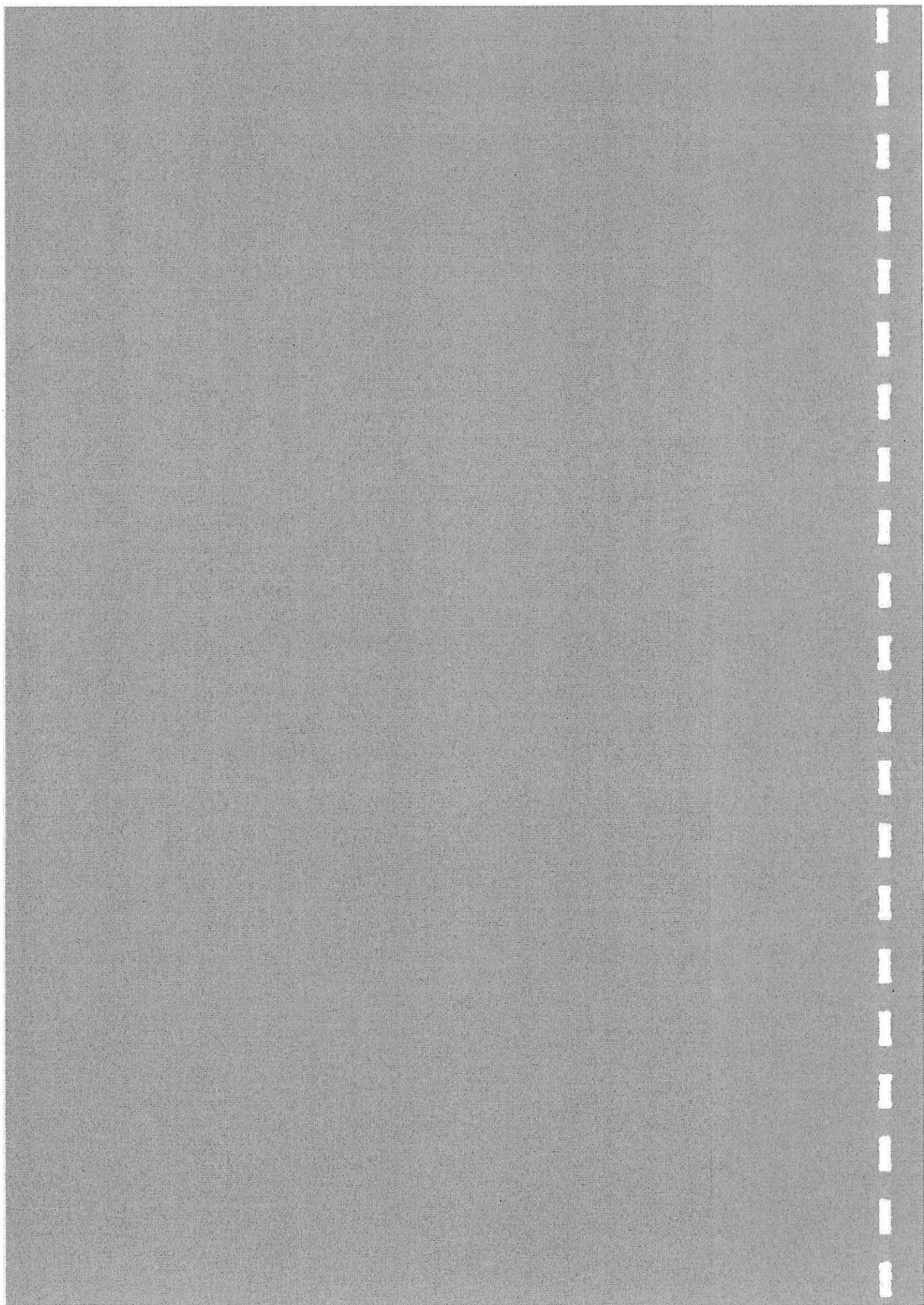


SESSION 2

Regulations and Standards

Chair: Dr. Ryuji Yamaguchi, ILSI Japan



Nutrition Labeling and Claims Regulations in Japan – An Update

Mr. Hiroaki Hamano
Consumer Affairs Agency
Japan

Nutrition Labeling and Claims Regulations in Japan – An Update

Mr. Hiroaki Hamano
Consumer Affairs Agency
Japan

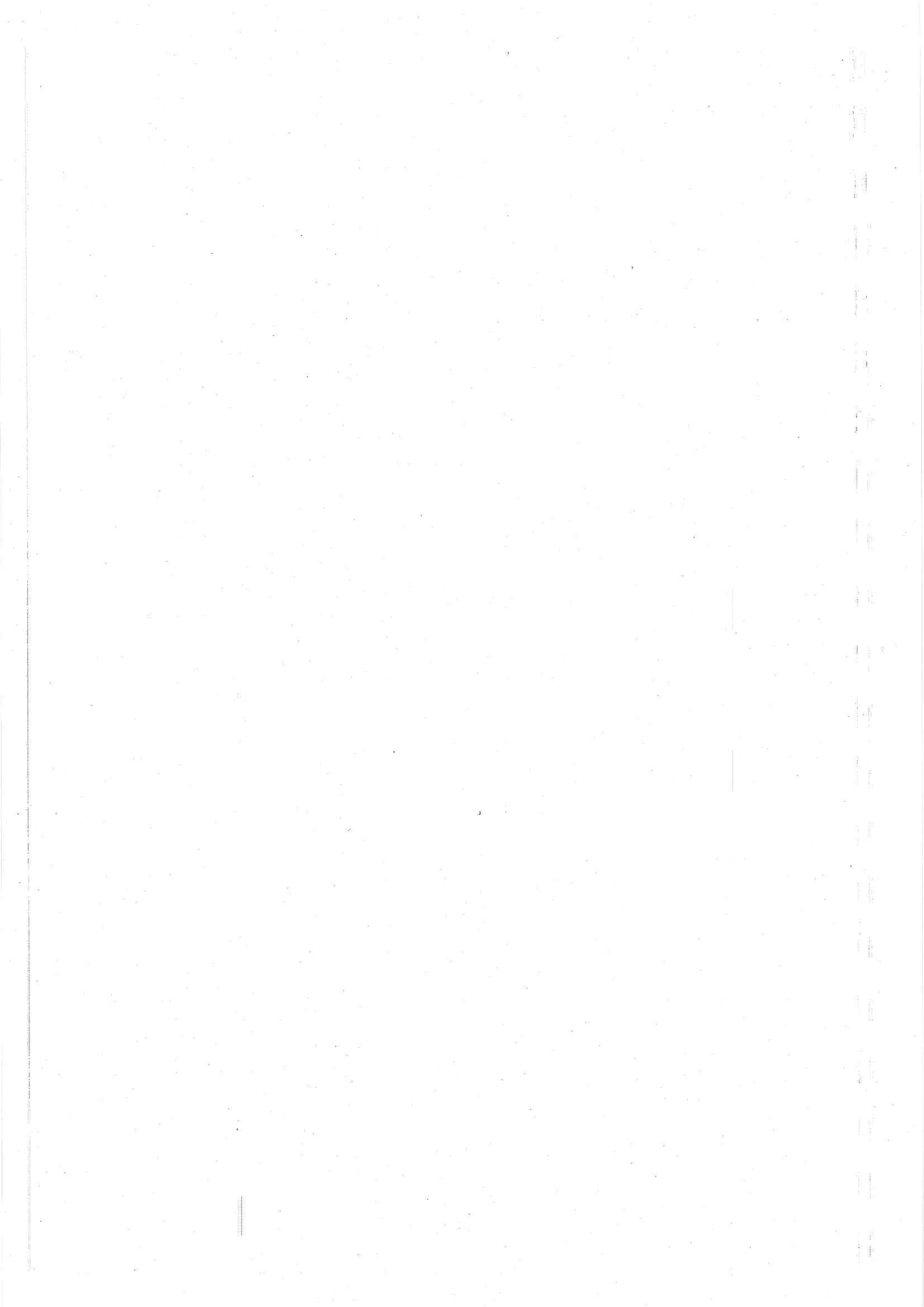
In order to ensure consumers' safety and their ability to choose foods independently and rationally, the Food Labelling Bill was passed into Act on June 21st, 2013, and the Food Labelling Act was promulgated on June 28th, 2013. Under the Act, the existing voluntary Nutrition Labelling System became a mandatory framework.

The Consumer Affairs Agency (CAA), Government of Japan believes that such labelling framework is necessary to improve consumers' health, since it may enable consumers to manage their nutritional status and their own dietary habits. The CAA also believes that it is important not only to urge food business operators to use nutrition labelling on a wide range of food products, but also to educate consumers how to put their healthy dietary habits into practice by helping them understand nutrition labelling and how to make practical use of its information.

In Japan, Health and Function Claims have been allowed only for two food categories under the Food Sanitation Act and the Health Promotion Act: Foods with Nutrient Function Claims and Foods for Specified Health Uses. In April 2015, the government of Japan introduced a new system which enables food business operators to make Function Claims not only on processed foods (including so-called dietary supplements), but also on fresh foods according to the scientific evidence-based substantiation under their own responsibility.

The new system of "Foods with Function Claims" provides "opportunities for consumers to make voluntary and reasonable food choices". With a proper understanding of the new system, food business operators need to take their own responsibility for providing consumers with accurate information and for not misleading consumers.

In this presentation, the new Food Labelling Act will be presented with an introduction of mandatory nutrition labelling and the new system of Foods with Function Claims.



