



國立臺灣大學 National Taiwan University

Institute of Food Science and Technology  
National Taiwan University

# Key Trends in Functional Foods

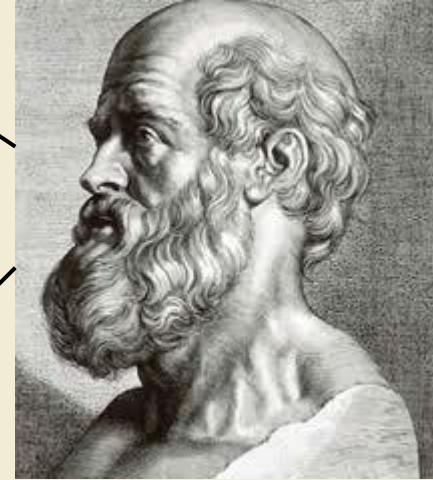
**Speaker: Lee-Yan Sheen, Ph.D., R.D.**

**Assistant: Kuan-Hung Lu, Ph.D.**



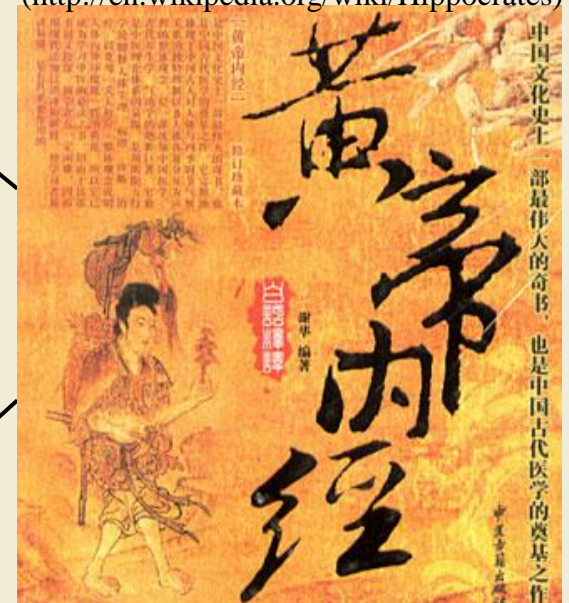
# Can food be dietary remedies?

**Let your food be your medicine,  
and let your medicine be your  
food - Hippocrates (The father of  
western medicine, 570~460 B.C.)**



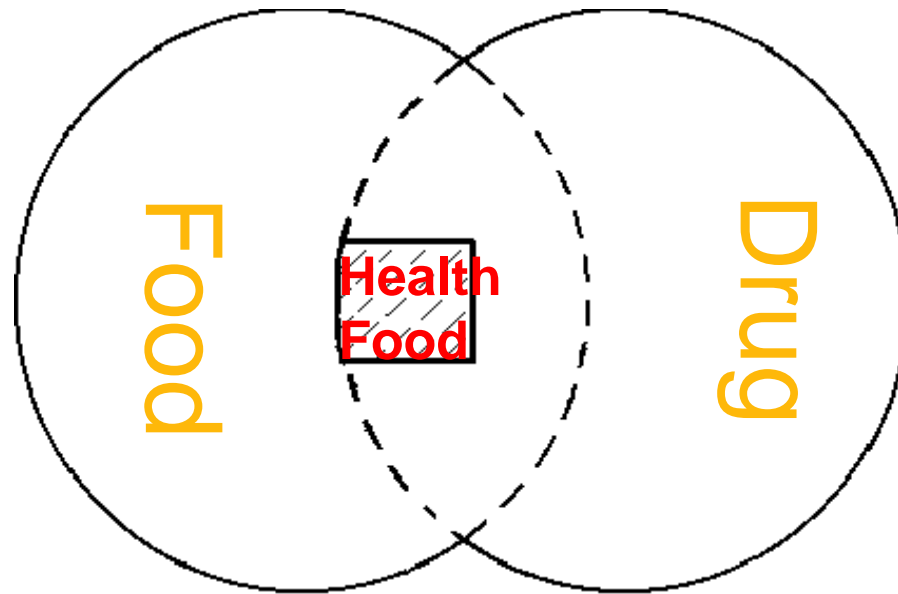
(<http://en.wikipedia.org/wiki/Hippocrates>)

**Emphasize the importance of  
dietary therapy concept for the  
preventive medicine - The  
Emperor's Inner Canon (黃帝內  
經 huáng dì nèi jīng; Medicine and  
Food are the same source, and this  
ideal was raised in 1000 B.C.)**



([http://big5.xinhuanet.com/gate/big5/news.xinhuanet.com/food/200506/06/content\\_3049770.htm](http://big5.xinhuanet.com/gate/big5/news.xinhuanet.com/food/200506/06/content_3049770.htm))

