Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

Scientific Integrity—Strengthening ILSI Scientific Foundation in Asia

11th BeSeTo Meeting
September 26, 2019
Alison Kretser

ILSI

Agenda

- Introduction of the Management Team Scientific Integrity Subcommittee
- Identification of 5 Major Priorities
- Status of Scientific Integrity Training Materials
- Scientific Integrity Officer
- Scientific Integrity Resource Guides
- 6th World Conference on Research Integrity

Composition of the ILSI Management Team Scientific Integrity Subcommittee

- Boon Yee Yeong, (Chair MT) ILSI Southeast Asia Region
- Alison Kretser (Chair), ILSI North America
- Ignacio Garamendi, ILSI Europe
- Isabelle Guelinck, ILSI Europe
- Andrew Roberts, ILSI Research Foundation
- Clara Rubinstein, ILSI Argentina
- Shawn Sullivan, ILSI
- Stephane Vidry, ILSI

Setting Priorities for our Scientific Integrity Work

5 major priorities were identified:

- Adoption to the Eight Guiding Principles by the ILSI Entities
- Preparation of an implementation plan
- Communications about ILSI's scientific integrity policies
- Guest Speaker on Scientific Integrity at ILSI Annual Meetings
- Consideration of an ILSI Scientific Integrity Officer

Setting Priorities for our Scientific Integrity Work

5 major priorities were identified:

- **Adoption to the Eight Guiding Principles by the ILSI Entities**
- Preparation of an implementation plan
- Communications about ILSI's scientific integrity policies
- Guest Speaker on Scientific Integrity at ILSI Annual Meetings
- Consideration of an ILSI Scientific Integrity Officer

ILSI Mandatory Policies on Scientific Integrity

Objectively Designed

Scientific research must be factual, transparent, and designed objectively with robust hypotheses.

Under Control of Scientific Investigators

Both the study design and the research itself must always be under the control of the scientific investigators.

No Renumeration

Scientific investigators must not be offered or accept remuneration geared to the outcome of the research project.

Freedom to Publish

ILSI entities must ensure that investigative teams have the freedom to publish research results without interference.

Full Disclosure

ILSI entities must require full disclosure of all financial interests of scientific investigators in publications and conference presentations.

No Undisclosed Authorship

ILSI entities must not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations.

Accessibility to All Data

ILSI entities must guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers.

Transparency of Afiliation

ILSI requires academic researchers who also act as contract researchers to clearly state their affiliations and publish under the auspices of the organization they are working for when undertaking studies.

Compliance with the 8 Principles on Scientific Integrity

- ILSI President—
  - Establishment of a formal process to ensure ILSI research (and publications) complies with the 8 Principles on Scientific Integrity
  - Recommendation to include standard language in the acknowledgment section of the manuscript

Setting Priorities for our Scientific Integrity Work

5 major priorities were identified:

- Adoption to the Eight Guiding Principles by the ILSI Entities
- **Preparation of an implementation plan**
  - **Policies & procedures to ensure compliance with scientific integrity best practices (Mandatory Policies)**
  - **Conduct Scientific Integrity Survey of the ILSI Entities**
  - **Develop training materials to keep ILSI staff, volunteers, and stakeholders well versed**
- Communications about ILSI's scientific integrity policies
- Guest Speaker on Scientific Integrity at ILSI Annual Meetings
- Consideration of an ILSI Scientific Integrity Officer

Scientific Integrity Survey of ILSI Entities

- Scientific Integrity Survey sent to each ILSI Entity
  - Addressing awareness among stakeholders
  - Policies in place to address scientific integrity
- The response rate was high, with 12 out of 17 responses
- Although answers vary considerably, there are some generalizable conclusions

Scientific Integrity Survey Result

- There is a high awareness of scientific integrity among Entities and their stakeholders
- Most Entities have an interest in scientific integrity
  - Most report that maintaining scientific integrity for their projects is not especially challenging
- Most Entities use a combination of ILSI's Mandatory Policies and peer review to ensure scientific integrity
  - These are likely adequate to ensure scientific integrity
  - But are probably not enough to proactively demonstrate scientific integrity to a skeptical public

Development of Training Materials on the ILSI Mandatory Policies

- Development of outline of the different modules discussed by the subcommittee (Q1 2020):
  1) Introduction to the ILSI organization and the federation of ILSI entities
  2) Scientific Integrity—What is it? What is the context for ILSI?
  3) ILSI's role as a scientific organization
  4) through 11) ILSI Mandatory Policies
- Intent is to leverage existing training materials in the development of our modules
- ILSI South Andean has offered to help translate training materials (Q2 2020)
- Pilot test with ILSI staff (Q1 2020)

Setting Priorities for our Scientific Integrity Work

5 major priorities were identified:

- Adoption to the Eight Guiding Principles by the ILSI Entities
- Preparation of an implementation plan
- **Communications about ILSI's scientific integrity policies**
  - **Develop a shared definition of scientific integrity**
  - **ILSI Annual Meetings**
  - **6th World Conference on Research Integrity 2-6 June 2019 in Hong Kong**
- Guest Speaker on Scientific Integrity at ILSI Annual Meetings
- Consideration of an ILSI Scientific Integrity Officer

Shared Definition of Scientific Integrity

"The condition that occurs when persons adhere to accepted standards, professional values, and practices of the relevant scientific community. Adherence to these standards ensures objectivity, clarity, and reproducibility, and utility of scientific and scholarly activities and assessments and helps prevent bias, fabrication, falsification, plagiarism, outside interference, censorship and inadequate procedural and information security."

Setting Priorities for our Scientific Integrity Work

5 major priorities were identified:

- Adoption to the Eight Guiding Principles by the ILSI Entities
- Preparation of an implementation plan
- Communications about ILSI's scientific integrity policies
- **Guest Speaker on Scientific Integrity at ILSI Annual Meetings**
    - **2019 ILSI Annual Meeting, Dr. Lex Bouter, Netherlands**
    - **2020 ILSI Annual Meeting, "Who is an Expert? Who gets to decide?"**
- Consideration of an ILSI Scientific Integrity Officer

2020 ILSI Science Symposium: Who is an Expert, Who Gets to Decide?

1. Defining the issues—Sylvia Rowe, SR Strategy
2. Policy Panel Selection Processes in North America—Ann Yaktine, Director of the Food and Nutrition Board of the National Academies of Sciences, Engineering, and Medicine
3. Expertise of Policy Panels—Connie Weaver, Purdue University Distinguished Professor Emerita
4. Role of Public-Private Partnerships—Alan Boobis, Professor Emeritus of Toxicology, Imperial College London (unconfirmed)
5. Panel Discussion

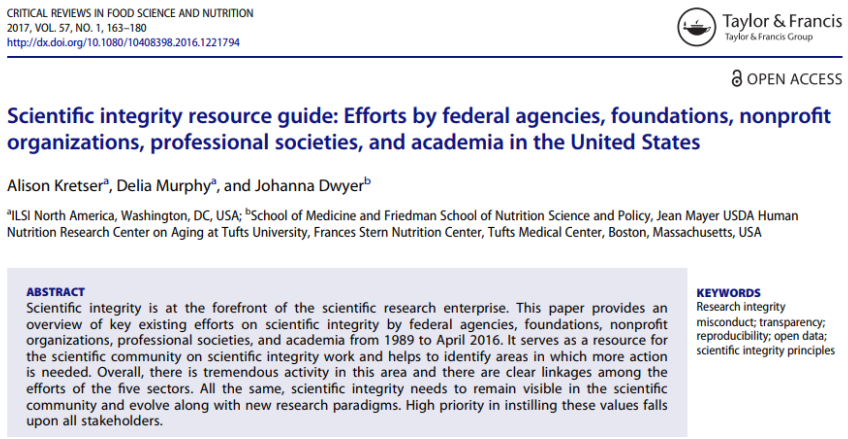
Setting Priorities for our Scientific Integrity Work

5 major priorities were identified:

- Adoption to the Eight Guiding Principles by the ILSI Entities
- Preparation of an implementation plan
- Communications about ILSI's scientific integrity policies
- Guest Speaker on Scientific Integrity at ILSI Annual Meetings
- **Consideration of an ILSI Scientific Integrity Officer**
  - **ILSI Global Board approved part-time position January 2019**
  - **Appointed a Scientific Integrity Officer March 2019**
  - **Scientific Integrity Officer will serve all the ILSI entities**

Scientific Integrity Resource Guide

- ILSI North America published a Scientific Integrity Resource Guide in 2016



CRITICAL REVIEWS IN FOOD SCIENCE AND NUTRITION
2017, VOL. 57, NO. 1, 163–180
http://dx.doi.org/10.1080/10408398.2016.1221794