Perspective of New Food Labelling Act and Function Claims in Japan – An Update

Seminar on Food Safety and Standards
Hanoi, Vietnam, December 15, 2015
Hiroaki Hamano, ILSI Japan

Provisions on Food Labelling in Japan

✓ There has been a number of various notifications under the three Acts.

Food Sanitation Act	Japan Agricultural Standard Act*	Health Promotion Act	Food Labelling	Other concerns
<p>[Purpose]</p> <ul style="list-style-type: none"> To prevent the sanitation hazards resulting from eating and drinking. 	<p>[Purpose]</p> <ul style="list-style-type: none"> To improve quality of agricultural and forestry products. To help consumers choose products by enforcing proper quality labelling of them. 	<p>[Purpose]</p> <ul style="list-style-type: none"> To improve nutritional status and promote health. 	<ul style="list-style-type: none"> Enactment of the necessary criteria for the labelling of food to serve for the purpose of marketing (Article 19) 	<ul style="list-style-type: none"> Enactment of nutrition labelling standards (Article 31) Compliance with Standards for Quality Labelling (Article 19-13-2) Enactment of Japanese Agricultural Standards Grading in accordance with Japanese Agricultural Standards etc.
<ul style="list-style-type: none"> Enforcing the regulations concerning Food and Additives Apparatus and Containers and Packaging Prohibition of the sales for the products which do not conform to the standards and/or criteria Giving approval to a person who intends to conduct business from the prefectural governor, etc. 	<ul style="list-style-type: none"> Enactment of nutrition labelling standards (Article 31) Compliance with Standards (Article 31-2) 	<ul style="list-style-type: none"> Set a general policies Implementation of the national health and nutrition survey Prevention of passive smoking License pertaining to Food for Special Dietary Uses, etc. 	<ul style="list-style-type: none"> “Unification of Food Labelling Provisions” (From Sept. 2011 to Aug. 2012) 	<ul style="list-style-type: none"> Report (Aug. 2012)

*Act on Standardization and Proper Quality Labelling of Agricultural and Forestry Products

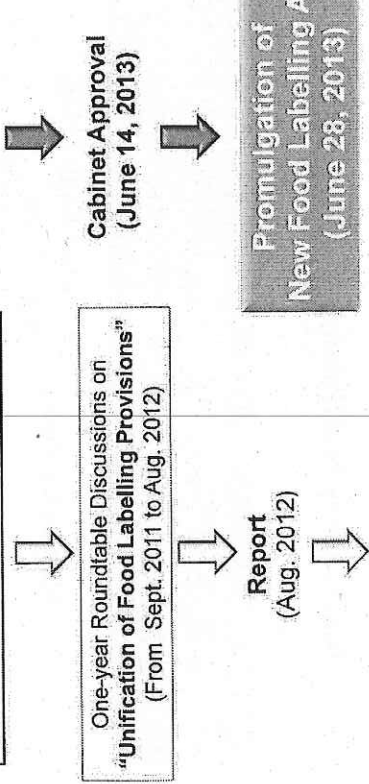
Today's Topics (1)