# What's Health Food from regulatory point of view?

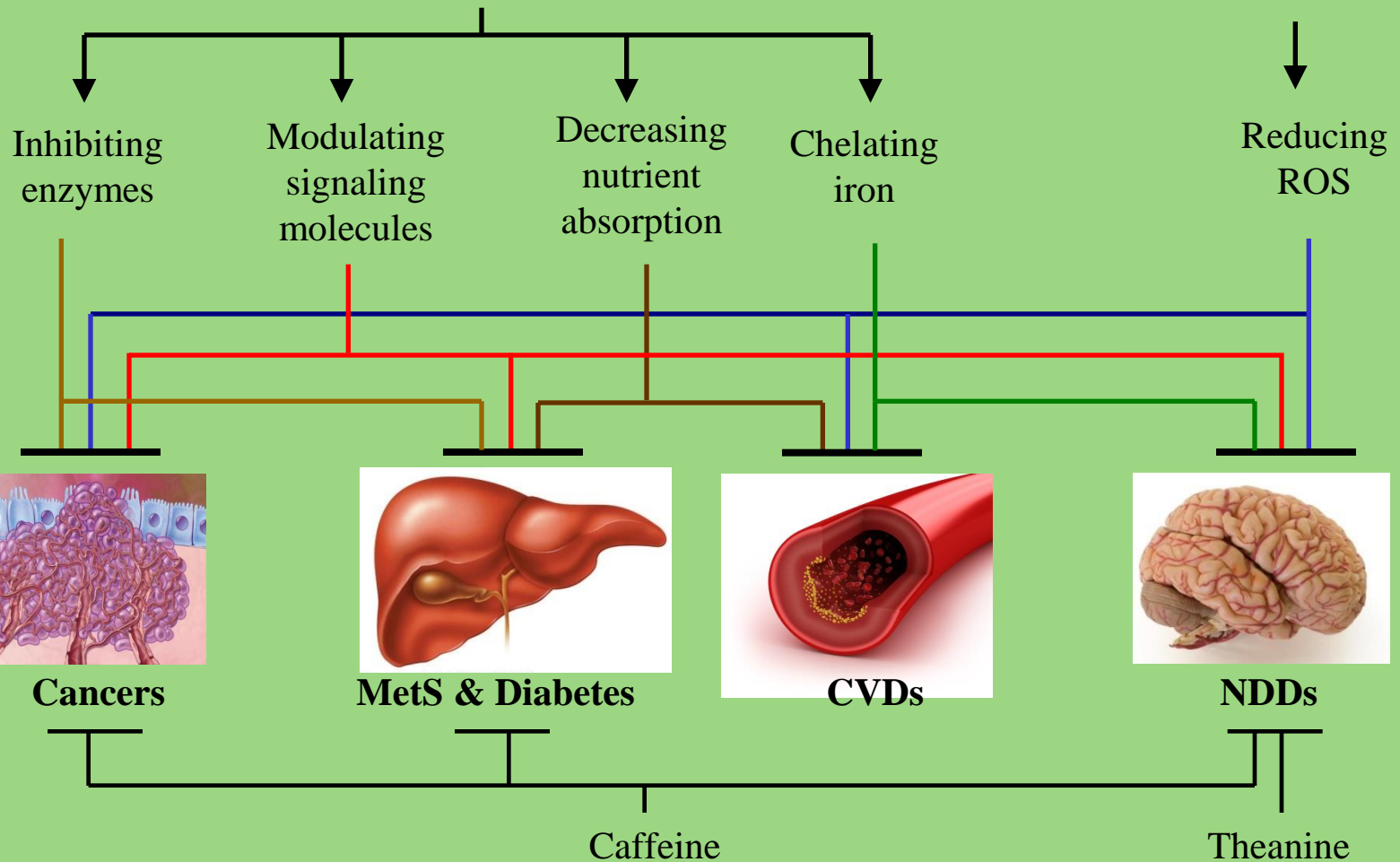




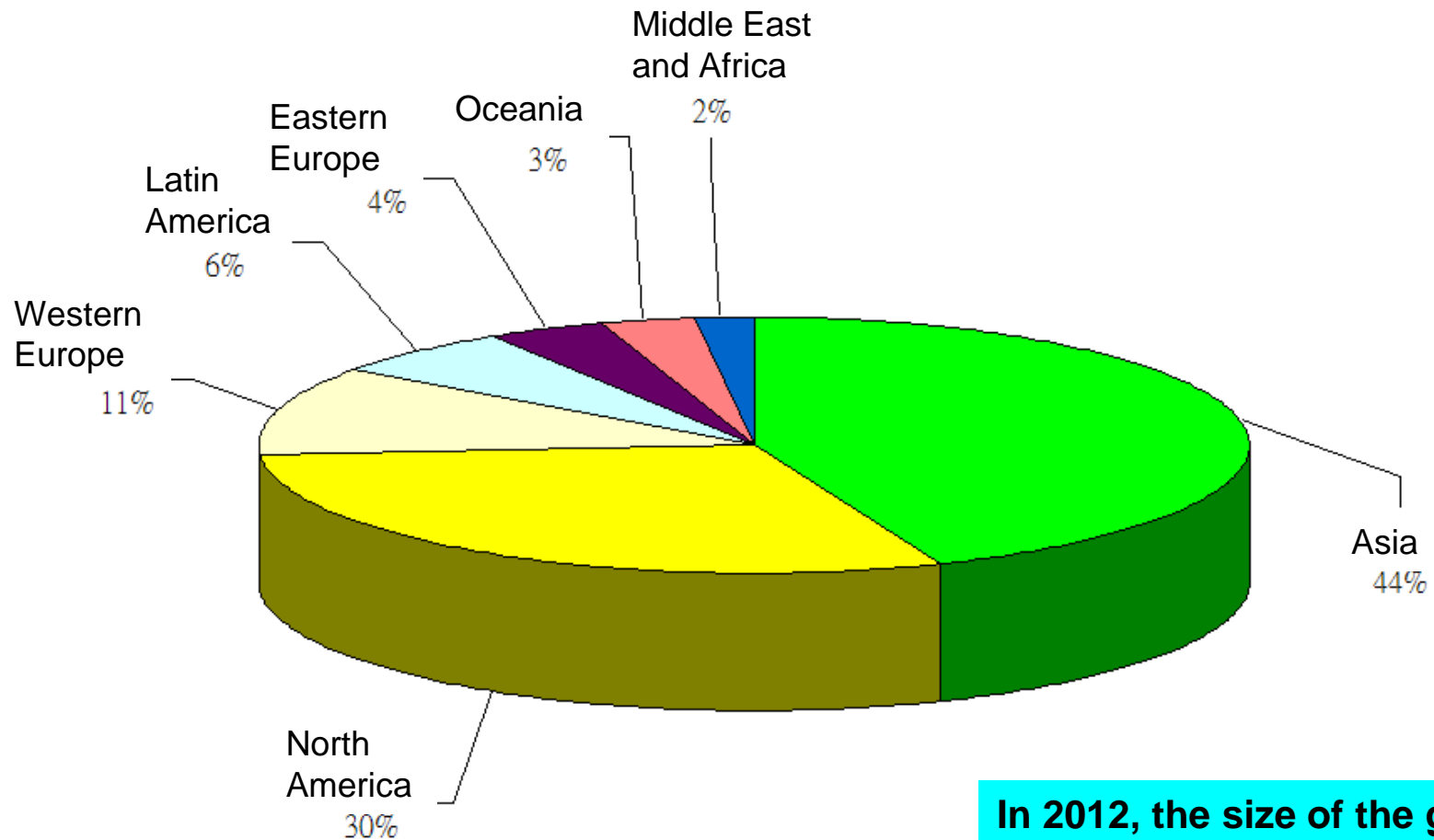
# Tea polyphenols

Binding to molecules

Antioxidant activity

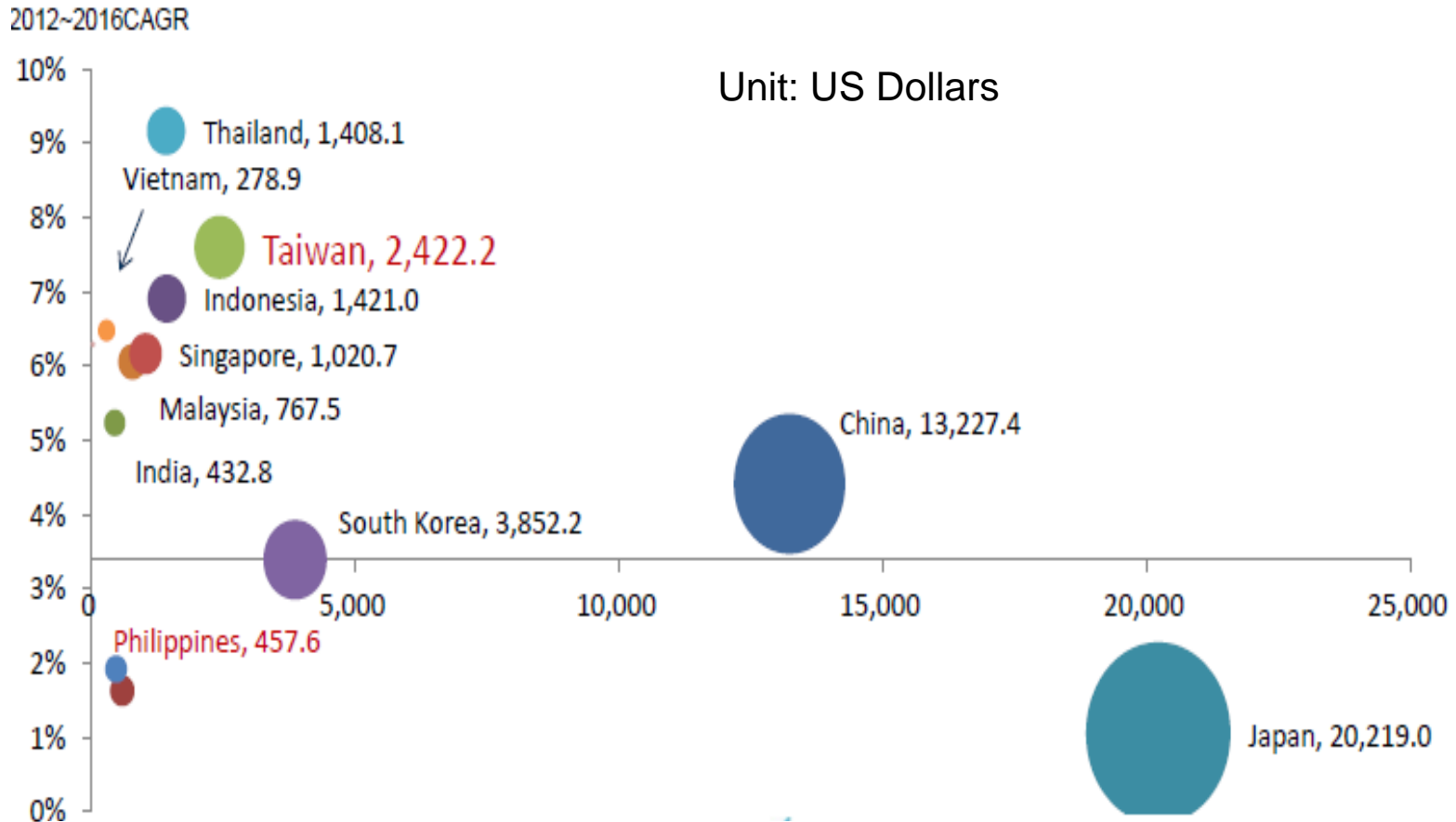


# 2012 Global Functional Food Market Distribution



**In 2012, the size of the global functional food market reached US\$109.8 billion**

# 2012 Health Food Market Distribution in Asia



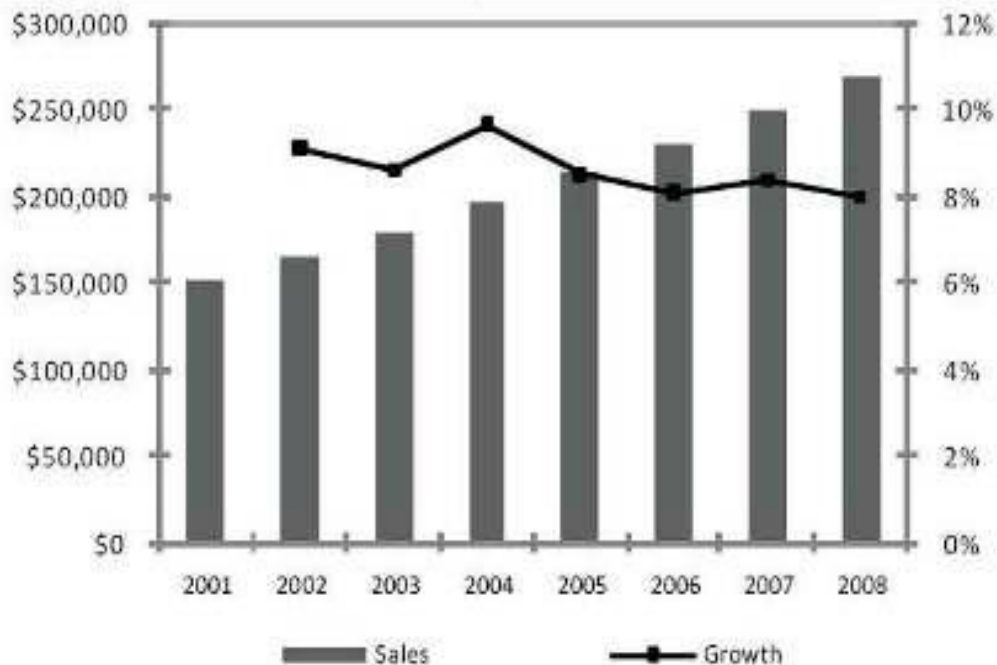
Mainland China accounted for about 28.6% of the 2012 market size, behind Japan at 43.7%. In emerging countries such as Indonesia and Vietnam, economic growth and health conscious constitute a fast-growing market. Due to the fact that the market is not yet mature and per capita expenditure in developing countries on all using basic nutritional supplement products (vitamins, dietary supplements, etc.) is limited (5-20 US\$ per capita per year range), the expenditure is 5-10 times lower compared with developed countries.





# Global Nutrition-Dietary Supplement Market

Global Nutrition Industry Sales & Growth: 2001-2008



Source: Nutrition Business Journal estimates (\$mil, consumer sales). Derived from a variety of sources, including NBJ company interviews and surveys, Euromonitor, United States Commercial Service, IADSA member associations, Organic Monitor, Mintel, Data Monitor, James W. Dudley and many others.

