

# Nutrigenomic Testing Promises vs. Reality!

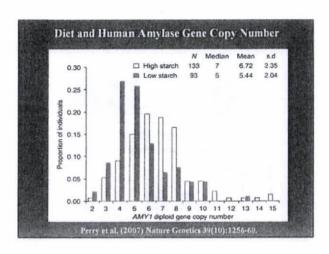
- · Commercial Nutrition-Gene Test
  - Sciona 19 genes determines whether your DNA contains gene variants that have been associated with 5 key health areas: bone health, heart health, antioxidant/detoxification, insulin sensitivity, and inflammation.
  - Cost about \$300.
- Genelex The panel examines 19 genes that play major roles in your body's detoxification capacity, antioxidant capacity, heart health, bone health, insulin sensitivity, and tissue repair.
  - -About \$500.

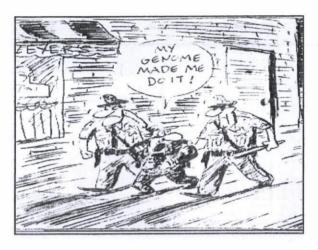
The overall contribution of Copy Number Variance (CNV) to complex phenotypes expression levels of 14,925 transcripts with SNPs and CNVs in individuals who are part of the International HapMap project was evaluated.

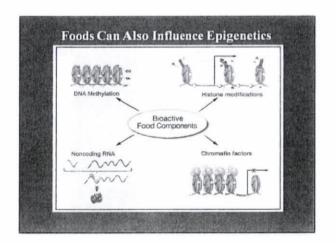
SNPs and CNVs captured 83.6% and 17.7% of the total detected genetic variation in gene expression, respectively.

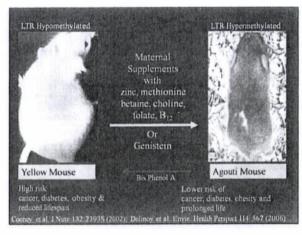
The signals from the two types of variation had little overlap

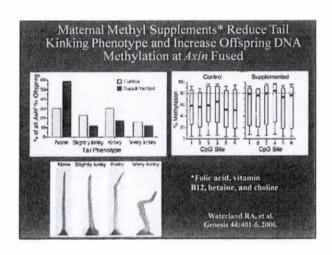
Stranger et al (2007) Science. 315(5813):848-53