- Provisions on Food Labelling
- New Food Labelling Act 2013
 - ✓ A newly promulgated Act on Food Labelling
 - ✓ Introduction of Mandatory Nutrition Labelling
- Perspective of new Function Claims System
 - ✓ Introduction of Self-determined Function Claims
 - ✓ Addition of New Nutrient Function Claims
 - ✓ Revision of Current FOSHU Procedures

Toward New Food Labelling Act

Issues to be addressed:

1. Different definitions among Acts
2. Many/various notifications under the Acts
3. Voluntary nutrition labelling



**New Food
Labelling Bill**

**Cabinet Approval
(June 14, 2013)**

**Promulgation of
New Food Labelling Act
(June 28, 2013)**

Specific Rules under the New Act



New Food Labelling Standards (came into effective on April 1st, 2015)

- Introduction of Mandatory Nutrition Labelling (new)
- Introduction of Self-determined Function Claims (new)
- Addition of New Nutrient Function Claims

Nutrition Labelling Formats

Energy (kcal)
Protein (g)
Fat (g)
Carbohydrate (g)
Salt equivalent (g)

OR

Energy (kcal)
Protein (g)
Fat (g)
- Saturated fatty acid (g)
- n-3/n-6 fatty acid (g)
Cholesterol (mg)
Carbohydrate (g)
- Available carbohydrate (g)
- Sugars (g)
- Dietary fiber (g)
Salt equivalent (g)
(Sodium mg)

Mandatory Nutrition Labelling (new)

Mandatory Labelling	Energy, Protein, Fat, Carbohydrate, Salt equivalent
Recommended	Saturated Fatty Acids, Dietary Fiber
Voluntary	Optional Sugars, Trans Fatty Acids, Cholesterol, Vitamins & Minerals, and others

Comparative Claims (revised) and Non-addition Claims (new)




Comparative Claims	Revised	Revised according to Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985)
Non-addition Claims on Sugars and Salts	Newly adopted	Newly adopted according to Codex Guidelines on Nutrition Labelling (CAC/GL 2- 1985)

Today's Topics (2)

- Provisions on Food Labelling
- New Food Labelling Act 2013
 - ✓ A newly promulgated Act on Food Labelling
 - ✓ Introduction of Mandatory Nutrition Labelling
- Perspective of new Function Claims System
 - ✓ Introduction of Self-determined Function Claims
 - ✓ Addition of New Nutrient Function Claims
 - ✓ Revision of Current FOSHU Procedures

Previous Categories on Health Claims

← Foods with Health Claims (2001: Rev. in 2005) →

Drugs (including quasi-drugs)	Foods for Special Dietary Uses (FSDU, 1952) 	Foods with Nutrient Function Claims (FNFC, 2001) Standardized labelling system 12 vitamins 5 minerals Nutrition facts Nutrient function claims Warning Statements	Foods for Specified Health Uses (FOSHU, 1991) Product-specific approval system 1. FOSHU 2. Qualified 3. Standardized 4. Reduction of Disease Risk Claims  Nutrition facts Health claims Warning statements	[Unregulated] All other types of food (including the majority of so-called health foods)  Nutrition facts only
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“The Council of Regulatory Reform” formed under Cabinet Office (Jan.-Jun., 2013)

<Background>

- To respond to the public need to reduce noncommunicable disease burdens and promote health so as to live longer
- To lead the world as the longest longevity society



- Introduction of Self-determined Function Claims
- Addition of New Nutrient Function Claims
- Revision of Current FOSHU Procedures



Cabinet Approval: June 14, 2013

Previous Health Claims System & Issues (1)

Only two food categories, FNFC and FOSHU were allowed bearing health claims on food in Japan:

- Foods with Nutrient Function Claims (FNFC)
 - Pre-authorized claims
 - Self-determined according to the pre-set standards
 - No pre-marketing authorization required
 - Limited to claims only for 12 vitamins (A, D, E, B1, B2, Niacin, Biotin, Pantothenic acid, B6, Folic acid, B12, C) and 5 minerals (Ca, Fe, Zn, Cu, Mg)
- ⇒ Vitamin K, Potassium and n-3 Fatty acids are added (2015.04.01)

Newly Authorized Nutrient Function Claims (as of 2015.04.01)

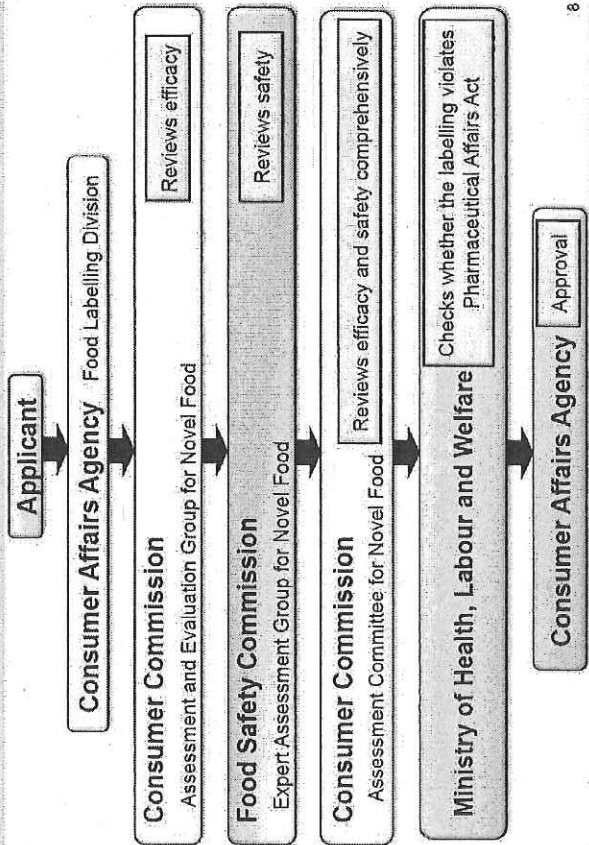
NUTRIENTS	Min./Max. per Day	NUTRIENT FUNCTION CLAIMS
Vitamin K	45/150 (µg)	A nutrient which helps maintain normal coagulation of blood
Potassium	840/2,800 (mg)	A nutrient which is necessary to maintain normal blood pressure (Tablet or capsule types of food are not applicable)
n-3 Fatty acids	0.6/2.0 (g)	Nutrients which help maintain healthy skin