2008

USD270  
billion

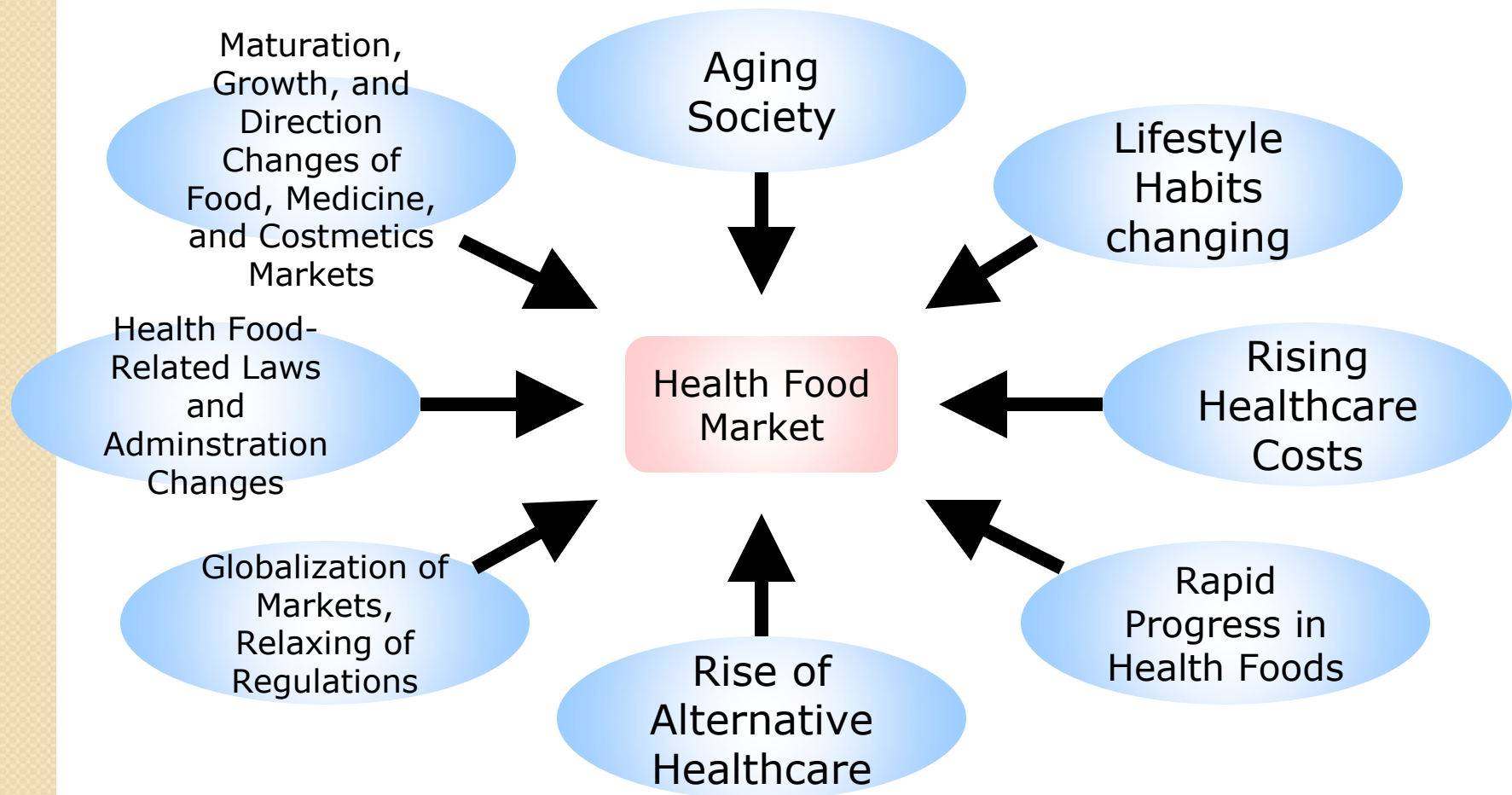
Growth:  
8%

2009

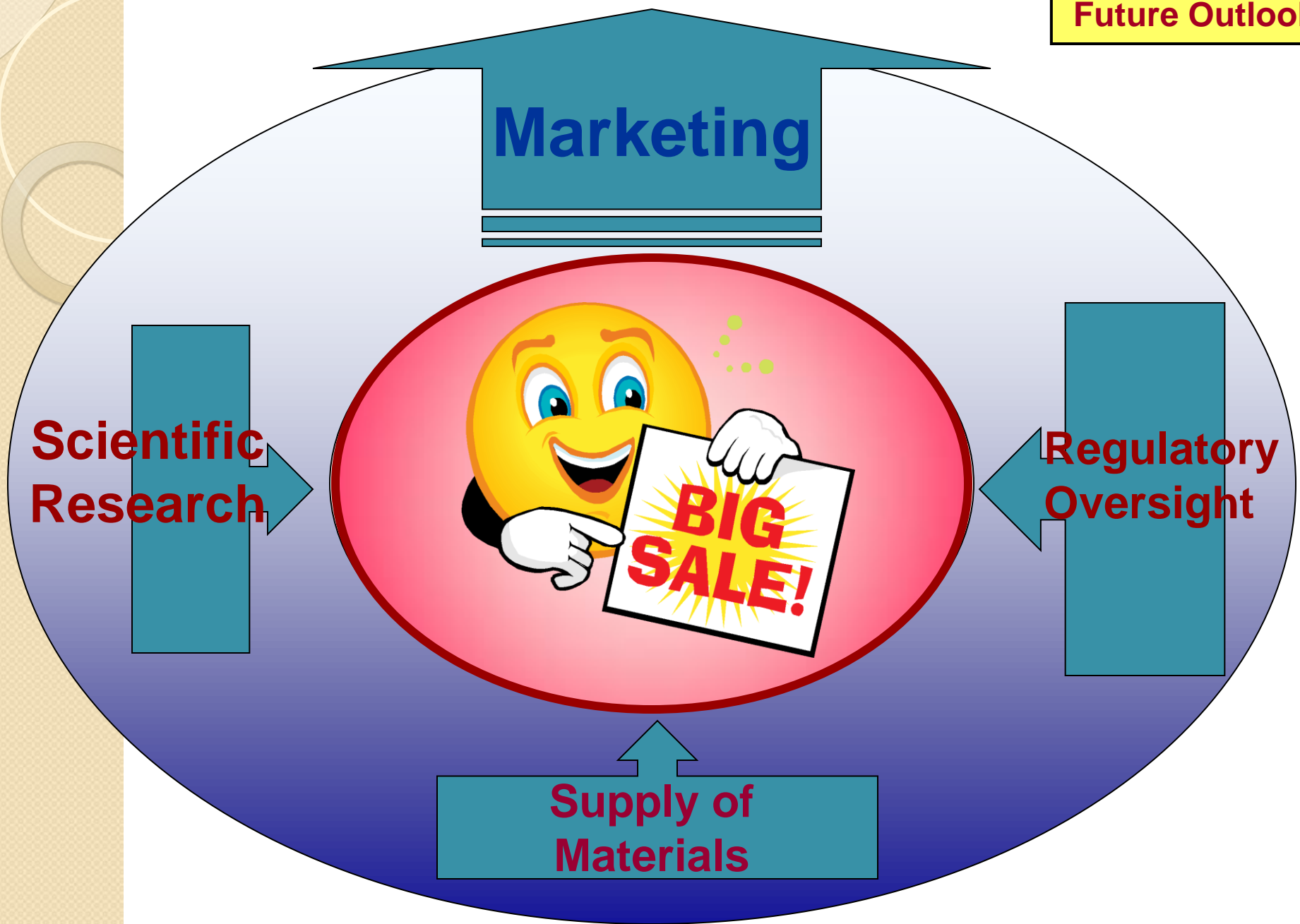
Growth:  
6-10 %

New Nutrition Business  
Journal, Dec 2009

# Drivers and Growth Incentives in the Health Food Market







# Certified Health Foods - Japan

- 1991: The world's first system for individual review and licensing of health foods is established**
- 1995: First license issued**
- December 2007: 755 licensed items on the market**
- Market size as of 2007: 6,798,000,000 ¥**
- May 2015: around 1100 licensed items on the market**

(Japanese Ministry of Health, Japan Health and Nutrition Association)



# Dietary Supplements-FDA's role

## Before

Dietary Supplement = Food

1994

**After DSHEA: dietary supplement health and education act**

This new law, which amended the Federal Food, Drug, and Cosmetic Act, created a new regulatory framework for the safety and labeling of dietary supplements.



# Dietary Supplements-FDA's role

- **Under DSHEA:** a firm is responsible for determining that the dietary supplements' **manufactures** or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that **they are not false or misleading.**
- This means that **dietary supplements do not need approval from US FDA before they are marketed.**
- Except in the case of a new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products.

(U.S. Food and Drug Administration)





# Dietary supplement- Sample Label

## Supplement Facts

Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children Under 4 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	†	< 1%*
Sugars	1 g	†	†
Vitamin A (50% as beta-carotene)	2500 IU	100%	50%
Vitamin C	40 mg	100%	67%
Vitamin D	400 IU	100%	100%
Vitamin E	15 IU	150%	50%
Thiamin	1.1 mg	157%	73%
Riboflavin	1.2 mg	150%	71%
Niacin	14 mg	156%	70%
Vitamin B <sub>6</sub>	1.1 mg	157%	55%
Folate	300 mcg	150%	75%
Vitamin B <sub>12</sub>	5 mcg	167%	83%

\* Percent Daily Values are based on a 2,000 calorie diet.

† Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, stearic acid, gelatin, maltodextrins, artificial flavors, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, beta-carotene, folic acid, cholecalciferol, and cyanocobalamin.

Dietary supplement  
containing multiple  
vitamins for children  
and adults

(U.S. Food and Drug Administration)

# China Health Food Act

## Health Food Management Approach

- Order 46, passed by the Ministry of Health on March 15, 1996
- Defined 'health foods'
- Defined the approval, production, management, labeling, and advertising processes for health foods
- Included specific provisions for health food supervision and management

## Health Food Registration Management

- Decree 19, passed by the Secretary of the China FDA on April 30, 2005, with implementation by July 1 of that year
- Included specific provisions for application and approval of health food products, raw and auxiliary materials, labels and instructions, testing and inspection, re-registration, review, and legal responsibilities.



# The Development of Healthy Functional Food Law in Korea

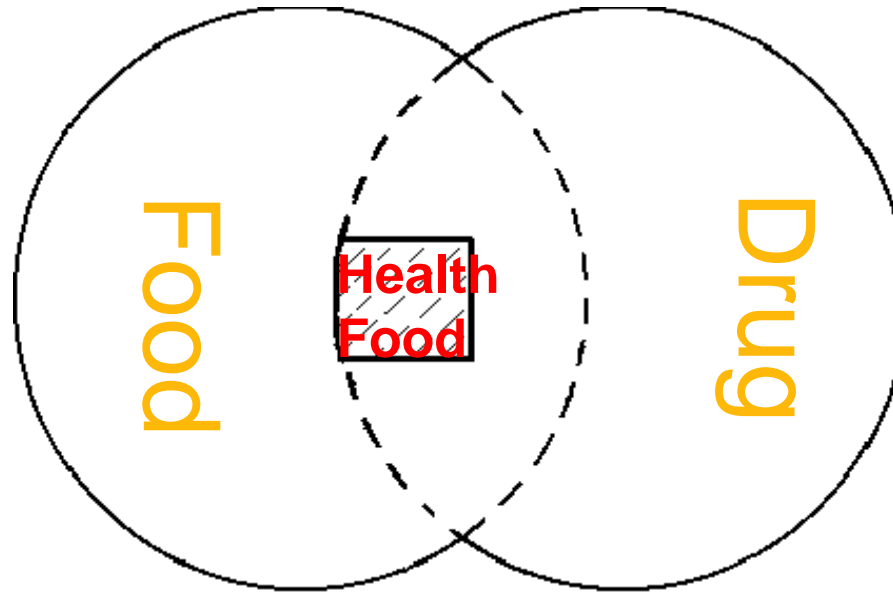
## Legislative Background

- ✱ Encourage consumer protection and provides correct information to consumers
- ✱ Promote the growth of high-value functional health food industry

## Legislation Passed

- ✱ 2000.11.29 Development and promotion of a national legal agenda for healthy functional foods
- ✱ 2002. 8. 26 Healthy Functional Food Law 6727 is announced
- ✱ 2003.12.18 Presidential decree announced
- ✱ 2004. 1. 31 Regulations applied
- ✱ 2004. 1. 31 Related announcements made

# Health Food Control Act in Taiwan



**Health Food Control Act was announced on Feb. 3, 1999 in Taiwan.**  
**The definition of Health Food: “scientifically proven to be capable of improving people’s health, and decreasing the risks of diseases, but not for medical treatment”**



# Legislative History

1. Promulgated on February 3, 1999.
2. Amended on December 22, 1999.
3. Amended and promulgated on November 8, 2000.
4. Amended and promulgated on January 30, 2002.
5. Amendments of Articles 2, 3, 14, 15, 24 and 28 promulgated on May 17, 2006.