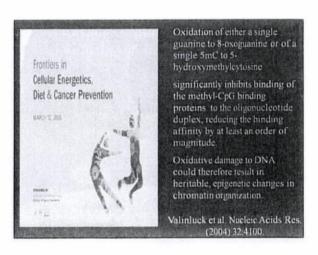


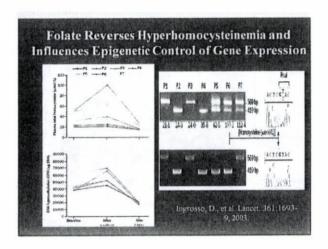


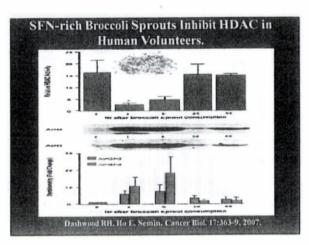


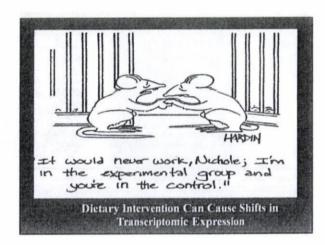


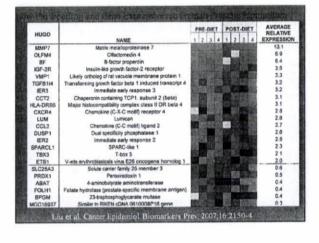


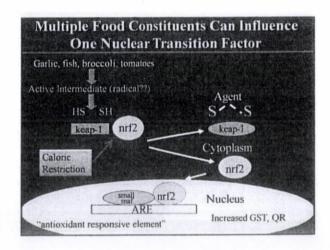


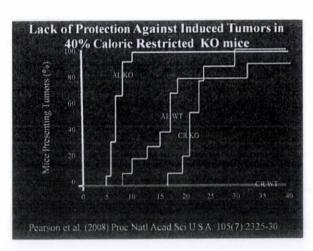


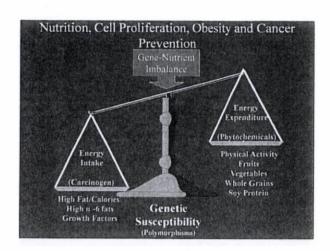


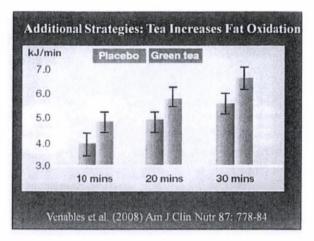


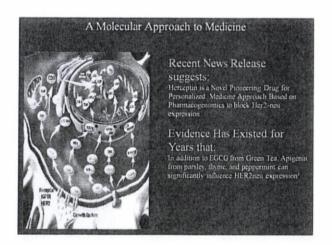


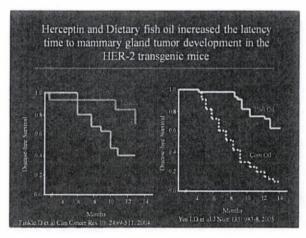


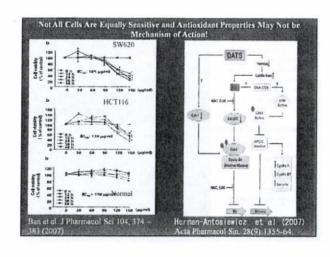


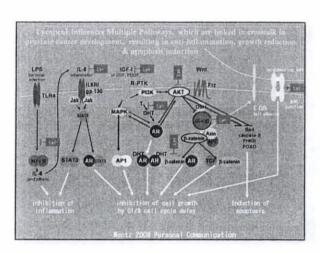


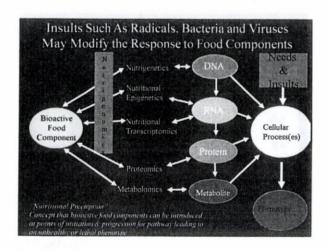


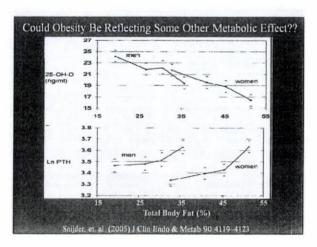


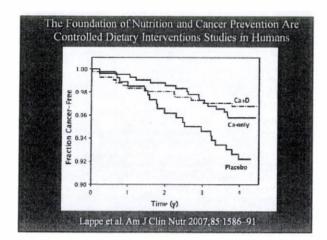


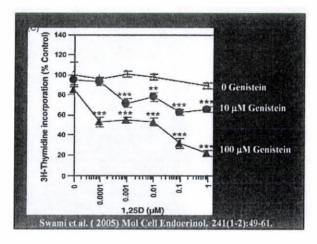


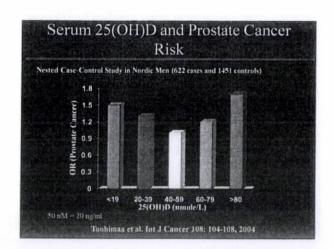


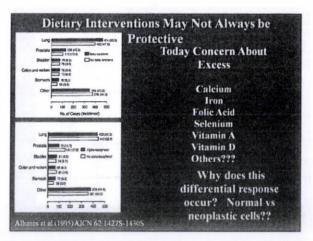


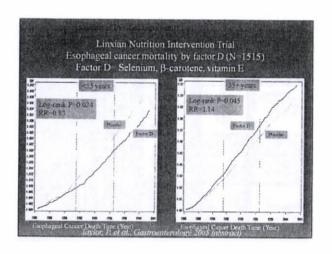


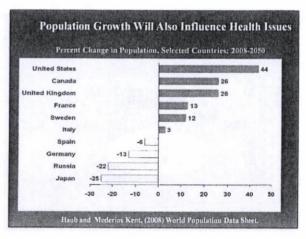


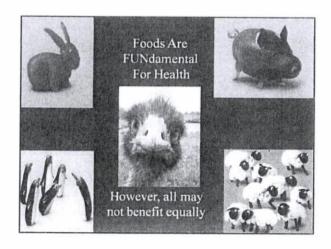




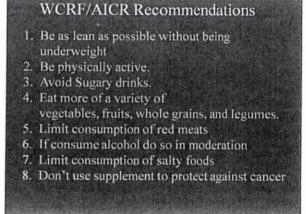


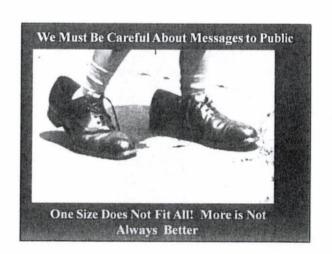


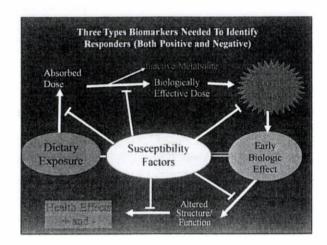


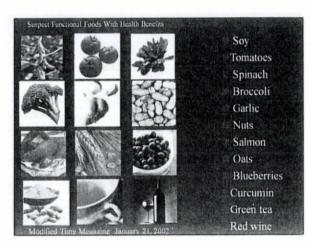


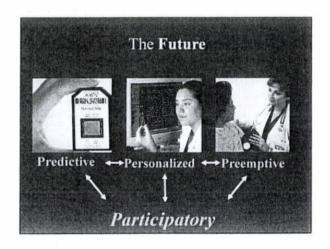














Jun Tamagawa Director,

Office of Health Policy on Newly Developed Foods Department of Food Safety, Pharmaceutical and Food Safety Bureau Ministry of Health, Labour and Welfare

April 2007-present Director