Previous Health Claims System & Issues (2)

Only two food categories, FNFC and FOSHU were allowed to bear health claims on food in Japan:

- **Foods for Specified Health Uses (FOSHU)**
 - Claims are evaluated/approved individually by Consumer Affairs Agency
 - Structure/function claims and reduction of disease risk claims are allowed
 - Required scientific substantiation from human (intervention) studies, which may generally require large amounts of time and costs, to evaluate its safety and effectiveness for approval ⇒ High burden especially for small and medium-sized industries
- ⇒ **Revision of the Procedures – underway –**

Procedure Flow for Foods for Specified Health Uses (FOSHU)



Proposals from "The Council of Regulatory Reform": June 5, 2013

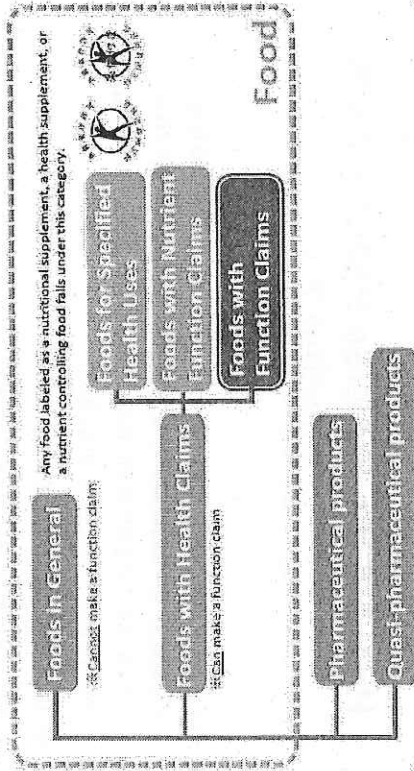
Cabinet Approval: June 14, 2013



- A new system under which **fresh and processed foods** in addition to supplement type of products can make function claims should be developed.
- **Food Labelling Act (Food Labelling Standards)** came into effective on **April 1st, 2015**.
- **Food Business Operators** are responsible for safety assessment and scientific substantiation of the function claims

Foods with Function Claims

Under the food business operator's own responsibility, Foods with Function Claims can be labeled with function claims based on scientific evidence. Information on the evidence supporting the safety and effectiveness of the product are submitted to the Secretary-General of the Consumer Affairs Agency before the product is marketed. However, unlike FOSHU, the product is not individually pre-approved by the Secretary-General of the Consumer Affairs Agency.



Foods with Function claims = Challenges =

- Assurance of the Safety of the product and
- Scientific Substantiation of the Function Claims are
- Food Business Operators' Own Responsibility.
- Notification and Publication systems are introduced.

How are the Safety and Effectiveness of Foods with Function Claims ensured?

- ◆ Food business operators, on their own responsibility, are required to evaluate the safety and effectiveness in accordance with rules prescribed by the government (Guidelines on Notification of Food with Function Claims, 20150330).
- ◆ They must then submit the information to the Secretary-General of the Consumer Affairs Agency 60 days prior to marketing the product (Notification Number provided from Consumer Affairs Agency).
- ◆ Submitted documents are disclosed on the website of the Consumer Affairs Agency (www.caa.go.jp/foods/index23.html).
- ◆ Consumers can check the product information on how the safety and effectiveness of the product is ensured before the product is placed on market.

How is the Safety evaluated ?

The safety is evaluated by one of the following methods.

- ◆ A history of safe use/consumption of a finished product or a functional substance therein by humans
 - ◆ Research of existing informational/studies on safety of the product or a functional substance therein
 - ◆ Safety testing on the product or a functional substance therein by using animals or humans
- Any interactions with drugs, etc. is also evaluated.

How is the Effectiveness evaluated ?

The effectiveness of the product is evaluated by one of the following methods.

- ◆ A clinical trial with a finished product
 - ✓ When the scientific evidence is provided by a clinical trial with a finished product, the product package bears a claim that the product has a function to
- ◆ A literature review (Systematic Review) on a finished product or a functional substance therein
 - ✓ When the scientific evidence is provided by a literature review, the product package bears claim that the product/functional substance has been reported to have a function to

follow Codex guideline on health claims

How are the production, manufacturing and quality control system managed ?

- ◆ For processed food, structures of sanitary control for facilities and employees,
- ◆ For fresh food, sanitation control procedure for producing, harvesting, or fishing,
- ◆ Systems designated to prevent distribution of out-of-specification products,
- ◆ Analytical methods for the functional substances, etc.
- ◆ Consumers can check the product information on how the systems of production, manufacturing and quality control are managed before the product is placed on market

How are the Adverse Health Events collected ?

- ◆ Food business operators should establish a system to collect/receive information on the adverse health events, etc. from consumers, health professionals, etc.
- ◆ The contact information of the food business operator is always stated on the product label (a telephone number, etc.).
- ◆ Consumers can check the product information on how the adverse health events are collected before the product is placed on market

Foods with Function Claims Registered (Apr.13-Oct.05, 2015)

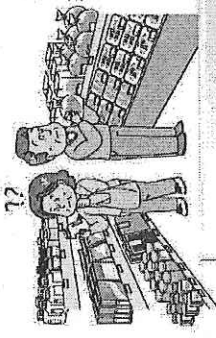
Food Category	Number of Products	%
Supplements (Capsules, Tablets, etc.)	84	54.2
Other Processed Foods (Ordinary Foods)	67	43.2
Fresh Foods (Agricultural, Fishery Products)	2	1.3
Withdrawn	2	1.3
TOTAL	155	100

請留意

消費者

What are "Foods with Function Claims"?

The new system of Foods with Function Claims has been launched. This is different from Foods for Specified Health Uses and Foods with Nutrient Function Claims.



● Foods with Claims for Specified Health Uses
● Foods with Nutrient Function Claims

Thank you very much for your attention !