# Health Food Control Act

- Chapter I General Provisions ( §1~5)
- Chapter II Health Food Permit ( §6~9)
- Chapter III Management of Safety and Sanitation of Health Food ( §10~12)
- Chapter IV Labeling and Advertisement of Health Food ( §13~15)
- Chapter V Inspection and Enforcement on Health Food ( §16~20)
- Chapter VI Penal Provisions ( §21~29)
- Chapter VII Supplementary Provisions ( §30~31)



**Amendments of Articles were promulgated on May 17, 2006.**

**Dual tracts for the application of Health Food were performed in Taiwan**

**Regular approval:  
Case by case**

**takes 180 days**



**Fast tract:  
Monograph standard**

**takes 60 days**



**Total: 325 items**





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# Health Claims for Health Food in Taiwan

## Regular approval: Case by case

**Total: 271 items**

1. Regulation of blood lipid (82)
2. Promotion of gastrointestinal functions (71)
3. Regulation of immune system (41)
4. Protection of the liver (33)
5. Regulation of blood sugar level (14)
6. Attenuation of body fat accumulation (12)
7. Reducing allergic reactions (12)
8. Alleviation of osteoporosis (9)
9. Relieving physical fatigue (8)
10. Maintenance of dental health (6)
11. Anti-aging (5)
12. Promotion of iron absorption (4)
13. Aiding blood pressure regulation (2)

## Fast tract: Monograph standard

**Total: 54 items**

1. Red yeast rice (35)



2. Fish oil (19)







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# Safety Assessment of Health Food





# Safety Assessment

Category 1	Category 2	Category 3	Category 4
Conventional food in commonly processed form	Conventional Food in uncommonly processed form	Unconventional food	Food with carcinogenic risks
Complete set of literature and information (Toxicity test is not required)	1. Genotoxicity test 2. 28-day feeding toxicity test	1. Genotoxicity test 2. 90-day feeding toxicity test 3. Teratogenicity test	1. Genotoxicity test 2. 90-day feeding toxicity test 3. Teratogenicity test 4. Carcinogenicity test 5. Reproduction test



# Classification: Category 1

No further toxicity test is required if one of the following two conditions is met –

1. The raw materials of the product are conventional foodstuff and are usually consumed as processed food.
2. There is a complete academic literature report on the toxicity safety of the product and a record of human consumption; the raw materials, composition of ingredients and manufacturing procedure of the product are completely in line with the findings stated in the academic literature report submitted.





*L. casei Shiota strain*  
*L. casei Shiota* 乳酸杆菌



# Yogurt







## Classification: Category 2

If the raw materials of the product are conventional foodstuff but are consumed in uncommonly processed form, information on the following toxicity tests should be provided for assessment.

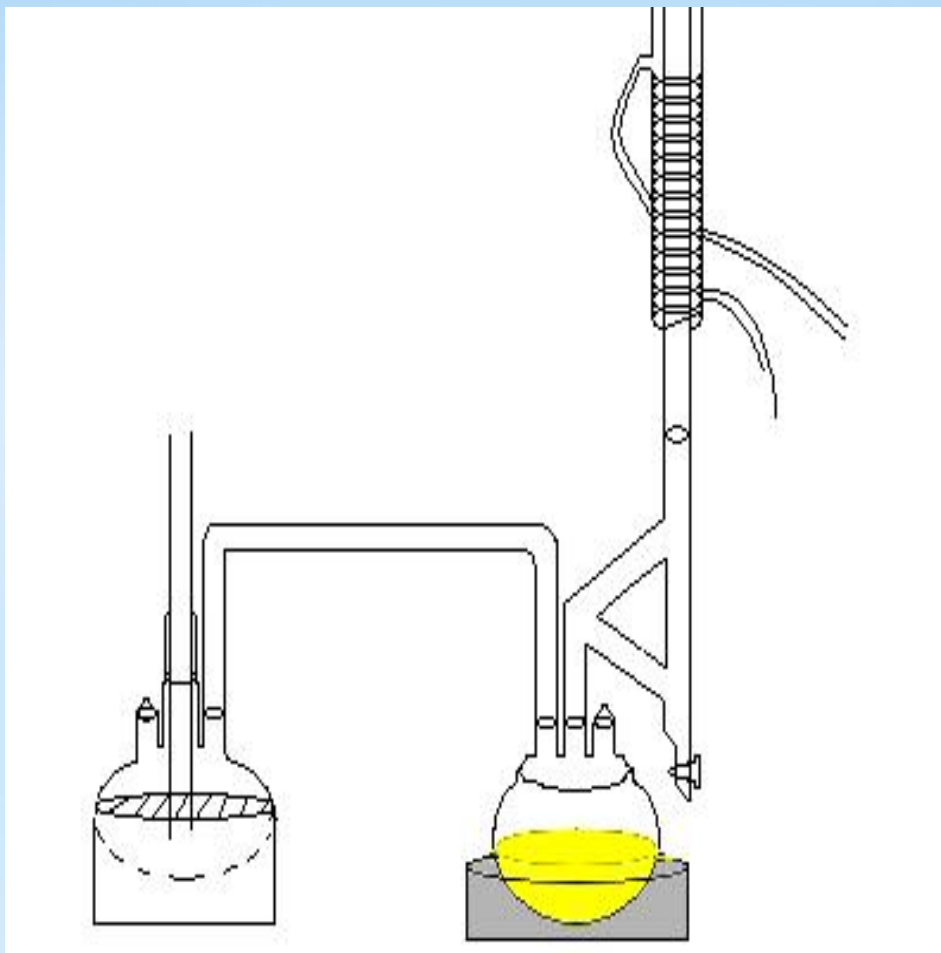
1. Genotoxicity test
2. 28-day feeding toxicity test







# Steam Distillation





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# Garlic Essential Oil







## Classification: Category 3

If the raw materials of the product are not conventional foodstuff, information on the following toxicity tests should be provided for assessment.

1. Genotoxicity test
2. 90-day feeding toxicity test
3. Teratogenicity test



## ***Antrodia cinnamomea* (AC)**

- It is well-known in Taiwan as a traditional Chinese medicine.
- It is rare and expensive because it grows only on the inner heartwood wall of the endemic evergreen *Cinnamomum kanehirai* and can not be cultivated.



photo by Dr. Chee-Jen Chen



牛樟樹(左)與台灣槲芝(上)





# 5L fermentor







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# Product of *Antrodia cinnamomea*





# Classification: Category 4

If the raw materials of the product are not conventional foodstuff and contain carcinogenic or similar substances, information on the following toxicity tests should be provided for assessment.

1. Genotoxicity test
2. 90-day feeding toxicity test
3. Teratogenicity test
4. Carcinogenicity test
5. Reproduction test



# The 6<sup>th</sup> International Conference on Nutrition and Physical Activity 2015

October **21** to **24**, 2015

GIS NTU Convention Center

 **Call for abstract**

## Important Dates

### Abstract submission

Online abstract submission closes May 30, 2015  
Notification of abstract acceptance June 30, 2015

### Registration

Registration opens April 1, 2015  
Early bird deadline July 31, 2015  
Pre-registration closes September 15, 2015

## Topics

### Area 1: Nutrition

Nutrition and Obesity  
Nutrition and Cancer  
Nutrition and Aging  
Nutrition and Mental Health  
Preventive Medicine and Health Food

### Area 2: Physical Activity

Taichi and Health  
Aerobic Exercise and Healthcare  
Weight Training Exercise and Health  
Physical Performance and Nutrition

### Area 3: Mental Health

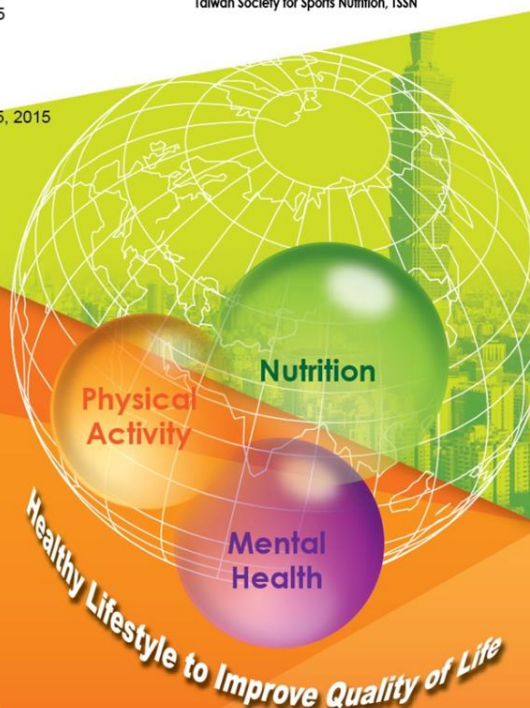
Mental Health and Diet  
Mental Health and Meditation  
Mental Health and Pressure  
Prevention of Mental Disorders  
Mental Status and Physical Performance