Taylor & Francis
Taylor & Francis Group

OPEN ACCESS

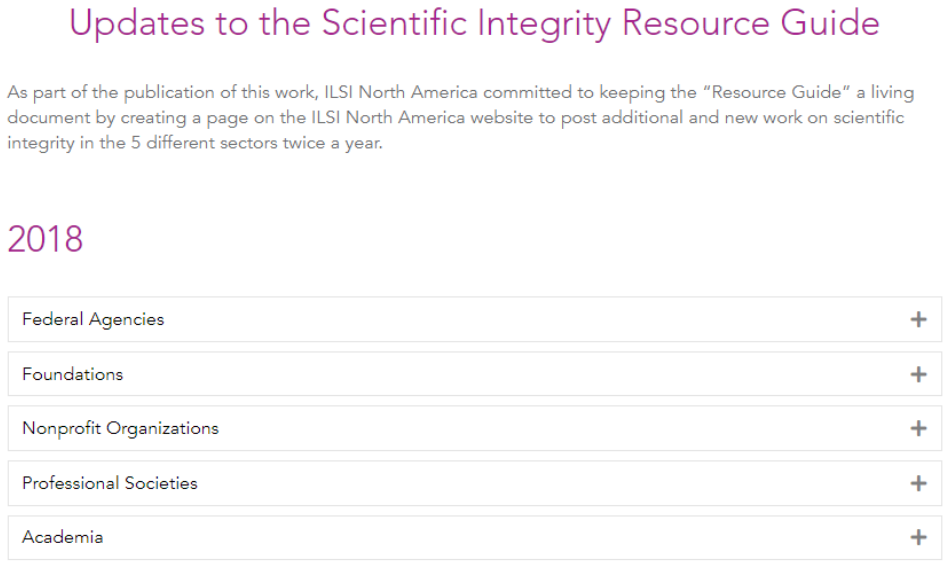
Scientific integrity resource guide: Efforts by federal agencies, foundations, nonprofit organizations, professional societies, and academia in the United States

Alison Kretser[a], Delia Murphy[a], and Johanna Dwyer[b]

[a]ILSI North America, Washington, DC, USA; [b]School of Medicine and Friedman School of Nutrition Science and Policy, Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University, Frances Stern Nutrition Center, Tufts Medical Center, Boston, Massachusetts, USA

ABSTRACT
Scientific integrity is at the forefront of the scientific research enterprise. This paper provides an overview of key existing efforts on scientific integrity by federal agencies, foundations, nonprofit organizations, professional societies, and academia from 1989 to April 2016. It serves as a resource for the scientific community on scientific integrity work and helps to identify areas in which more action is needed. Overall, there is tremendous activity in this area and there are clear linkages among the efforts of the five sectors. All the same, scientific integrity needs to remain visible in the scientific community and evolve along with new research paradigms. High priority in instilling these values falls upon all stakeholders.

KEYWORDS
Research integrity misconduct; transparency; reproducibility; open data; scientific integrity principles



Updates to the Scientific Integrity Resource Guide

As part of the publication of this work, ILSI North America committed to keeping the "Resource Guide" a living document by creating a page on the ILSI North America website to post additional and new work on scientific integrity in the 5 different sectors twice a year.

2018

- Federal Agencies +
- Foundations +
- Nonprofit Organizations +
- Professional Societies +
- Academia +

ILSI

Scientific Integrity Resource Guide

- Scientific Integrity Subcommittee developed “How To” Manual on Developing a Resource Guide

- ILSI Entities Developing their Own Resource Guide on Scientific Integrity
  - ILSI Southeast Asia
  - ILSI Global
  - ILSI Europe
  - ILSI Argentina (identifying resources)

6th World Conference on Research Integrity
2-6 June 2019

– Poster on ILSI's scientific integrity activities was presented at the conference

6th World Conference on Research Integrity

The Hong Kong Principles for Assessing Researchers: Fostering Research Integrity

- Draft shared with MT Scientific Integrity Subcommittee
- Submitted comments on 26 April to WCRI
- Additional input gathered from the WCRI conference participants at 2 sessions held during the conference.
- Third draft posted on the conference website on 9 September
  - http://wcri2019.org/index/programme/focus-tracks
  - Scientific Integrity Consortium's manuscript is cited
  - Manuscript will be submitted for publication

ILSI

6th WCRI 2019

6th World Conference on Research Integrity
2-6 June 2019 in Hong Kong

The WCRI Singapore Statement on Research Integrity

- Released after the 2nd WCRI, September 2010
- 4 components: Honesty, accountability, professional courtesy and fairness, duty of care
- During the 6th WCRI, Singapore Statement was updated to include 2 new components: transparency (in the research process and in the presentation of results) and clarity of communications

ILSI

6th WCRI 2019

Concluding Remarks

USDA SCIENTIFIC INTEGRITY POLICY

Instilling Public Confidence in USDA Research and Science-Based Decisions

APPLICABILITY

All USDA employees, *political and career*, who conduct or supervise scientific activities, and/or analyze, publicly communicate, or utilize information derived from scientific activities.

KEY POINTS

Scientific findings and products must not be suppressed or altered for political purposes and must not be subjected to inappropriate influence.

Ensure the quality, accuracy, and transparency of scientific information used in decision-making.

- Use scientific information derived from well-established scientific processes.
- Ensure that scientific data and research undergo independent peer review by qualified experts.
- Reflect scientific information appropriately and accurately.
- Make scientific findings that are relied upon publicly available online and in open formats.

USDA scientists may communicate their scientific findings objectively without political interference or inappropriate influence.

- When publicly communicating findings in their official capacities, USDA scientists should *refrain from making judgments or recommendations on Federal policy.*

USDA scientists are encouraged to participate in communications with the media regarding their scientific findings.

- Scientists should *coordinate media opportunities* with their supervisors & public affairs offices.

USDA scientists are encouraged to interact with the broader scientific community.

- Such interactions must be consistent with Federal rules of ethics, job responsibilities, and existing agency policies.

USDA employees who uncover and report allegations of compromised scientific integrity in good faith must not be subjected to retaliation for reporting such allegations.

CONTACT INFORMATION

For questions or to report a scientific integrity concern, USDA employees should contact their Agency Scientific Integrity Officer or the Department Scientific Integrity Officer (DSIO).

Contact information and other resources may be found on the Office of the Chief Scientist Website.

The DSIO may be reached directly by email at researchintegrity@usda.gov

Questions?

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

Act on promotion of “FOOD LOSS” reduction in Japan

Fumiko Sekiya ILSI Japan

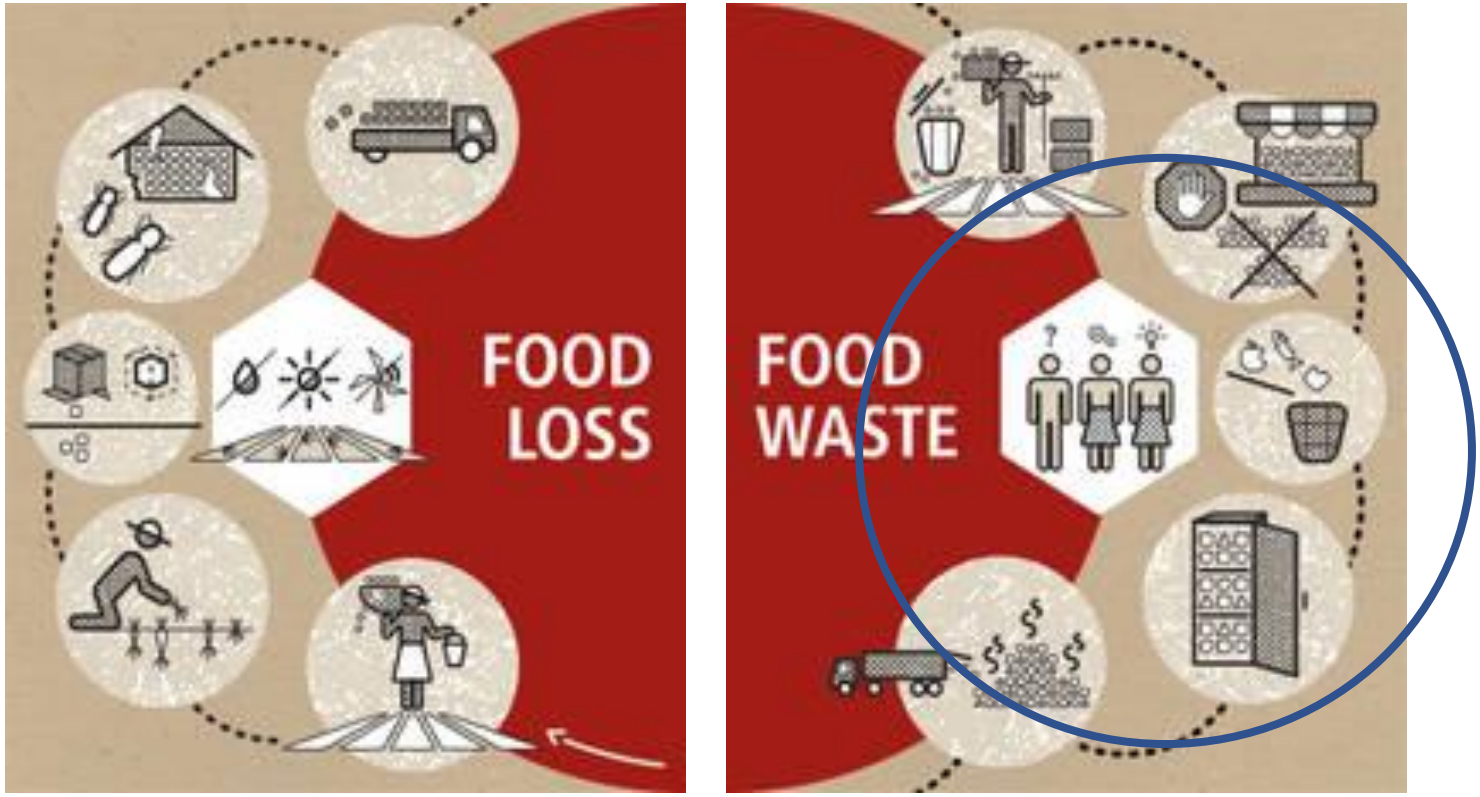
Sep. 26, 2019

ILSI BeSeTo meeting@Penang

Note:

- In this presentation, the term “フードロス(FOOD LOSS)”means “waste of foods that still be edible*”.