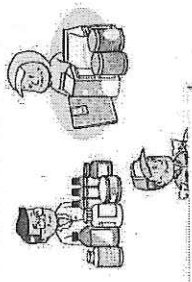
消費者

請留意

消費者

The system of "Foods with Function Claims" has been launched!

Before considering development and sale of products



Thank you very much for your attention !

消費者

Analyses and Tolerance Limits of Nutritional and Functional Food Ingredients – Topics in View of Global Standards and the Latest Japanese Regulations

Dr. Tomoji Igarashi
Japan Food Research Laboratories
Japan

Analysis and Tolerance Limits of Nutritional and Functional Food Ingredients – Topics in View of Global Standards and the Latest Japanese Regulations

Dr. Toru Igarashi
Food Safety and Quality Assurance
2012

Analyses and Tolerance Limits of Nutritional and Functional Food Ingredients – Topics in View of Global Standards and the Latest Japanese Regulations

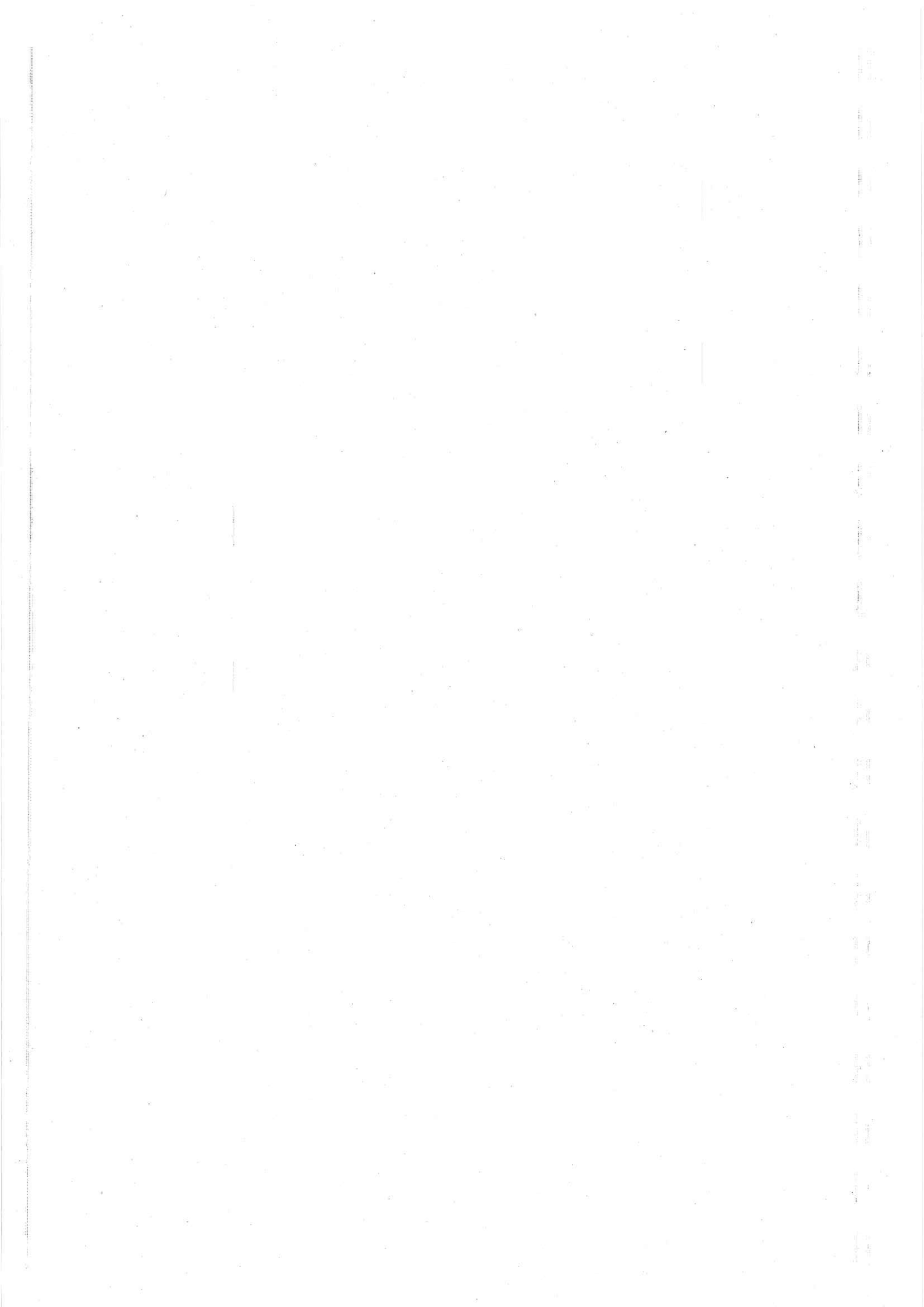
Dr. Tomoji Igarashi
Japan Food Research Laboratories
Japan

Needless to say, the health effects of Nutritional and Functional Food Ingredients (NFFI) on the human body largely depends on their quantities. Therefore, the analytical process to quantify NFFI is of critical importance not only in relation to variation of the analytical data, but also to the definition of NFFI itself. Analysis values of NFFI are often used for Quality Control (QC) and/or nutrition labeling, and an expected and/or allowance range always exists for the obtained data.

There are two characteristics of NFFI that cause difficulties in the analyses. Firstly, there is a wide range of matrices from fresh food to health food; and secondly, there are diverse chemical structures and/or molecular sizes of the analytical items.

This presentation will cover the following two areas related to the analysis of NFFI in relation to the tolerance levels in nutritional labeling, according to global and Japanese rules and regulations:

- 1) The validation of NFFI analyses will be reviewed, referring to the relationship between the measurement uncertainty and the tolerance limit (TL) on the labeling. Emphasis will be made on the dependence of precision and variation on concentration of the analyte, since measurement uncertainty virtually depends on the concentration of the NFFI. In light of global standards, the presentation will also discuss, firstly, the CODEX guidelines on assessing the competence of testing laboratories, and secondly, the complication that arises when the methods category system in CODEX is used to define dietary fiber analysis.
- 2) The current Japanese rule on tolerance limits will be introduced, specifically, that when an “estimated value” falls outside the tolerance limits, it is acceptable when the conditions satisfy the official requirements for evidence and traceability. The presentation will explain the practical aspects to consider when the variation of NFFI of the labeled value is out of the control range due to inevitable causes.