Office of Health Policy on Newly Developed Foods Department of Food Safety,

Pharmaceutical and Food Safety Bureau Ministry of Health, Labour and Welfare

April 2004-

Associate professor

Faculty of Humanities, Law and Economics

Mie University

August 2003-

**Deputy Director** 

Policy Planning and Communication Division

Department of Food Safety

Pharmaceutical and Food Safety Bureau Ministry of Health, Labour and Welfare

July 2003-

**Deputy Director** 

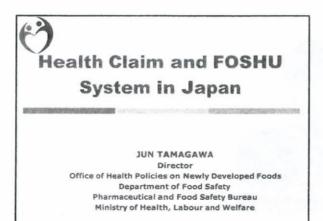
Office of Health Policy on Newly Developed Foods

Department of Food Safety

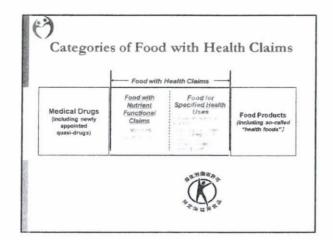
Pharmaceutical and Food Safety Bureau Ministry of Health, Labour and Welfare

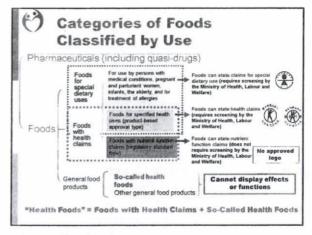
## <u>玉川 淳</u> 厚生労働省医薬食品局食品安全部基準審査課 新開発食品保健対策室長

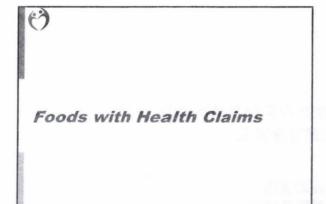
平成19年 4月 現職
平成16年 4月 国立大学法人三重大学人文学部助教授
平成15年 8月 医薬食品局食品安全部企画情報課長補佐
平成15年 7月 医薬食品局食品安全部基準審査課 新開発食品保健対策室室長補佐

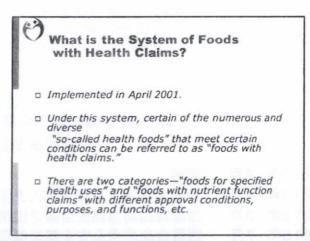














#### Background to the Creation of the System of Foods with Health Claims

- Concern about the health of the public is increasing against a backdrop of confusion concerning eating habits, increases in lifestyle-related diseases, rising healthcare costs, etc. and demands concerning food functions are becoming more complex and diverse.
- Advances in food science and technological development are leading to the development of new foods with varied functions.