  * In FAO definition, it is classified into “food waste”.

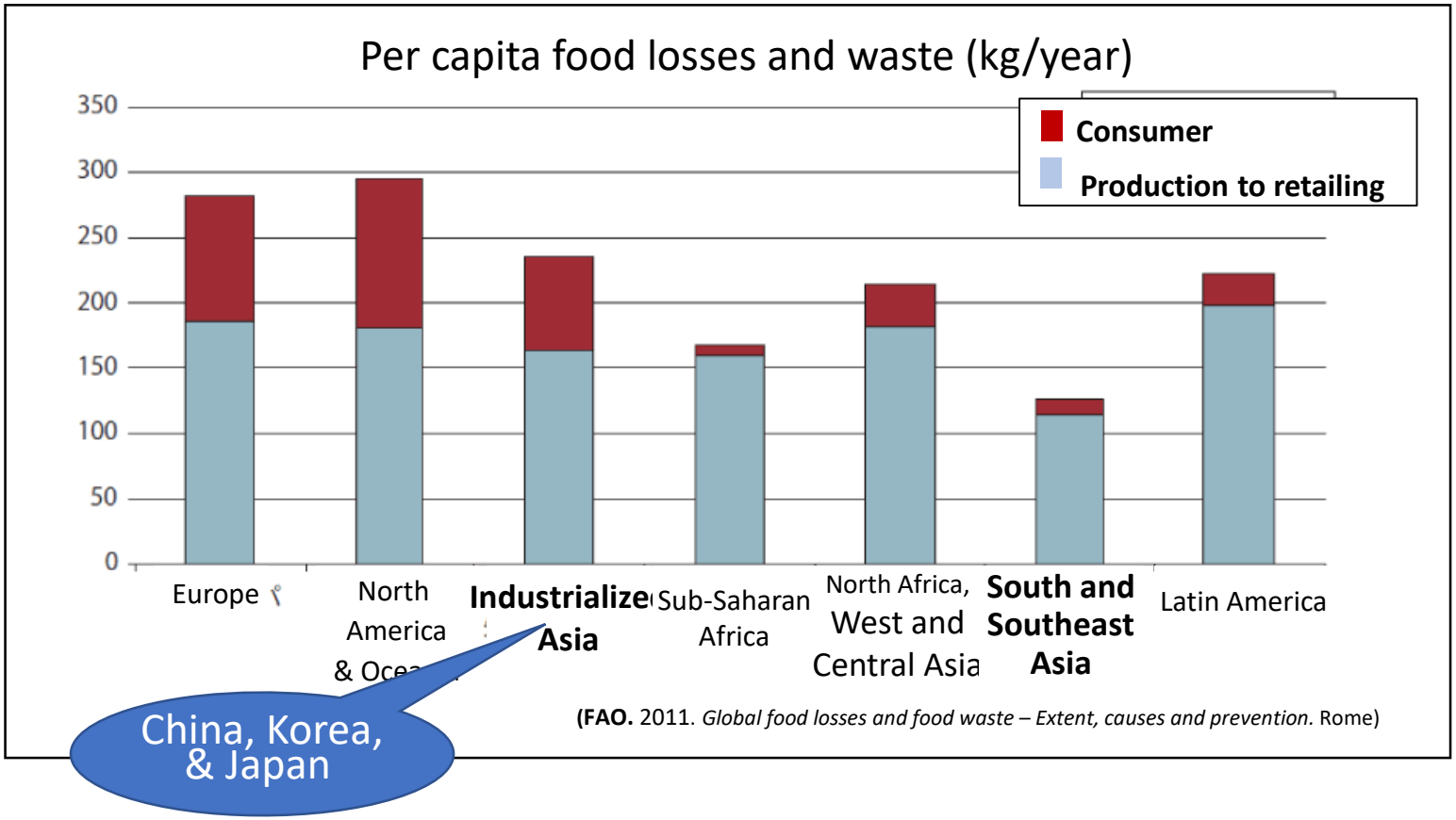


(Pictures from: http://www.fao.org/platform-food-loss-waste/en)

Background info:

--- global Loss & Waste volume ≒ 1.3 billion ton/year

(1/3 of edible parts of food produced for human consumption)



- "FOOD LOSS" in Japan: 6.4million ton/year
  - About 45% is wasted @consumer level

Why is “FOOD LOSS” a problem in Japan?

Economically,

- High cost in disposal
- Highly rely on import (Self-sufficiency ratio: 38%)
- Can not expand the harvest area

Ecologically,

- CO_2 and ashes derived from incineration of wastes have a negative impact on the environment

and Ethically,

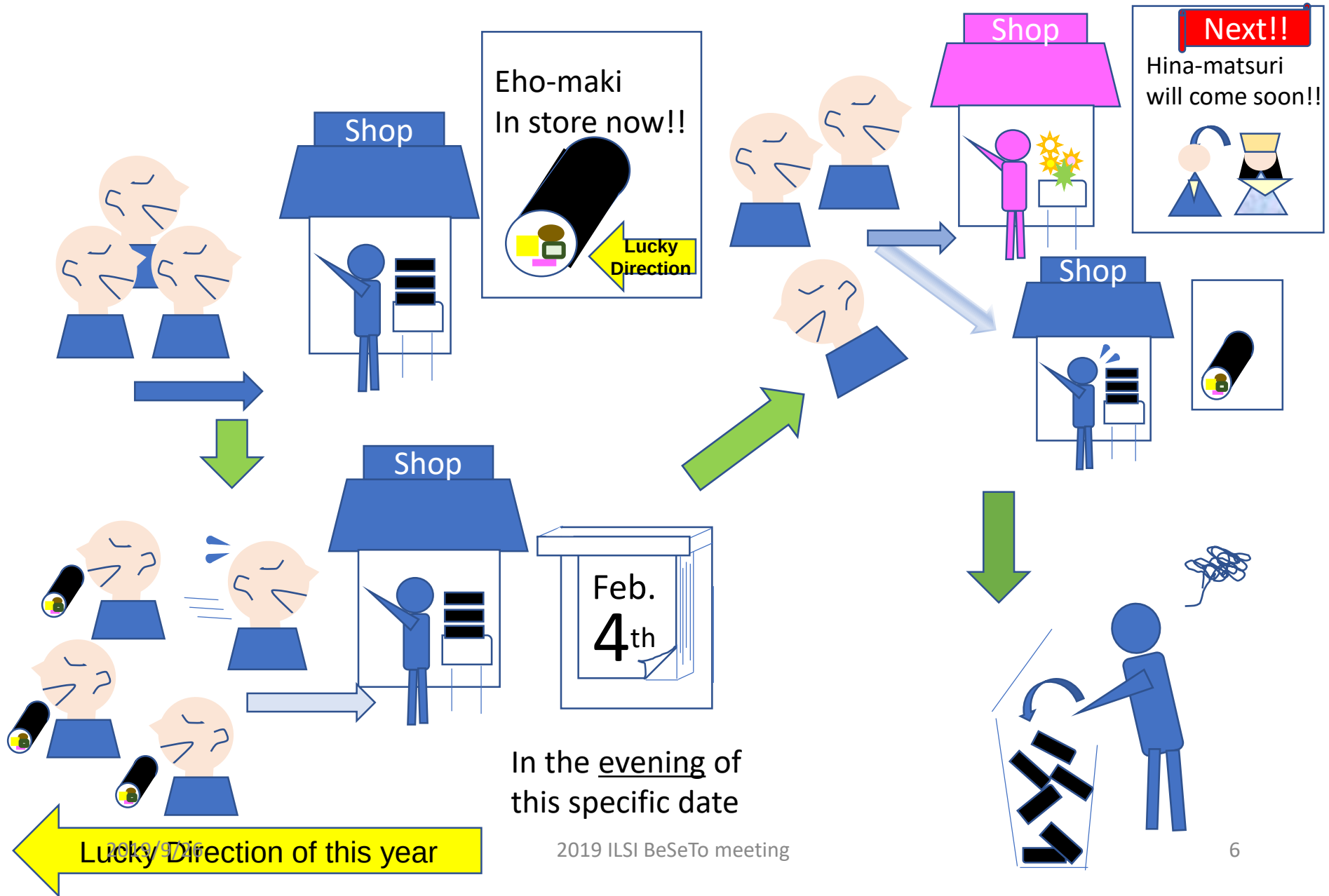
- Non-balanced distribution--- 1in7 children are in hunger

Plus

- Japanese culture-specific background:
  - Strong demand on “high” quality (shape, size, etc.)
  - Interest in seasonal events + Heat up & Cool down easily

⇒leads to waste of special foods for specific event

Example: Eho-maki (special sushi roll for the good fortune)



Efforts in the past:

- Establishment of Food recycle act
- Several project had started at MAFF, MoE since2014

  Example: Eho-maki:MAFF issue a notification recommending to stake holder to take actions to reduce the discard of Eho-maki
  http://www.maff.go.jp/kinki/keiei/syokuhinkigyo/syokuhin_recycle/attach/pdf/syokuri_index-1.pdf (Jpn.)

  But as a result, the waste volume was not so reduced.