Conference Organizer:

Taiwan Association for Food Protection  
Affiliate of International Association for Food Protection

Taiwan Society for Sports Nutrition, TSSN



[www.napa2015.org.tw](http://www.napa2015.org.tw)







## 2<sup>nd</sup> International Conference of Traditional and Complementary Medicine on Health 2015

October **24** to **27**, 2015

GIS NTU Convention Center

 **Call for abstract**

### Important Dates

#### Abstract submission

Online abstract submission closes May 30, 2015  
Notification of abstract acceptance June 30, 2015

#### Registration

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Conference Organizer:

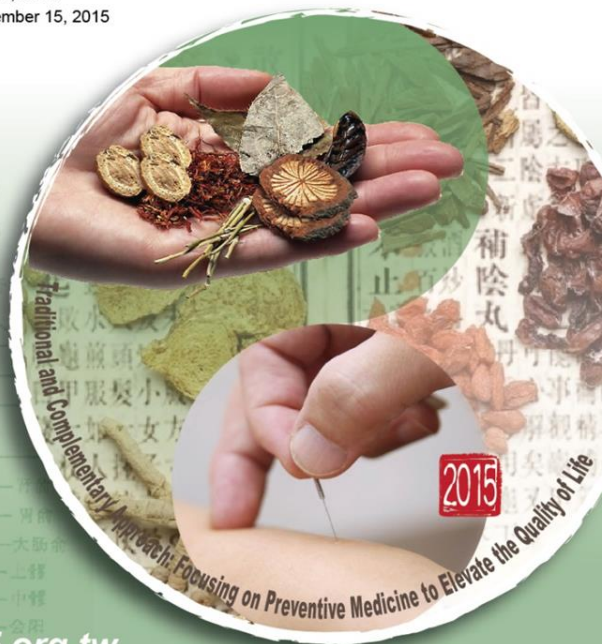
Journal of Traditional and Complementary Medicine



Taiwan Association for Traditional and Complementary Medicine

### Topics

1. Traditional medicine
2. Herbal medicine
3. Folk medicine
4. Preventive medicine
5. Dietary therapy
6. Mind-body therapies
7. Other traditional and complementary therapies



[www.ictcmh2015.org.tw](http://www.ictcmh2015.org.tw)





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# Thanks for your attention!



# 生活習慣疾病成為主要死因

生活習慣疾病(life-style disease)

解決之道

飲食 + 運動 + 休息

指因飲食、運動、休息、飲酒、抽菸等長期不當活動累積所造成的疾病。

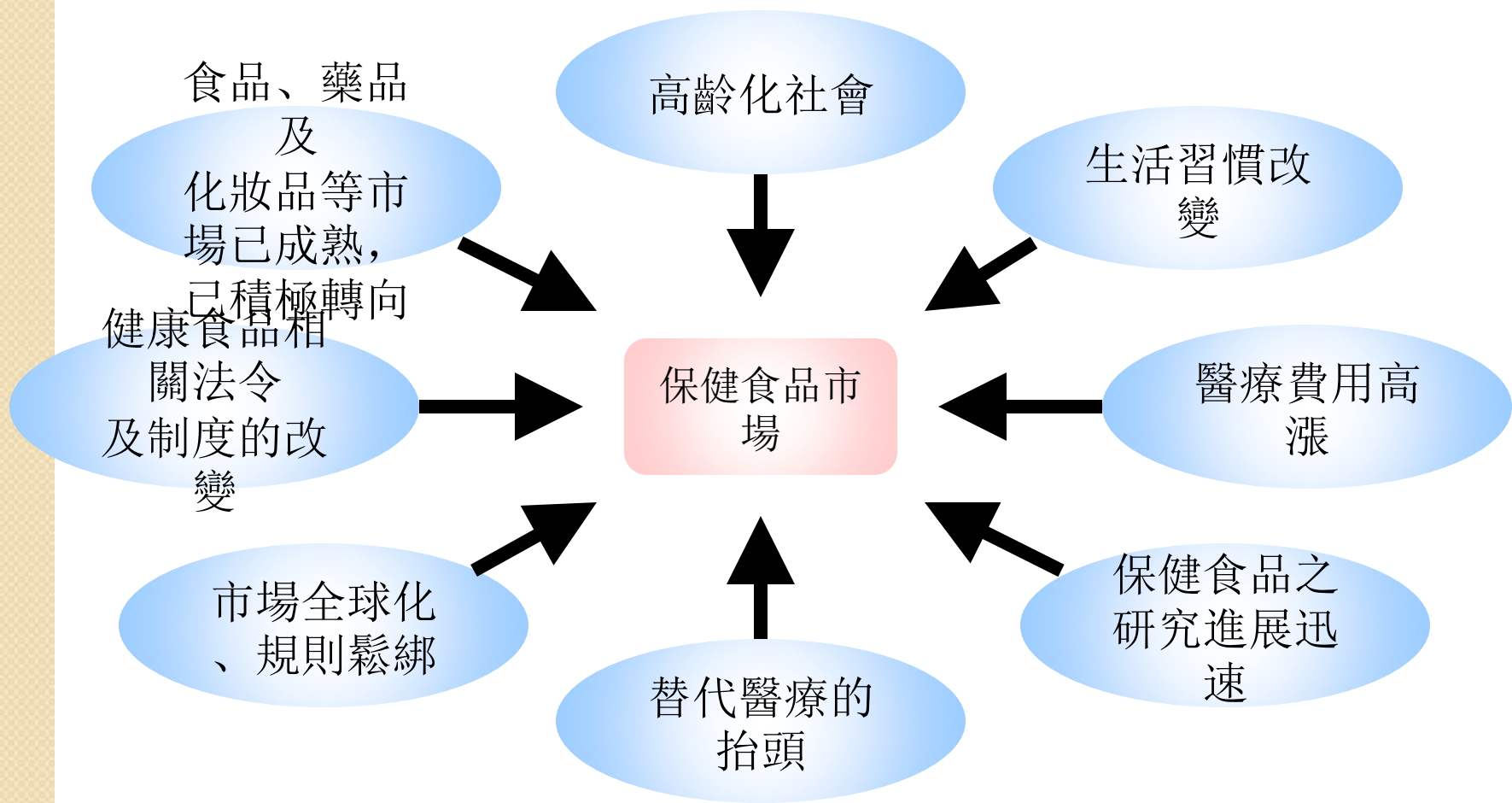
常見的此疾病有：癌症、肥胖、心臟病、腦血管疾病(中風)、高血壓性疾病、腎臟病、糖尿病、高血脂、胃及十二指腸病、肝病(酒精性)、牙週病、蛀牙、骨質疏鬆、貧血(缺鐵)等。

## 我國十大死亡排名(2012年)

- |         |                 |
|---------|-----------------|
| 1.惡性腫瘤  | 6.意外事故          |
| 2.心臟疾病  | 7.慢性下呼吸道疾病      |
| 3.腦血管疾病 | 8.高血壓           |
| 4.肺炎    | 9.慢性肝病及肝硬化      |
| 5.糖尿病   | 10.腎炎、腎徵候群及腎性病變 |

(行政院衛福部, 2013)

