

Japan

North America

EU

Eastern Europe

Latin America

BRIC



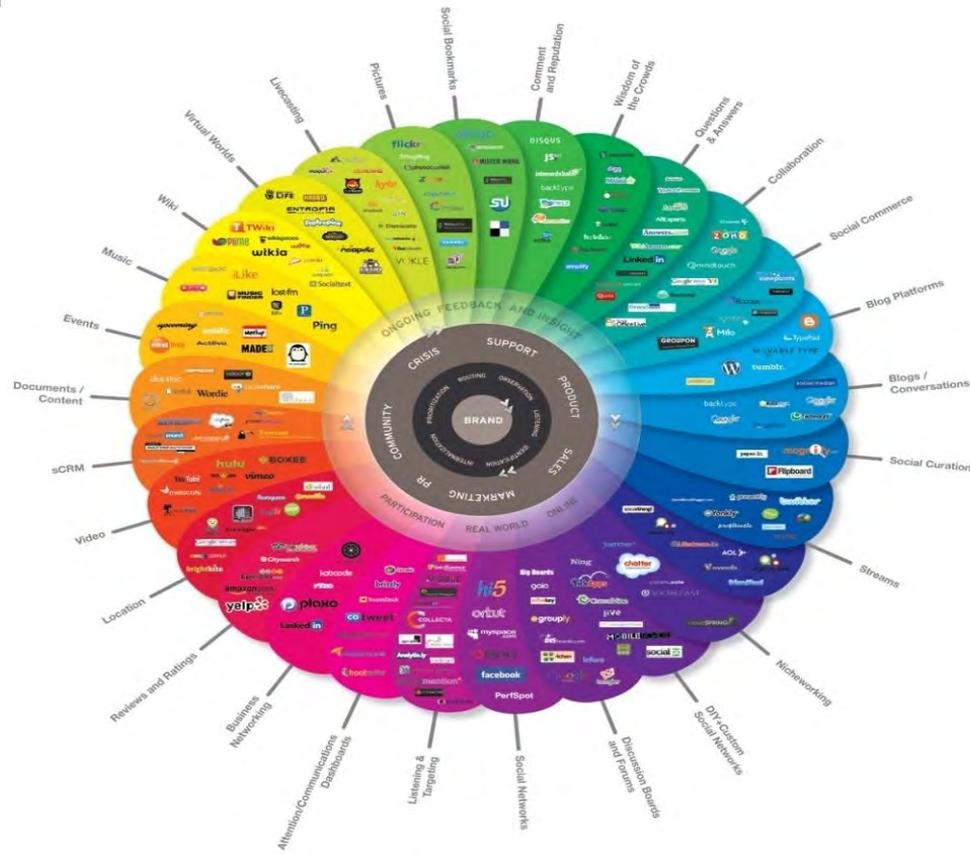
Marketing and other forces

Social media
Branding and the natural consumer
Sustainability and social consciousness
carbon footprint, travel miles etc.
Future of Wellness
Leveraging aura



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The Social environment (movement)

- Infancy / perpetual 'Beta'
- Fragmentation
- Poorly integrated strategies from industry or scientific community outside of government and select examples
- Entrepreneurs ahead of pragmatists
- How do you measure?



Other Business Considerations

Defining ready
Regulations
Intellectual property
The state and applicability of research
 Product specific research
 Population specific research
 Can you even communicate it?
Demographics
Market and marketing trends



Putting it all together

Do your homework
Be bold and fast
Get 'legs' on the ground quickly
Construct the unique value proposition
There is always an opportunity
...and it will change....





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