★ Needs more promotion at national level

⟶ establishment of

"FOOD LOSS reduction promotion act"

Date of publication: May 31st, 2019

Will be effective within 6 months from publication

“FOOD LOSS reduction promotion act”(FLRPA) : summary

- Responsibility of Government: to plan and act related implement regulations
- Responsibility of Local authorities：while in corporation with government and other local authorities, to plan and act related implement local regulations considering its specific circumstances
- Responsibilty of Industries/distributers：
  - To try to contribute in enactment of above-mentioned regulations
  - To act proactively to reduce “FOOD LOSS”
- Role of consumers：
  - To enhance interest and understanding of the importance of “FOOD LOSS”-reduction
  - To act voluntary to reduce “FOOD LOSS” by reconsider one’s behavior in food purchase, brushing up the way of cook, etc.
- Set one-month promotion event in October, in order to enhance the interest and understanding of consumer/industries

FLRPA : summary(2)

- Basic plan

  1) promote education and learning of Consumers and Industries about “FOOD LOSS” reduction

  2) support the activities by Food-related business

  3) Commendation for those with outstanding achievements

  4) to research on current situation of “FOOD LOSS” and effective activities of reduction of “FOOD LOSS”

  5) to collect and distribute of information: e.g. advanced activities, etc.

  6)To support “FOOD BANK” system/activities, investigate / examine the responsibilities that arise from supporting food bank activities and providing food for food bank activities

Examples of actions in each stakeholders:

1）Local authorities

- Reduce the food discard in corporation with local restaurants
- Promote a nation-wide “clear your plate” action through enhance the connection with other authorities

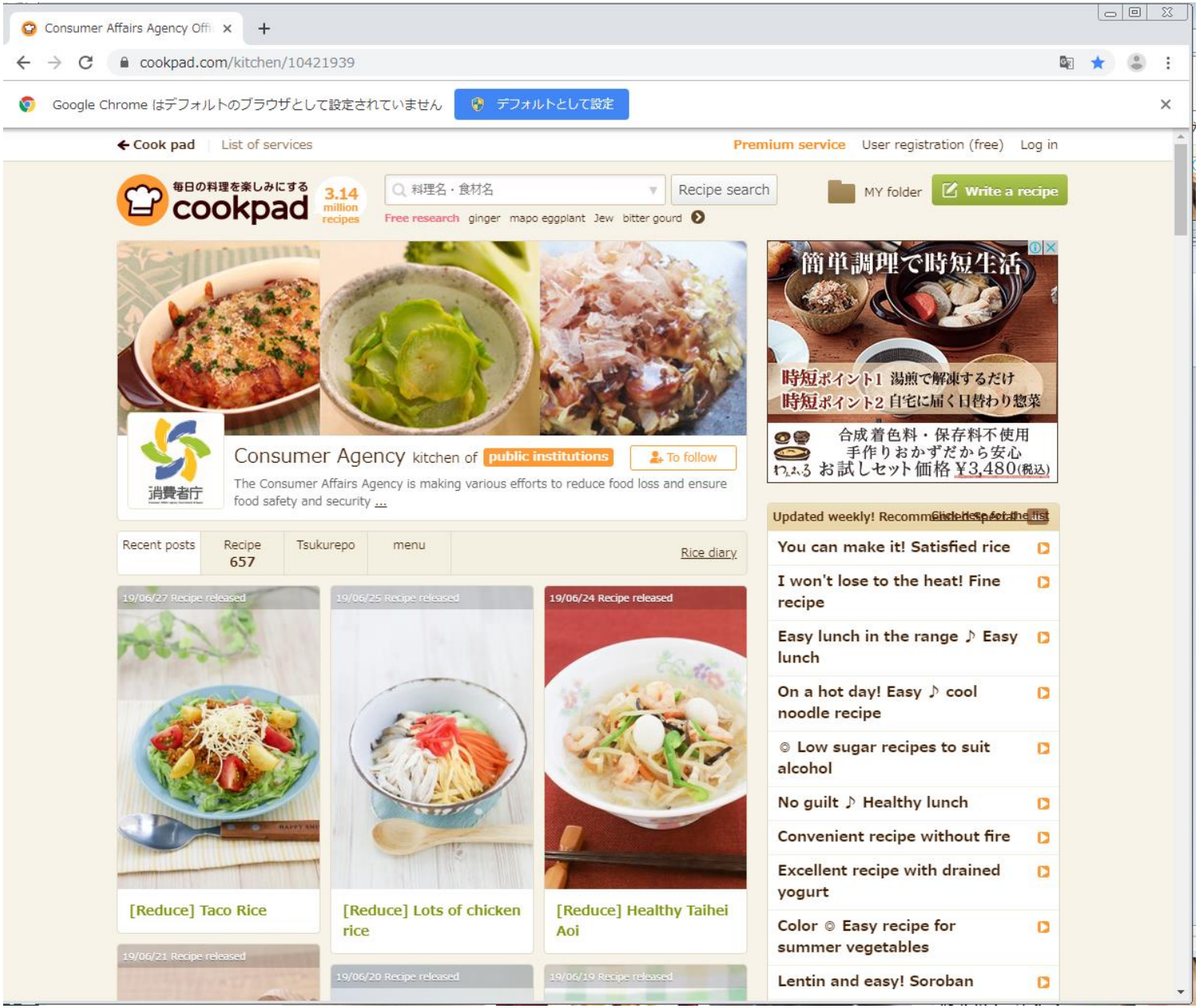
2）Industries/Distributers

- Effort for extending the period of “quality assured” by advancing the quality of packaging/vessels
- Prevent leftovers by serving small-size packaging
- Developing IT-supported food tracking services in corporations between System-developers and food restaurants
- Considering to change the date-of- expired declaration format from Y/M/D to Y/M for some food categories(under discussion)
  ＊ also under consideration at the government side

3）Schools/Universities

- Develop recipes helpful for the reduction of “FOOD LOSS”.
- Educational activities in local events, free paper, etc.
- Contribution to FOOD BANK　　etc.

https://cookpad.com/kitchen/10421939



To achieve SDG 12.3…..

!Promote “Mottainai”!

Wangarĩ Muta Maathai
(1940-2011)

THANK YOU!

By 2030, halve per capita global food waste at the retail and consumer levels and reduce food losses along production and supply chains, including post-harvest losses.

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

African Swine Fever in China

Wendy Gao
Cargill Hong Kong Ltd.
September 26th, 2019

Agenda

- ✓ ASF Outbreak in China
- ✓ ASF Prevention and Control
- ✓ ASF Impact

ASF Outbreak in China

- African Swine Fever (ASF) is a fetal animal disease affecting pigs and wild boars with up to 100% mortality.
- No effective vaccine is available.
- It is a very serious health risk to pigs, but not to human beings.
- ASF virus is sensitive to high temperature. The survival days of ASF in blood are 18 months at 4°C, 15 weeks at room temperature, 70 minutes at 56°C, 30 minutes at 60°C.
- The first ASF outbreak was in Shenyang, Liaoning Province in August, 2018. The pig-seller managed to avoid of quarantine and inspection, illegally trading infected pigs.

ASF Outbreak in China

From 02/08/2018 to 11/09/2019

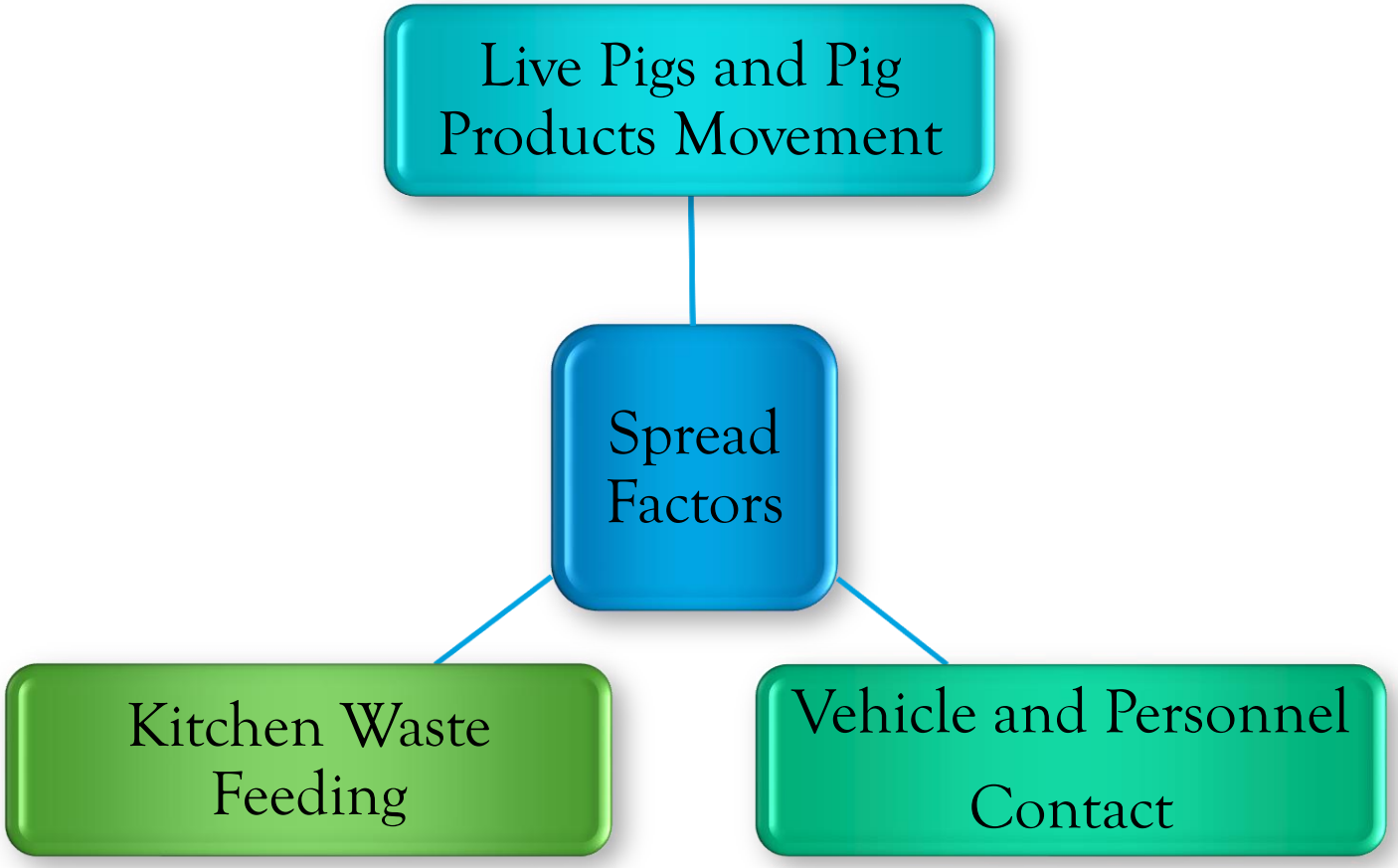
- A total number of 157 ASF outbreaks in 32 provinces(cities) in China.