- Developments in regulatory schemes and internationalization are leading to reviews of food and pharmaceutical classifications.

  Demands from consumers for the provisions of appropriate information concerning foods are increasing. There have been some incidents of improper labeling and ingestion methods leading to risks to health and complaints concerning foods.
- In overseas, there has been increased consideration of regulatory standards for foods that have certain functions such as labeling that emphasizes health.



Foods with Nutrient Function Claims



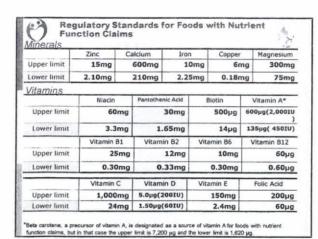
#### What are Foods with Nutrient Function Claims?

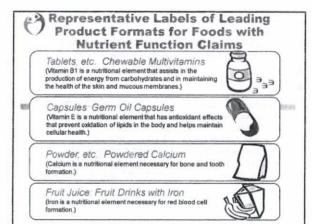
- Foods with nutrient function claims are foods that supply or supplement the nutritional components (vitamins, minerals, etc.) that are necessary for sound growth, development of the body and the maintenance of health.
- With advancing age, confusion concerning proper eating habits, and others, it has become increasingly difficult to maintain normal eating habits; and foods with nutrient function claims are foods that supply or supplement nutritional components when it is not possible to obtain the necessary nutritional components each day.



#### Handling of Foods with Nutrient Function Claims

- The system for foods with nutrient function claims is a selfcertifying one that does not require the filing of individual applications for approval or notice, etc. to the Minister of Health, Labour and Welfare (MHLW).
- The standards adopted by MHLW include bellows; - Regulatory standards that set upper and lower limits on nutrient functional components included that are ingested daily
- Labeling standards that specify the content of functions that can be indicated and warnings concerning the nutritional components that are ingested Products with nutrient function claims must comply with these standards.
- Foods whose nutritional component functions may be labeled as foods with nutrient function claims are currently 12 vitamins and five minerals.







#### **Nutrient Function Claims** and Warning Indication

Nutritional Ingredient	Function Claims	Warning Indication	
helps to maintain vision in the dark, and helps to maintain skin and mucosa health. Please compl daily intake. Women months of pregnancy considering to be pre		Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake. Women within the third months of pregnancy or women considering to be pregnant should be careful of over consumption.	
Vitamin C	helps to maintain skin and mucosa healthy and has anti-oxidizing effect.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.	
Calcium	necessary in the development of bone and teeth.  Increased intake of this product we result in curing diseases nor prom health. Please comply with the adally intake.		



#### Ingredients Added to Foods with Nutrient Function Claims (Review)

Adoption of regulatory standards is currently being reviewed for the remaining vitamins and minerals for which nutrient function claims have not been approved (eight nutritional elements) from the perspective of normalization of function claims and providing appropriate information to consumers.

\*\*The remaining vitamine and minerals are vitamin K, phosphorus, potassium, iodine, manganess selenium, chronium, molybdanum

<Vitamin K, Phosphorus, and Potassium>

According to the nutritional element intake volumes from a national nutrition survey, the required amounts of these three nutritional elements are obtained across all ages groups.

Iodine, Manganese, Selenium, Chromium, and Molybdenum No surveys of intake volumes, etc. have been conducted.

Accordingly, from the perspective of providing appropriate information to consumers concerning these eight nutritional elements, the database on safety and effectiveness for health foods of the National Institute of Health and Nutrition will be used for the time being to provide scientific information concerning nutritional ingredients.