Analyses and Tolerance Limits of Nutritional and Functional Food Ingredients

Topics in View of Global Standards and the Latest Japanese Regulations

Tomoji IGARASHI

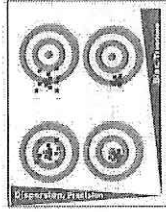
Japan Food Research Laboratories



20151215

Outline

- Characteristics and Definition for Nutritional/Functional Food Ingredients (NFFI).
- Method Validation on NFFI in relation between Uncertainty and Tolerance Limits (TL).
- The Latest Japanese Regulations for TL of NFFI.



Variety in NFFI

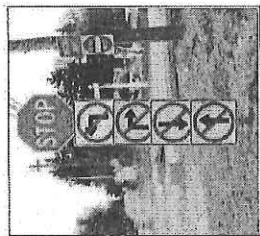
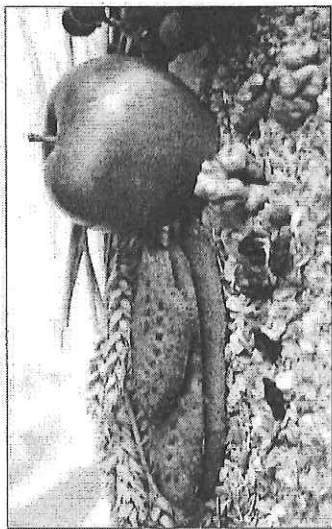
Food Ingredients	Analytical Items (Analyte)	Items phân tích (chất phân tích)
Nutritional	Protein, Amino Acids	Protein, Amino Acids
	Fat, Fatty Acids	Chất béo, axit béo
	Carbohydrate, Sugars, Amino-Sugars	Carbohydrate, Đường, A.a. tức-Đường
	Dietary Fibers, Oligosaccharides	Sợi Thực ăn, oligosaccharides
	Vitamin A: Retinol, Carotens, Cryptoxanthin	Vitamin A: Retinol, Carotene, cryptoxanthin
	Vitamin B1: Thiamines	Vitamin B1: Thiamines
	Vitamin B2: Riboflavin	Vitamin B2: Riboflavin
	Vitamin B6: Pyridoxine	Vitamin B6: Pyridoxine
	Vitamin B12: Cyanocobalamin	Vitamin B12: Cyanocobalamin
	Other-Vitamin B group: Nicotins, Pantothenic Acid, Biotin, Folic Acid	Vitamin B khác: Nicotin, Pantothenic Acid, Biotin, Acid Folic Biotin, Folic Acid
	Vitamin C: Ascorbic acids	Vitamin C: Axit Ascorbic
	Vitamin D: Ergocalciferol, Cholecalciferol	Vitamin D: ergocalciferol, Cholecalciferol
	Vitamin E: Tocopherols	Vitamin E: Tocopherols
Functional	Minerals: Na, K, Fe, Mg, Ca, Mo, Mn, I, P, Cu, Se, Cr, Zn	Khoáng sản: Na, K, Fe, Mg, Ca, Mo, Mn, I, O, Cu, Fe, Cr, Zn
	Phytosterols	Phytosterols
	Carotenoids: Lutein, Lycopene, Astaxanthin	Carotenoids: Lutein, Lycopene, Astaxanthin
	Flavonoids: Anthocyanins, Isoflavones, Catechins	Flavonoids: Anthocyanins, Isoflavones, Catechins
	Glycosaminoglycan: Hyaluronic Acid, Chondroitin	Glycosaminoglycan: Hyaluronic Acid, Chondroitin

Characteristics in Analysis of NFFI

- Wide range of matrices from fresh food to health food
- Diverse chemical structures and/or molecular sizes of the analytical Items (Analyte)
- Expected/allowed range always exists for the obtained value/data. The results can be taken as different from those used for the negative contaminants (e.g. pesticides) where “Not Detected” is welcome.

Complicated definition of NFFI in relation to Global Standards

The methods category system in CODEX used to define "Dietary Fibers"



What do Type 1 methods quantify ?

Type 1 methods: non-analyte-specific methods
 The quantity measured is defined by the result found by following the stated method ... in extremely speaking the obtained data are employed regardless of the trueness.

Although only single type 1 method should be desirable for the same analytical item in the same matrix, currently there exist 9 kinds of type 1 methods for the Dietary Fibers in foods.



Method Category in the CODEX Procedural Manual

<http://www.fao.org/docrep/012/t1400e/t1400e00.htm>

Type 1: Empirical/Defining methods

Protein, Fat, Moisture, Dietary Fibers...

for example Protein converted from N₂, or

Fat from gravimetric method on solvent extract

Type 2: Reference methods

Type 3: Alternative approved methods

Type 4: Tentative methods

Definition of Dietary Fibers in CODEX

- Carbohydrate polymers with ten or more monomeric units, which are not hydrolysed by the endogenous enzymes in the small intestine of humans...
- Synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit ...

A confused background

- 1: Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities
- 2: Some water-soluble dietary fibers can be measured only by an additional size-exclusion HPLC

CODEX Guidelines for the Assessment of Competence of Testing Laboratories Involved in the Import and Export Control of Food

1. Compliance with the general criteria for testing laboratories laid down in ISO/IEC Guide 17025 (ISO 17025)
2. Participation in appropriate Proficiency Testing (PT) schemes for food analysis
3. Whenever available, use Validated Methods according to the Codex's principles
4. Use Internal Quality Control procedures

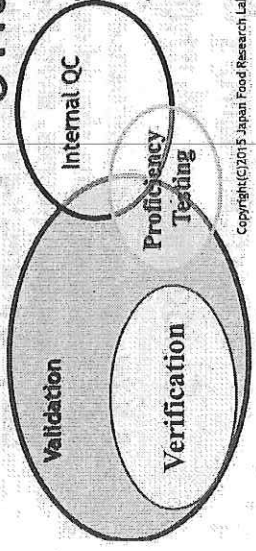
Required Parameter for Method Validation

- Applicability ✓
- Selectivity or Specificity ✓
- Linearity of Calibration Curve ✗
- Trueness ✗
- Precision ✗
- Range ✓
- Limit of quantification ✗
- Ruggedness or Robustness
- Measurement Uncertainty ✗