Continuing ASF outbreak provinces
ASF epidemic area have been released
Non-ASF area

Source: ***MARA***

ASF Outbreak in China

Main Transmission Routes of ASF Outbreaks



ASF Prevention and Control

Live Pigs and Pig Products Movement Control

- Restrict the movement of live pigs and pig products without high temperature treatment for the provinces having ASF outbreaks (MARA Notification, Aug 8, 2018).
- Restrict the movement of live pigs for the provinces neighboring to the province having ASF outbreaks, and close the live pig trading markets of the province having ASF outbreaks (MARA Notification, Sept 11, 2018).

ASF Prevention and Control

Ban Kitchen Waste Feeding

- ✓ Ban the kitchen waste feeding at national wide (State Council Notification, Oct 18, 2018).

Vehicles Management

- ✓ Proper conditions during the transportation; GPS in the vehicle for cross-province movement tracing; Strict cleaning and disinfection before and after loading (MARA Circular No. 79, Oct 31, 2018).

ASF Prevention and Control

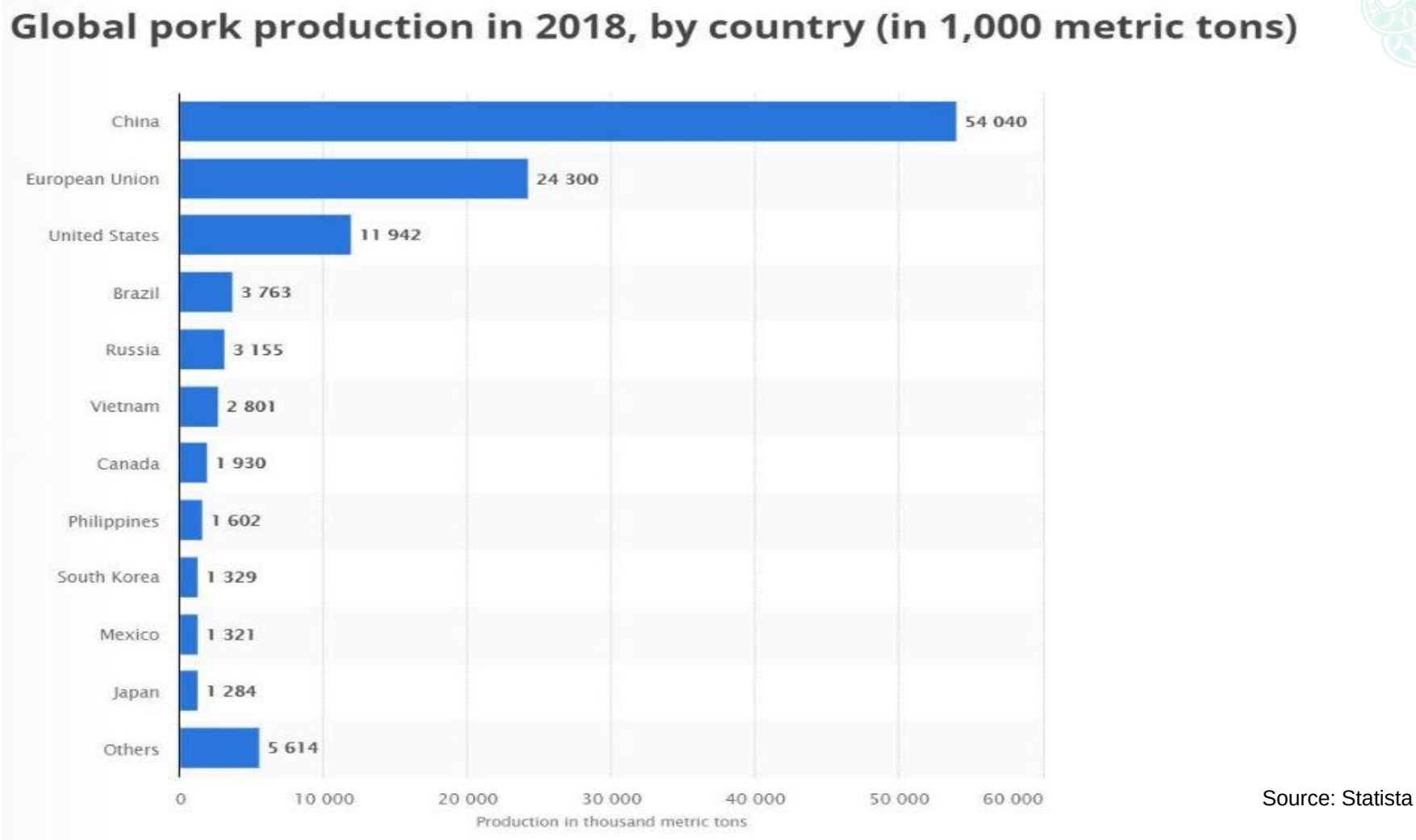
Other Measures

- ✓ Strengthen the inspection on slaughtering
  - ➢ ASF Testing for each batch of products in slaughterhouse is required since Feb 1, 2019. The animal health certificate is issued for the products whose ASF testing result is negative and confirmed by the resident official veterinarian. (MARA Circular No. 119, Jan 2, 2019)
- ✓ Pig product producers should check the animal health certificate and ASF testing result of the pig raw materials (MARA&SAMR Circular No. 17, Apr 3, 2019).
- ✓ Collaboration with all stakeholders nationally as well globally.

ASF Impact

- Although ASF does not directly impact human health, it has big negative impact on social stability, economics and food safety.
- China is the biggest country of pork production and consumption.
  - In 2018, China's pork production is 54,040,000 metric tons, and pork consumption 55,900,000 metric tons.
  - In China, the pork production accounts for more than 60% of the total meat production.
  - The most commonly consumed meat in China is pork.

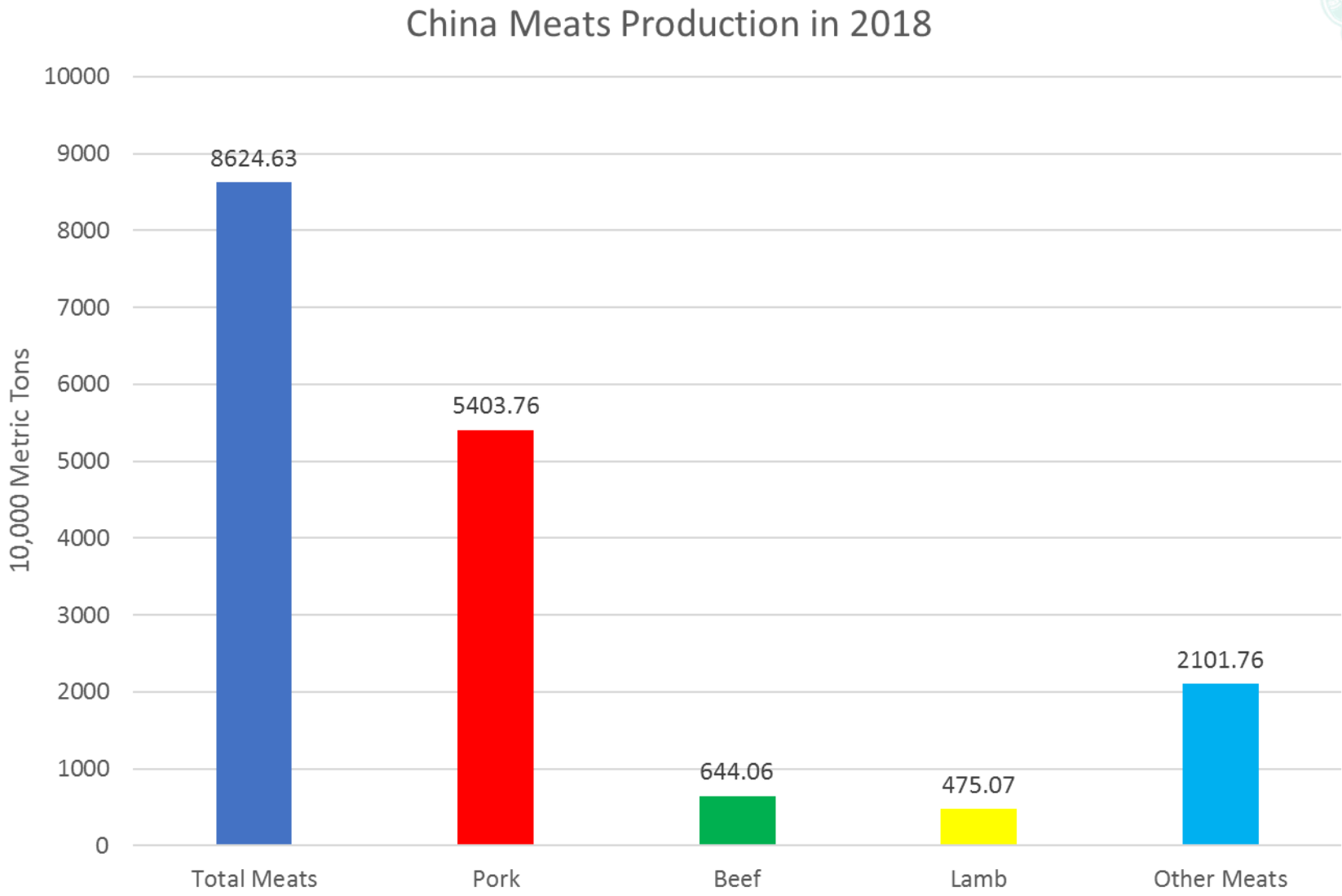
ASF Impact



Source: Statista

China held the first position in 2018. Its pork production was twice as much as the EU's.