# 驅動保健食品市場成長誘因



# 全民健保藥費支出逐年增加

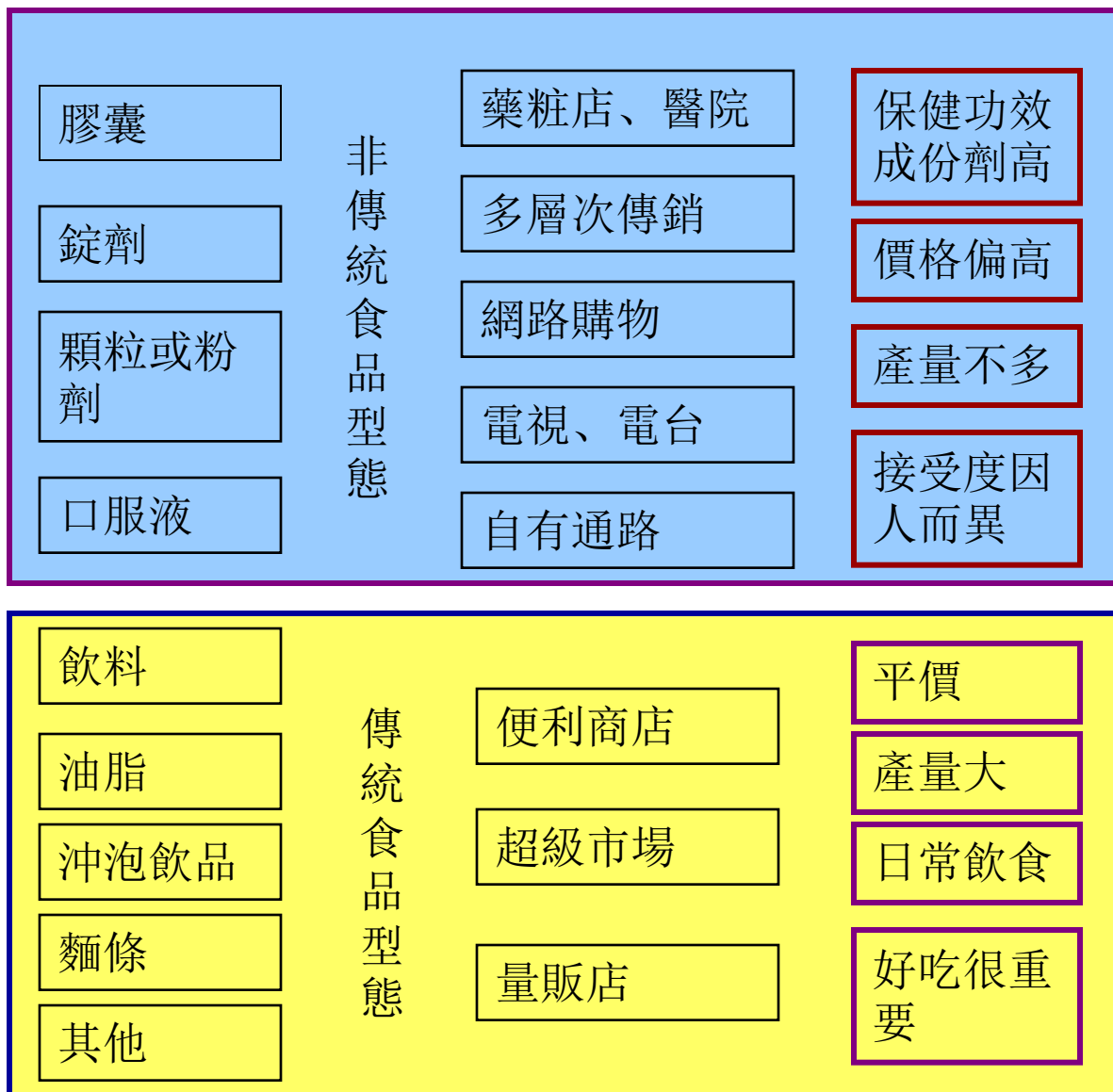
年度	藥費（億元）	成長率
96	1156.2	2.29%
97	1235.6	6.87%
98	1301.1	5.30%
99	1313.3	0.94%
100年第一季	350.8	13.65%
100年第二季	352.2	8.57%

- 100 年健保局醫療支出總計**4715億**元  
(其中包括門診費用3221億元及住院費用1494億元)