According to the Guidelines for Dietary Supplements and Botanicals by AOAC Int. 11

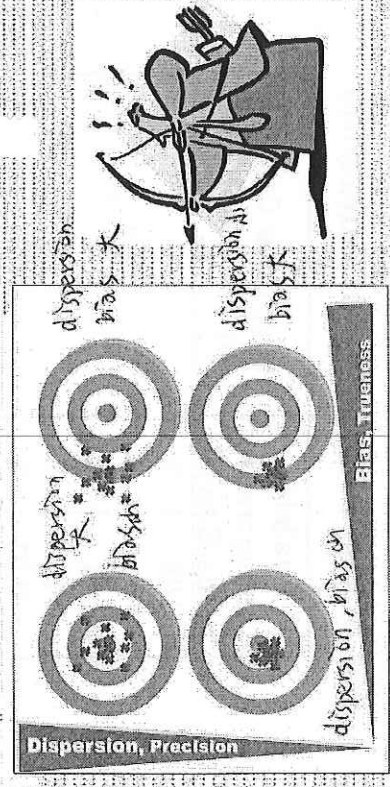
Relation of Method Validation to Internal Quality Control (QC) and Proficiency Testing

- **Validation**
 - for Method management
 - necessary for using a new method
 - including "Verification" which is for a minor change in the method
- **Internal QC**
 - for monitoring the indexes undertaking the validity of tests on each day
- **Proficiency Testing**
 - necessary for comparing own data with those of other laboratories



Component of Measured value

- Measured value = True value (unknown)
- + Random error (Dispersion, Precision)
 - + Systematic error (Bias, Trueness)



A Target-Arrow-Model for Repeated Measurements

Precision

- **Repeatability as RSDr :**
Relative Standard Deviation "Small r"
 Repeatability refers to the degree of agreement of results when operating conditions are maintained as constant as possible with the same analyst, reagents, equipment, and instruments performed within a short period of time.
- **Reproducibility as RSDR : . . . "Large R"**
 Reproducibility refers to the degree of agreement of results when operating conditions are as different as possible and obtained only by a Collaborative Study

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Uncertainty

Measurement Uncertainty (MU):

"a parameter associated with the result of a measurement that characterizes the dispersion of values that could reasonably be attributed to the measurand."

The range which contains unknown true value

Practically, Expanded MU (EMU) is used as follows;

$EMU = RSDr \times 2$ (repetition of ten or more experiment)

Observed Value \pm EMU includes true value at approximately 95% confidence.

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Acceptable Criteria for Repeatability in the AOAC International Guideline

Analyte Concentration in the Sample	Acceptable Criteria for Repeatability
100 %	1
~10 %	1.5
~1 %	2
~0.1 %	3
~0.01 %	5
~10 ppm	6
~1 ppm	10
~10 ppb	20

The RSDr and RSDR varies on analyte concentration in the sample

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Tolerance Limits from CODEX Guidelines on Nutritional Labelling

3.5 Tolerances and compliance

3.5.1 Tolerance limits should be set in relation to public health concerns, shelf-life, accuracy of analysis, processing variability and inherent liability and variability of the nutrient in the product, and according to whether the nutrient has been added or is naturally occurring in the product.

3.5.2 The values used in nutrient declaration should be weighted average values derived from data specifically obtained from analyses of products which are representative of the product being labelled.

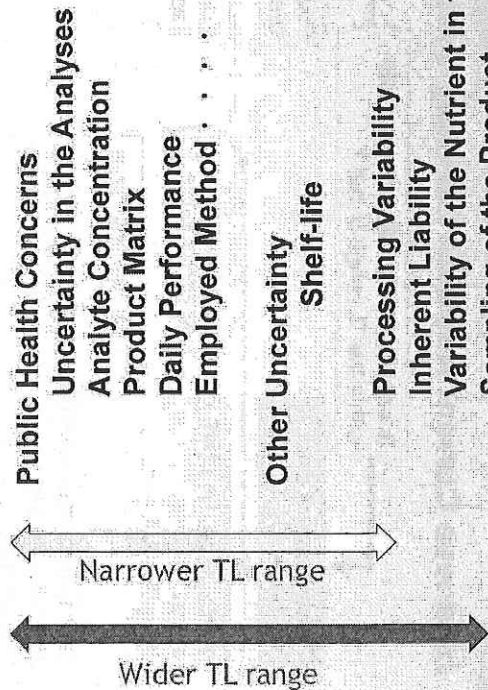
Labeled Nutrient Contents have various errors including those from Analyses

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Factors affecting on Tolerance Limits

Relation between TL and Variation factor



Current Regulation of TL in Japan

Recently, the “Estimated Value (EV)” was introduced in Japanese Nutrition labelling, which can be virtually “Free from TL*” for the first time in the world.

*When EV falls outside the tolerance limits, it is acceptable if the conditions satisfy the official requirements for evidence and traceability except for the nutrition claim

Tolerance Limits(TL) for Declaration of Nutrients* in Japan and other Regions

Analytical Items	Japan	U.S.A.	EU	Singapore	Hong Kong
Energy, Total Fat, Cholesterol, Sugars	80% ~ 120%	≧ 120%	80% ~ 120% (10-40g/100g)	≧ 120%	≧ 120%
Sodium	80% ~ 120%	≧ 120%	80% ~ 120% (≦ 0.5g/100g)	≧ 120%	≧ 120%
Saturated Fat	80% ~ 120%	≧ 120%	80% ~ 120% (≦ 4g/100g)	≧ 120%	≧ 120%
Carbohydrate	80% ~ 120%	≧ 120%	80% ~ 120% (10-40g/100g)	≧ 120%	≧ 80%
Protein, Dietary Fiber	80% ~ 120%	≧ 80%	80% ~ 120% (10-40g/100g)	≧ 80%	≧ 80%
Water-soluble Vitamins	80% ~ 180%	≧ 80%	65% ~ 150%	≧ 80%	≧ 80%
Fat-soluble Vitamins other than VA, VD	80% ~ 150%	≧ 80%	65% ~ 150%	≧ 80%	≧ 80%
Vitamin A, Vitamin D	80% ~ 150%	≧ 80%	65% ~ 150%	≧ 80%	80% ~ 180%
Minerals	80% ~ 150%	≧ 80%	65% ~ 145%	≧ 80%	≧ 80%

*Except for foods with added vitamins, minerals, and protein where the nutrient contents must be at least equal to the declared value.