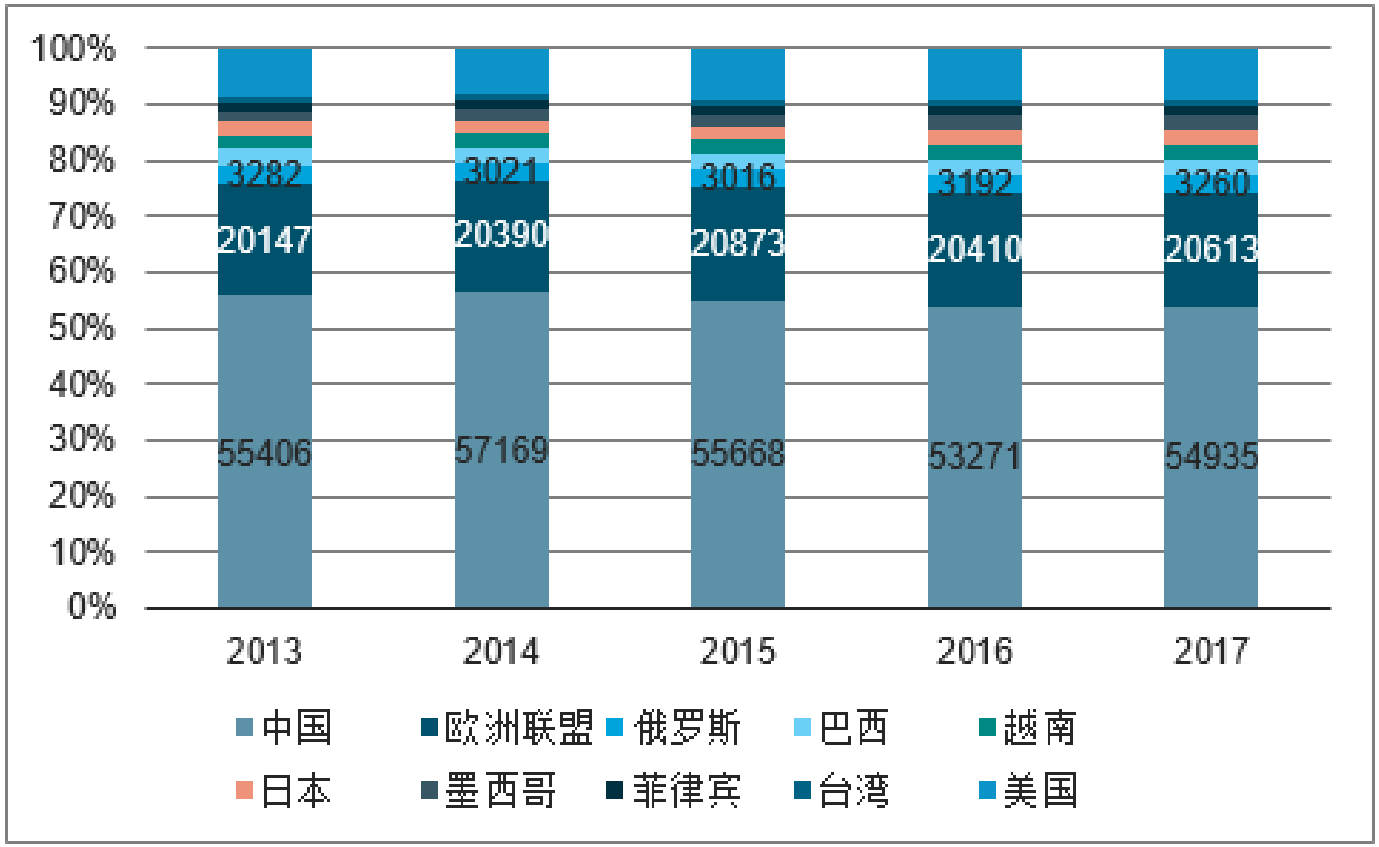
ASF Impact



Source: National Bureau of Statistics of China

ASF Impact

Global Pork Consumption in 2013-2017 by Country (in 1,000 Metric Tons)



Source: Public Data

ASF Impact

- The pork price is significantly increasing. According to the data of National Bureau of Statistics of China , in July, 2019, CPI achieved year-on-year growth of 2.8%. The pork price had year-on-year growth of 27%, which contributed 0.59% to the 2.8% of CPI year-on-year growth.
  - A large amount of suspected infected pigs are killed. The live pig supply has largely reduced.
  - More ASF testing as well as cleaning and disinfection requirements in the food chain leads to the increase of pig production cost.
- Farms has reduced pig breeding. It is expected the pork price will continue to rise in the next couple of years.

ASF Impact

- The China's food supply is increasingly affected by ASF. (1)
  - On February 15, 2019, three batches of frozen pork dumplings produced by Sanquan Company were suspected to be ASF virus nucleric acid positive. Sanquan is one of China's top frozen food brands.
  - Sanquan immediately recalled all products suspected of contamination with ASF.
  - The company's share price fell sharply by 3.58% on February 15, 2019.
  - Big damage to consumers' trust on Sanquan brand foods

ASF Impact

- The China's food supply is increasingly affected by ASF. (2)
  - Other Chinese food products have also been found being suspected to contain ASF since the Sanquan incident. Consequently, the government issued stricter rules for slaughterhouses including a requirement on ASF testing for each batch of products.
  - Consumers worry about eating infected port although ASF does not present a human health risk.
  - The government has issued dozens of notifications to strengthen the ASF inspection. However, the communication to public is not in place to avoid of the rumors leading to food safety perceptions and consumption disruption.

ASF Impact

- The need on the consumption of other meats such as beef and chicken is increasing, which leads to the price increase of other meats.
- Have negative impact on pork products export.
- ASF prevention and control is a long term battle and needs lots of social resources.

Thank you
for your attention!

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

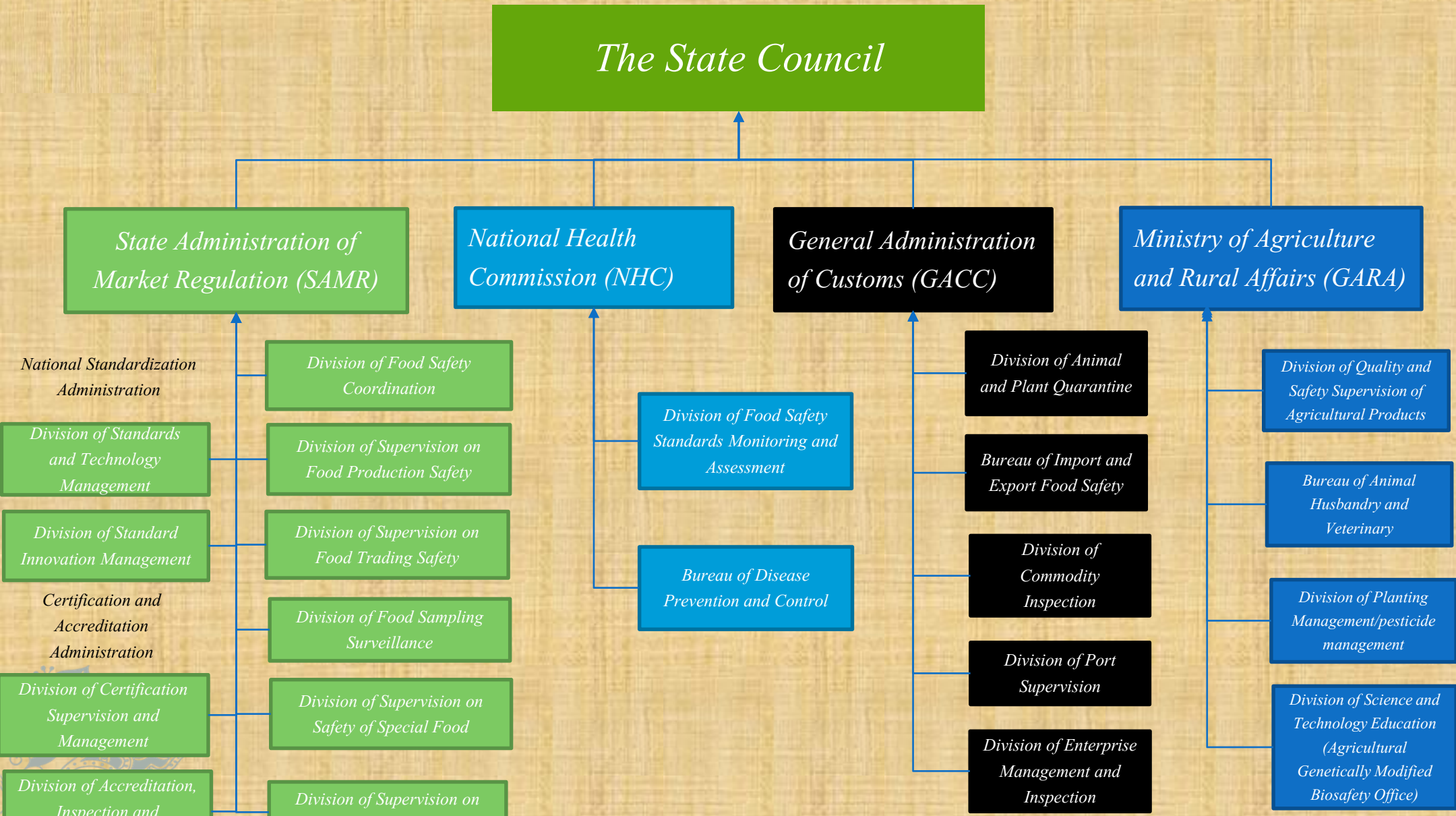
The New China National Food Control System