# 保健食品特性與通路

保健食品素材或原料



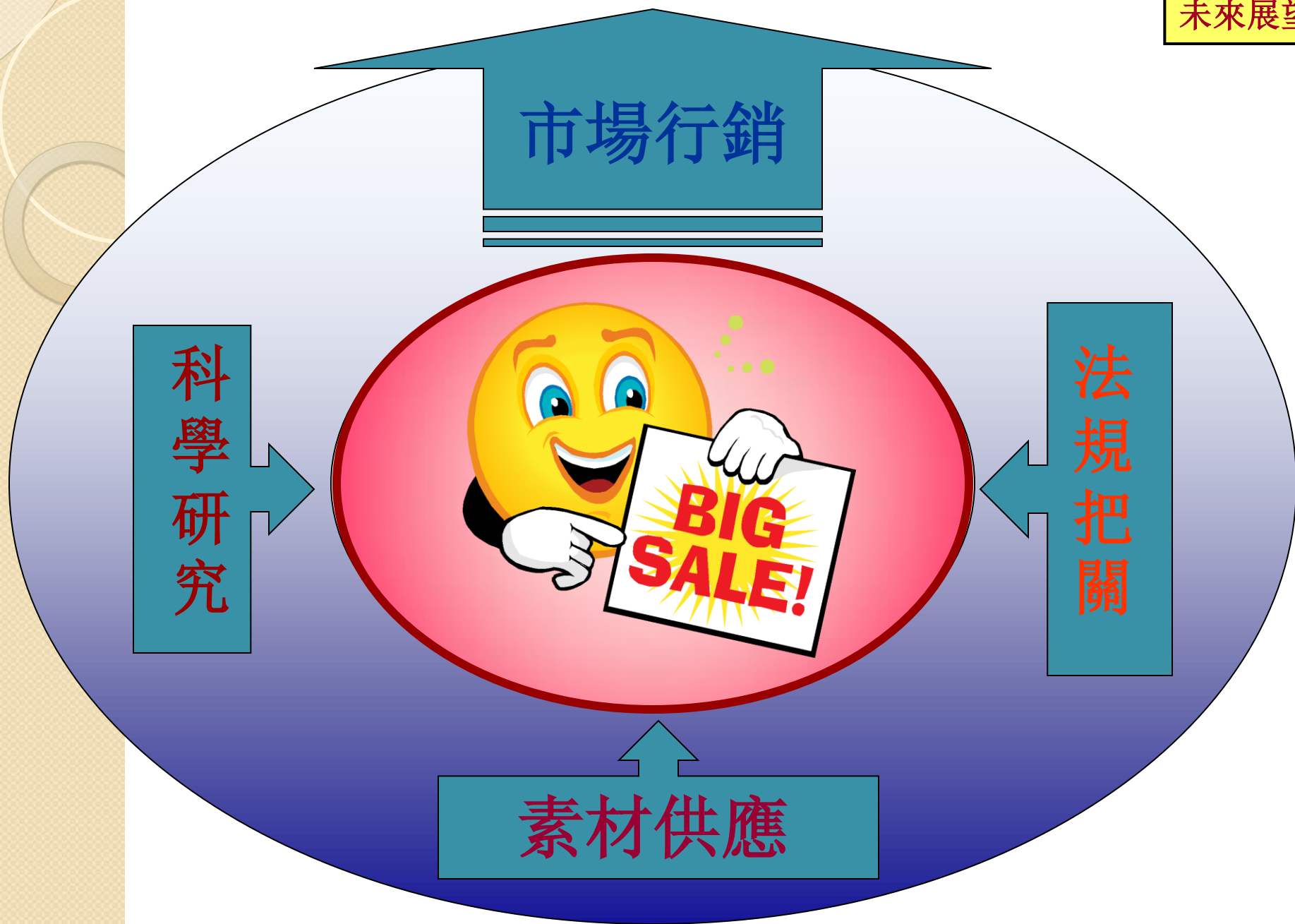
功效明確

安全

價值與價格相符

方便

好吃

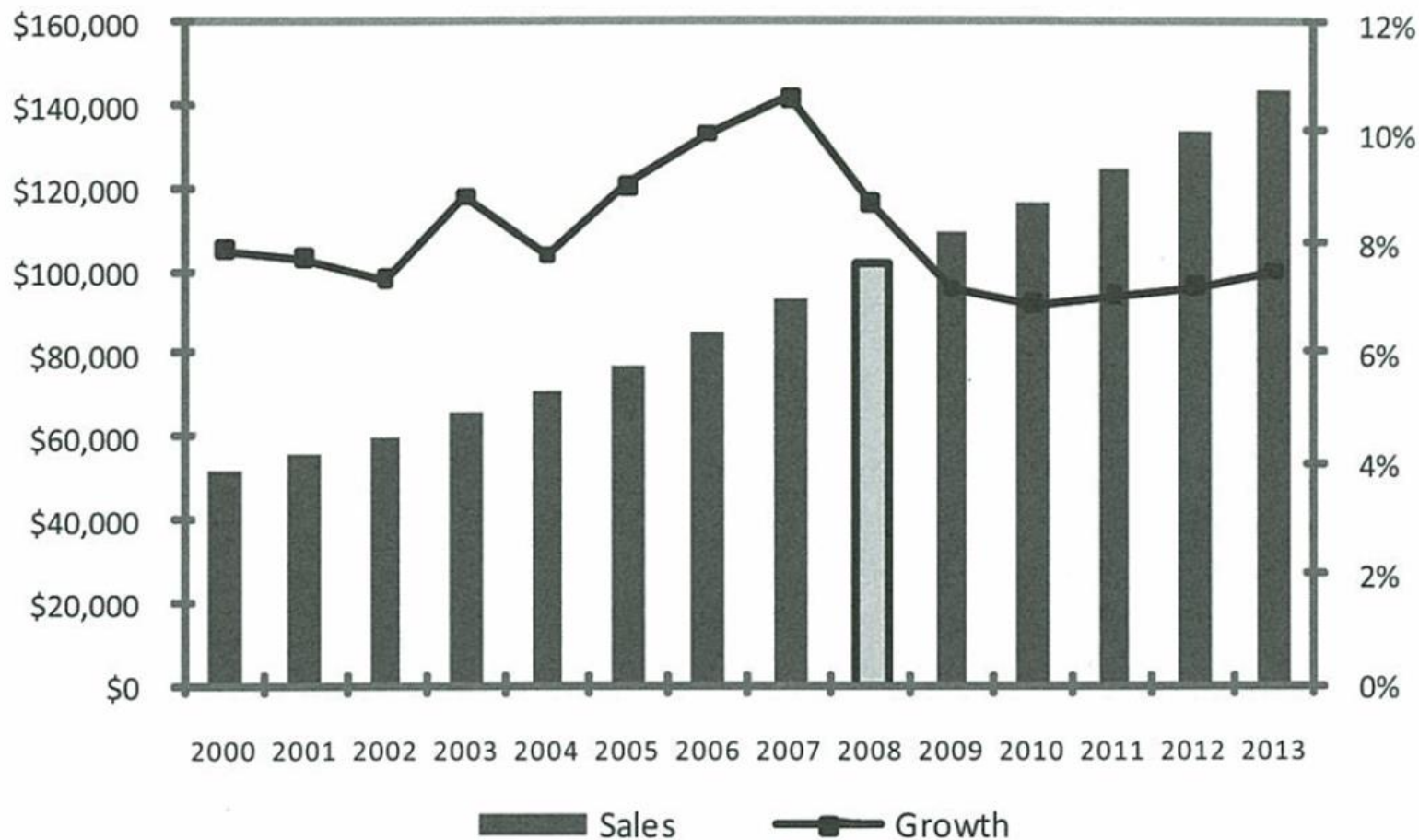


# Per Capita Consumption of functional Food by Asian Country

Country	Population	Market Size (Millions of U.S. Dollars)	Per Capita Income (U.S. Dollars)
Singapore	5,460,302	1020.7	186.9
Japan	127,253,075	20219	158.9
Taiwan	23,299,716	2422.2	104.0
South Korea	48,955,203	3852.2	78.7
Malaysia	29,628,392	767.5	25.9
Thailand	67,448,120	1408.1	20.9
Mainland China	1,349,585,838	13227.4	9.8
Indonesia	251,160,124	1421	5.7
Philippines	105,720,644	457.6	4.3
Vietnam	92,477,857	278.9	3.0
India	1,220,800,359	432.8	0.4



## U.S. Nutrition Industry Sales & Growth: 2000-2013



Source: Nutrition Business Journal estimates (\$mil., consumer sales)

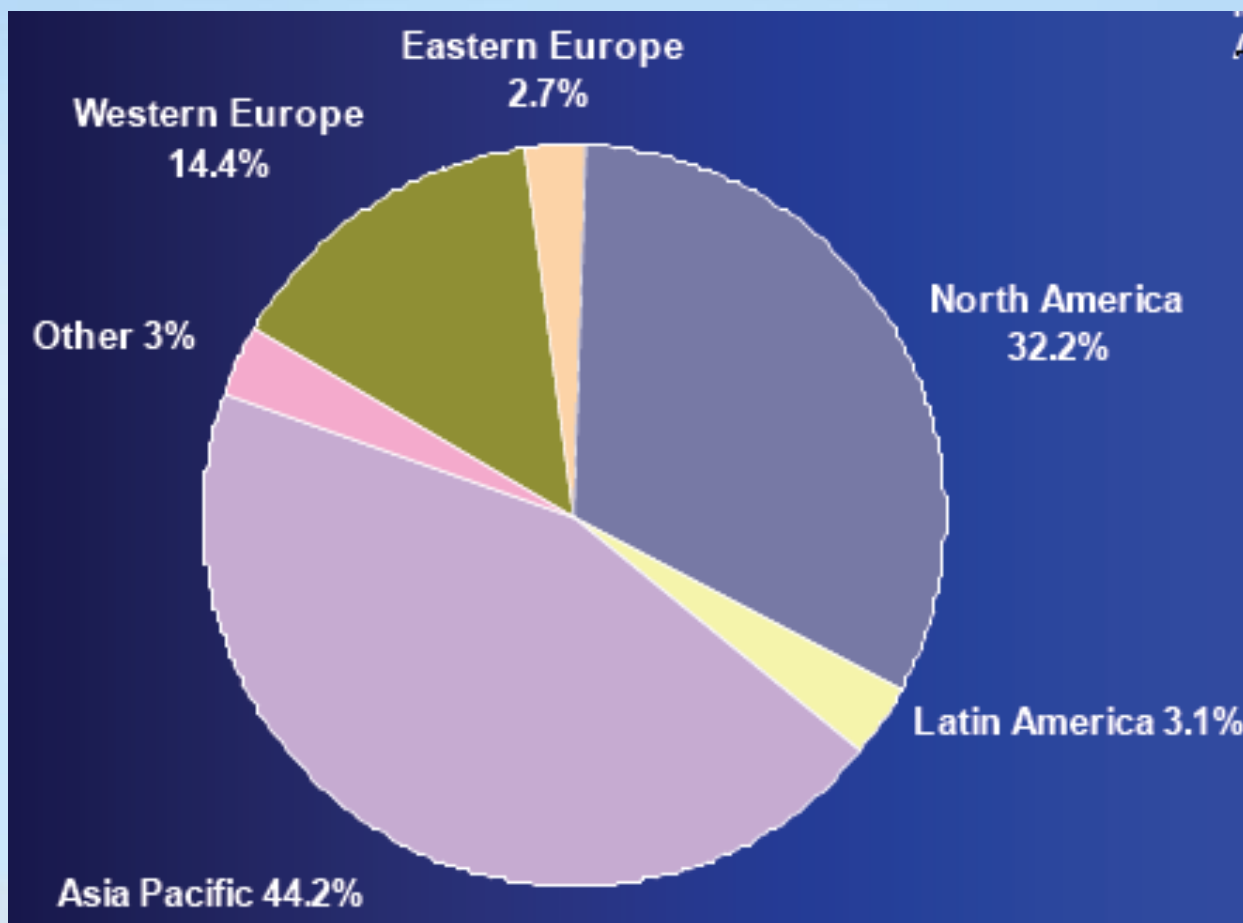
Source: **Supplements Stand Out As 2008 Sales Bright Spot for U.S. Nutrition Industry**

Recession motivates many consumers to buy more wellness products but watch spending on pricier natural, organic and functional offerings





# Overview market of dietary supplement



Data source; International Alliance of Dietary / Food Supplement Association, Annual meeting Apr. 2008, Euro Monitor Database 2008