Latest Rule

In addition to the conventional manner (①), the rationally estimated data (②) can be used when the conditions satisfy the official requirements

① When Labeled values seemed to be well controlled within the Tolerance range

~ Tolerance Limits for Labeled Values ~
 ± 20%

Nutrition Fact	
/1 serving (100g)	
Energy	100kcal
Protein	2.0g
Fat	5.0g
Carbohydrates	12.5g
Salts	0.5g

② When Labeled Values seemed to be out of control within the Tolerance range

~ Terms of the Labeled Values ~
 The rationally estimated data can be labelled. Free from TL when the conditions satisfy the official requirements for evidence and traceability.

Nutrition Fact	
/1 serving (100g)	
Energy	100kcal
Protein	2.0g
Fat	5.0g
Carbohydrates	12.5g
Salts	0.5g

(This is Estimated Value)

Official Requirements for Evidence and Traceability

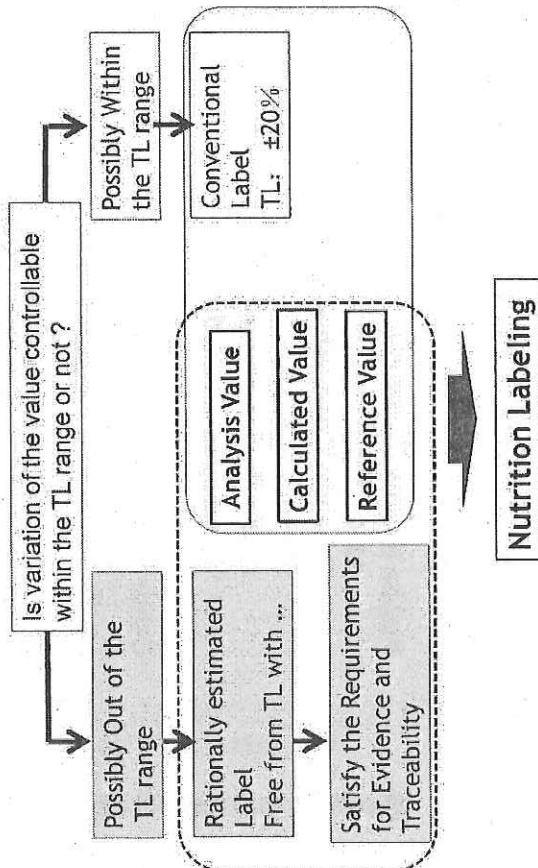
- EV can be used when the NFFI data are basically out of control range due to the inevitable causes... such as for Japanese-style packed Lunch etc
- “This is an estimated value” or “(Estimated Value)” should be shown at the bottom of the labeling.
- Rational explanation should be made for the evidence and traceability when the authority asks about the labeled data.

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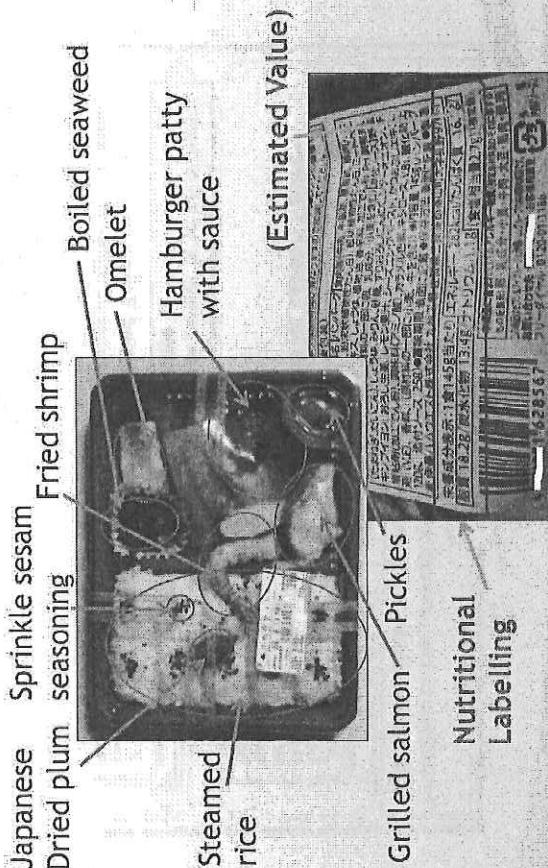
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should keep the documents

Japanese Current Nutrition Labeling System



Labelled Values are virtually out of TL range due to lots of side dishes in the Japanese packed Lunch



Data Origins of Nutrition Labelling in Japan

Analysis Value: obtained basically from the official analytical methods for the Japanese Nutrition Labeling.

Calculated Value: obtained from the calculation by nutrition data of individual raw material which are from official databases or the specifications.

Reference Value: obtained from the estimation by set of nutrition data from official databases in which the target sample should be almost the same with that in the databases such as orange juice or other agricultural products.

Summary

- Due to the complex definition of NFFI, discrepancy may exist in CODEX Dietary-Fiber-Analysis.
- The trueness and precision, crucial for method validation, are allowed to vary depending on analyte concentrations.
- For NFFI-label-value in relation to TL, uncertainty arising from nutrients stability, processing, sampling, together with the errors in analysis should be considered.
- Japan has taken a practical approach for the TL, where "Free from TL" is allowed if the conditions satisfy the official requirements for evidence and traceability.
- Standard Tables of Japanese Nutrition Food Composition has been used for "Calculation Value" or "Reference Value" as an evidence.

Standard Tables of Food Composition in Japan http://www.mext.go.jp/english/science_technology/1347490.htm

食品番号 Item No.	食品名 Food and description	水分 %	エネルギー kcal	たんぱく質 g	脂質 g	炭水化物 g	繊維 g	灰分 g	ビタミン類 mg	ミネラル類 mg
06001	野菜類 VEGETABLES アーティチョーク Artichoke 花びら、生 Flower bud, mk	75	48	201	84.1	2.3	0.2	11.3		

English version became available in this fiscal year.