Leon Liu, Qinxuan

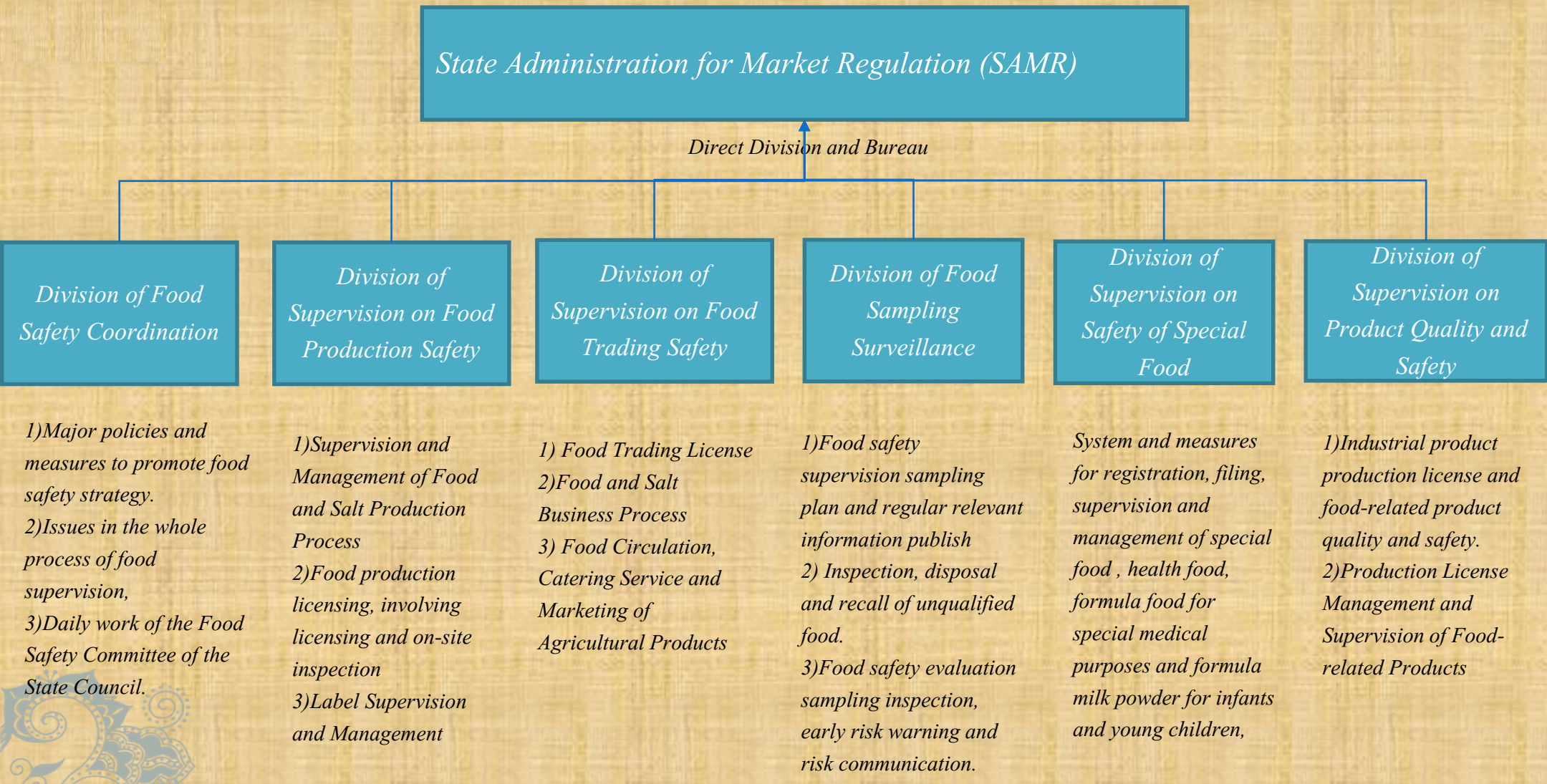
International Flavors & Fragrances (China) Ltd.

11th BeSeTo Meeting, Penang, Malaysia

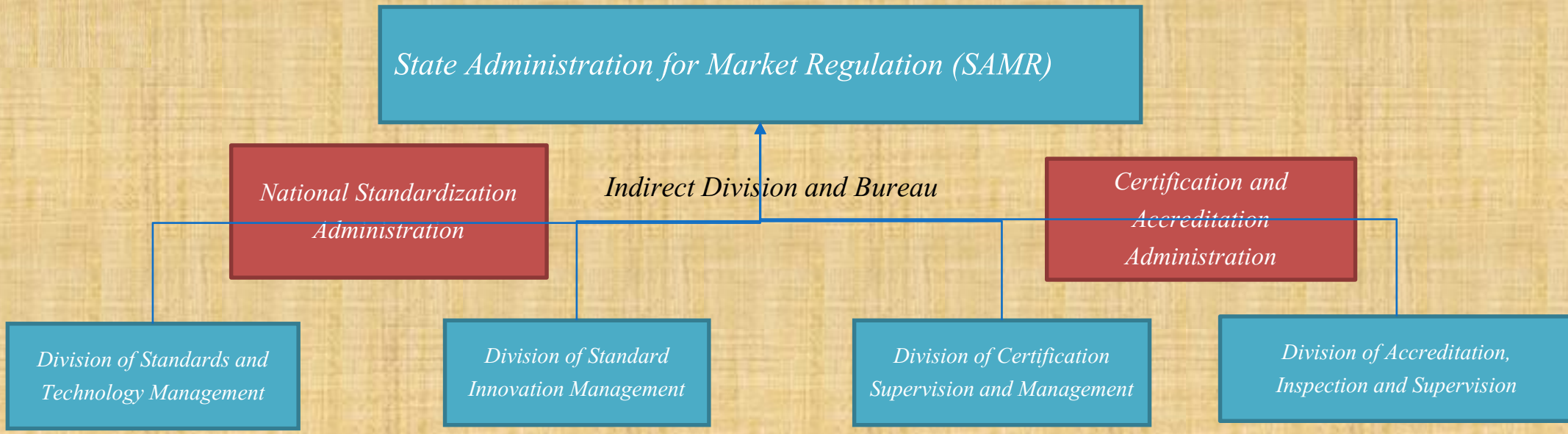
Overview of the New Authorities



State Administration of Market Regulation (SAMR)



State Administration of Market Regulation (SAMR)



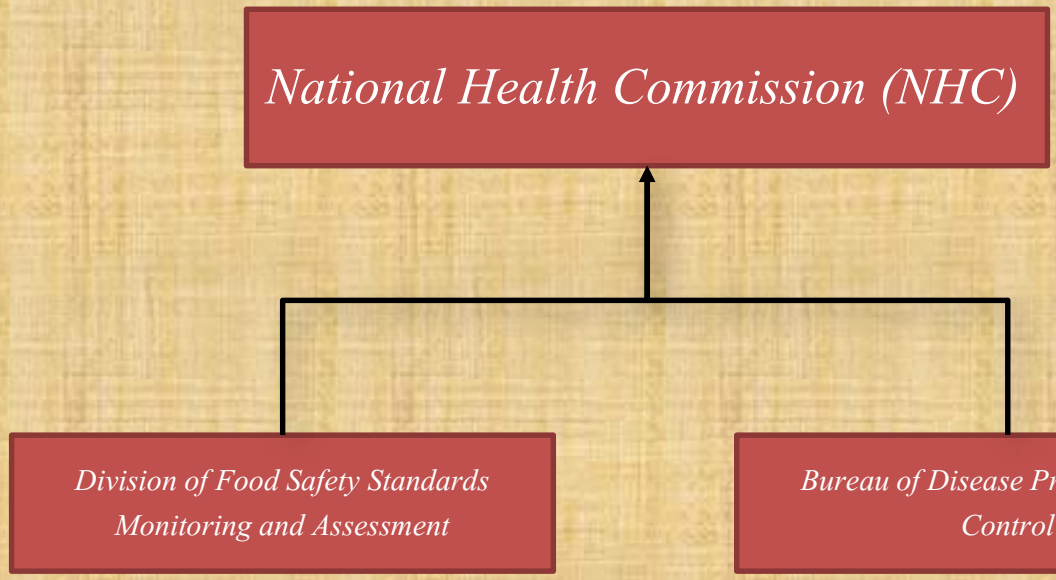
1)Standardization strategies, plans, policies and management systems
2)Mandatory national standards, recommended national standards (including standard samples) and international standards related work
3)National Technical Committee for Professional Standardization.