### Foods for Specified Health Uses





#### What are Foods for Specified Health Uses?

- Foods for specified health uses are foods that include functional health ingredients with physiological functions and biological activity of the body and that state claims to the effect that the expected health functions can be expected from intake of the food with the intention of achieving a specific health function in eating habits.
- When foods are sold as foods for specified health uses, a screening by the national government must be conducted concerning the efficacy of the individual physiological functions and specified health functions as well as safety, etc. and approval must be obtained.



#### Applicable Scope of Foods for Specified Health Uses (Part 1)

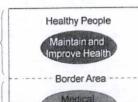
Foods for specified health uses are foods that contribute to improving diets and thereby maintaining or improving the health of persons who have not yet contracted lifestyle-related diseases, etc. that arise from eating habits or who are on the verge of contracting such diseases.



#### Applicable Scope of Foods for Specified Health Uses (Part 2)

Foods for Specified Health Uses

Pharmaceuticals



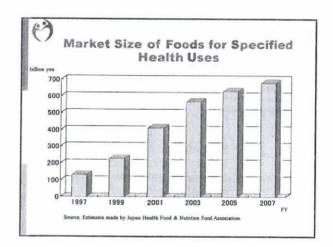
Treatment Persons with diseases (persons who have contracted lifestyle-related diseases, etc.)



Sick

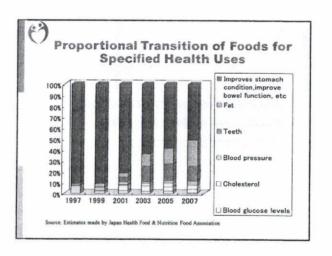


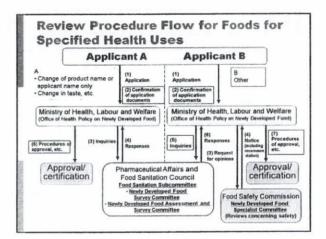
(as of November 19, 2008)			
Category	Number		
Foods for specified health uses	531		
Conditional foods for specified health uses	1		
Foods for specified health uses (regulatory standard type)	18		
Foods for specified health uses (disease risk reduction claims)	6		
Foods for specified health uses (re-approved, etc.)	264		
Total	820		

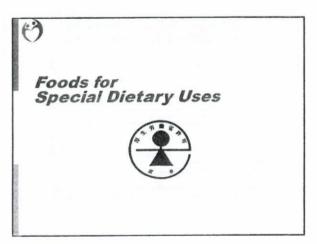


Approval Requirements for Foods for Specified Health Uses
□ Efficacy in humans has been clearly established.
□ There are no recognized safety problems (toxicity testing using animals, confirmation of effects in case of overdose, etc.)
• There are no nutritional problems (excessive salt, etc.)
<ul> <li>Compliance with products standards until the food is consumed has been confirmed.</li> </ul>
<ul> <li>Quality control methods are established (product and ingredient standards, manufacturing methods, testing and inspections, etc.)</li> </ul>

for Spe	lassification of Approved Fecified Health Uses by Heal		cts
Content of Labeled Health Effects	Representative Ingredients	Number Approved	Percentage to total approved products (820 products)
Improves stomach condition, improve bowel function, etc.	Various oligosaccharides, lastulose, bilidebacteria, various lactic acid bacteria, dietary fiber (indipestible dectrie, polydextrose, gwar gwm, psyllium seed cast, etc.)	301	36.7
Blood glucose levels	Indigestible dextrin, wheat albumin, guara leaf polyphenol, L-arabinose, etc.	119	14.5
Blood pressure	Lactotripeptide, caseindodecapeptide, euconomia leaf glycoeide (geniposidic acid), sardina peptide, etc.	102	12.4
Cholesterol	Chitosan, say bean protein, law-molecular sodium alginate	95	11.6
Teeth	Paratinose, multitose, erythritol, etc.	65	7.9
Fat	Discylghycerul, globin protein resolvent, etc.	60	7.3
Cholesterol and stemech candition, cholesterol and fal, etc.	Law molecular sodium alginate, payllium seed coal dietary fiber, etc.	33	4.0
Benes	Say isoflavon, myelin basic protein (MBP), etc.	30	3.7
Mineral absorption	Calcium citrate malata, caseinphusphopeptides, heme iron, fructouligosaccharide, etc.	6	0.7







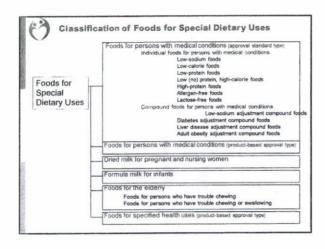
What are Foods for special Dietary Uses?

O Foods for special dietary uses are foods for persons with medical conditions, dried milk for pregnant and nursing women, formula milk for infants, foods for the elderly and that are labeled for special purposes such as the development of persons with medical conditions, etc. and maintenance and restoration of health.

O When approving labeling, the suitability of those items for which there are established approval standards is reviewed and individual assessments are conducted for those items without approval standards

O Food formats include individual foods (soy sauce, jams, etc.) and compound foods (combinations of multiple foods)

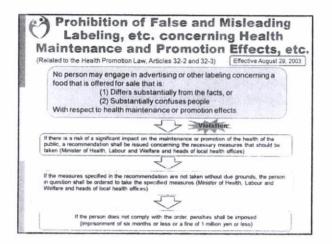
O Under the Health Promotion Law, approval for special-purpose labeling includes foods for specified health uses

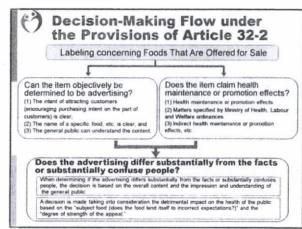


Regulations Prohibiting False and Misleading Advertising, etc.

0





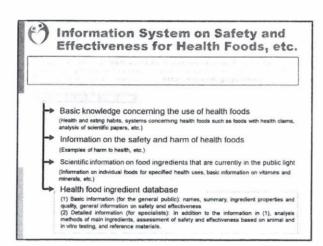




- Pharmaceutical Affairs Law (Prohibition of advertising of medical products prior to approval, etc.)
- Act against Unjustifiable Premiums and Misleading Representations (Regulations concerning transactions involving products and services)
- Specific Commercial Transaction Law (Fairness in transactions involving designated products and preventing harm to purchasers)
- JAS (Japanese Agricultural Standard) Law (Regulations concerning standardization and proper labeling of agricultural and forestry products)



Information System on Safety and Effectiveness for Health Foods, etc.



## Memo

本シンポジウムご参加により、栄養情報担当者(NR)認定:1単位(更新用)を取得できます。

This Symposium is pre-approved by National Institute of Health and Nutrition for 1 credit for Nutritional Representative (NR).

厚生労働科学研究費補助金(食品の安心・安全確保推進研究事業) 「特定保健用食品等の有効性・安全性を確保するための科学的根拠の評価方法に関する研究」 (研究代表者 芝池伸彰)研究班 主催 日米シンポジウム 「食品の機能と表示の最新動向」 プログラム

> 発行:平成20年12月1日 編集:厚生労働科学研究費補助金 (食品の安心・安全確保推進研究事業) 「特定保健用食品等の有効性・安全性を確保するための 科学的根拠の評価方法に関する研究」 研究班 研究代表者 芝池 伸彰

連絡先:独立行政法人国立健康・栄養研究所 国際産学連携センター 笠岡(坪山)宣代 電話 03-3203-5721(代表)、 E-mail ntsubo@nih.go.jp

Program for the US-Japan Symposium
"Trends in Food Function and Labeling"
Sponsored by Health Labour Sciences Research Grant, Research on Food Safety,
Research Project (Principal Investigator: Nobuaki Shibaike)
and

IAA National Institute of Health and Nutrition

Published: December 1, 2008

Edited by : Health Labour Sciences Research Grant, Research on Food Safety,
Research Project (Principal Investigator: Nobuaki Shibaike)

Contact Address: Nobuyo Tsuboyama-Kasaoka, Ph.D., R.D., Center for Collaboration and Partnership,
National Institute of Health and Nutrition
1-23-1 Toyama, Shinjuku-ku, Tokyo 162-8636
Phone: +81-3-3203-5721