1)Industry standards, local standards, group standards, enterprise standards
2)Certification of uniform social credit codes of legal persons and other organizations
3)Commodity bar code work.

1)Supervision and management system of certification and conformity assessment.
2)Development of certification industry
3)Activities of international or regional organizations for certification and conformity assessment.

1)Supervision and management system of accreditation and inspection.
2)Integration and reform of inspection and testing resources
3)plan and guide the development of inspection and testing industry

National Health Commission (NHC)



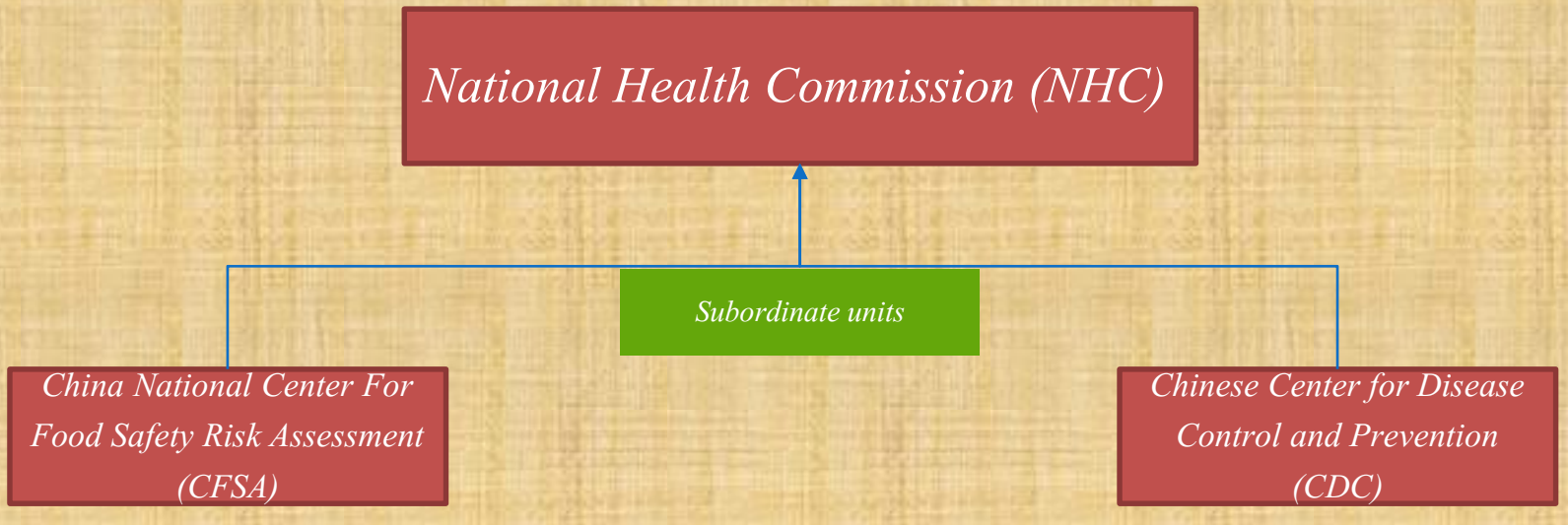
- Draft and renew National Food Safety Standards
- Approval of new food materials
- Approval of new food additives
- Approval of new food related materials
- Food-borne disease surveillance and traceability
- Food Safety Risk assessment

National food safety standards, food safety risk monitoring, assessment and communication, and safety assessment of new food materials, new food additives and new food-related materials.

Major disease prevention and control plans, national immunization plans and interventions plan for diseases, improve disease prevention and control system, and publication of epidemic information on infectious diseases.

- Prevention and control of foodborne diseases
- Information Circular on foodborne diseases

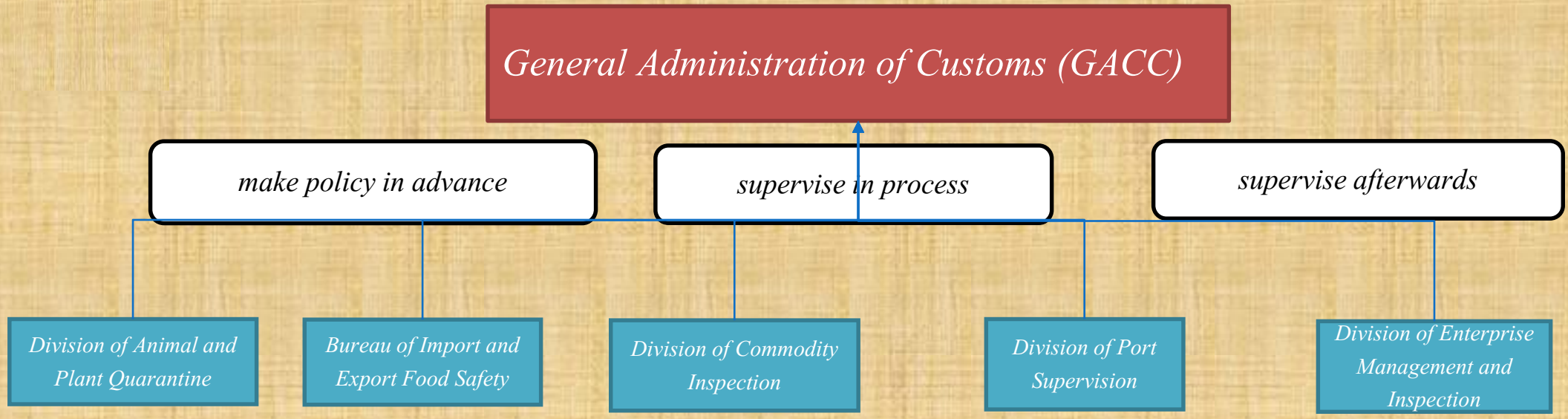
National Health Commission (NHC)



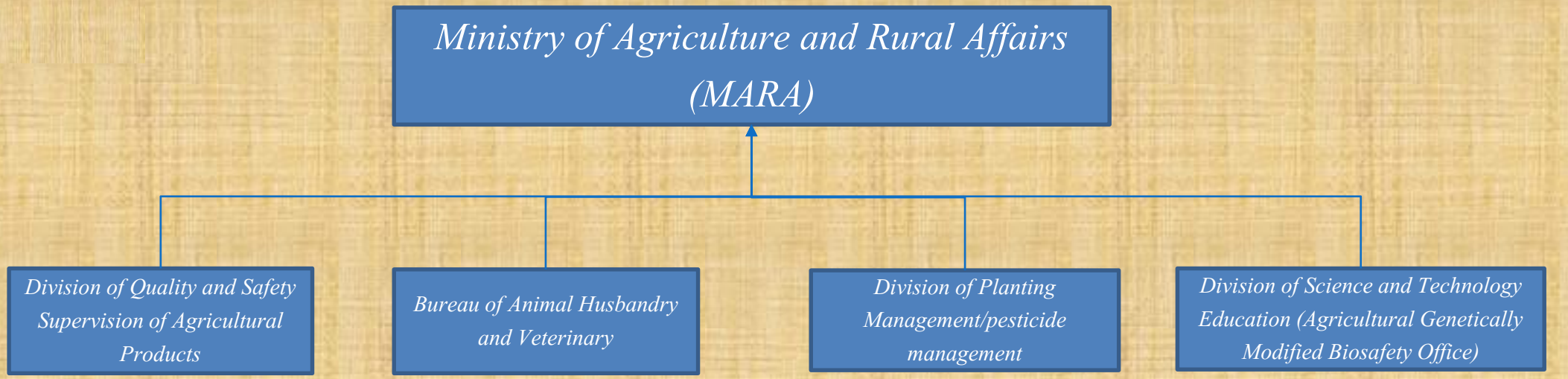
1)National food safety risk monitoring plan, carry out food safety risk monitoring work, and submit monitoring data and analysis results.
2)Technical guidance for food safety risk assessment; to undertake relevant work on food safety risk assessment;
3)To communicate the information about food safety risk assessment, food safety standards etc.
4)Secretariat work of the National Food Safety Risk Assessment Committee on and the National Food Safety Standards Committee

1)National public health monitoring system
2)Public health monitoring on nutritional food, labor, environment, radiation and school hygiene, as well as infectious diseases, endemic diseases, parasitic diseases, chronic non-communicable diseases and occupations.
3)Epidemiological surveillance of occurrence, development and distribution of major diseases, and provide preventive and control measures.

General Administration of Customs (GACC)



Ministry of Agriculture and Rural Affairs (MARA)



1)Quality and Safety of Agricultural Products
2)Agricultural product safety and quality standards
4) Revision of Standards for Residues of Veterinary Drugs

1) Development of Animal husbandry, feed industry etc.
2) Quality and Safety of livestock and poultry slaughtering, feed, raw milk
3)Registration, Approval and Management of Veterinary Drug, veterinary drug quality
4)Promoting Antibiotics Reduction

1)Fertilizer and pesticides, of pesticide Registration and quality
2)Revision of standards of residues of pesticides
3) Promoting Zero Growth of Pesticides

1)Safety Assessment and Management of Agricultural Genetically Modified Organisms
2) Formulation and Revision of Policies and Laws for Agricultural Genetically Modified Organisms
4) Management of Testing, Production and Processing of Agricultural Genetically Modified Organisms

THANK YOU FOR YOUR ATTENTION

Leon Liu, Qinxuan

leon.liu@iff.com

IFF (China) Ltd.

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

Pulmuone

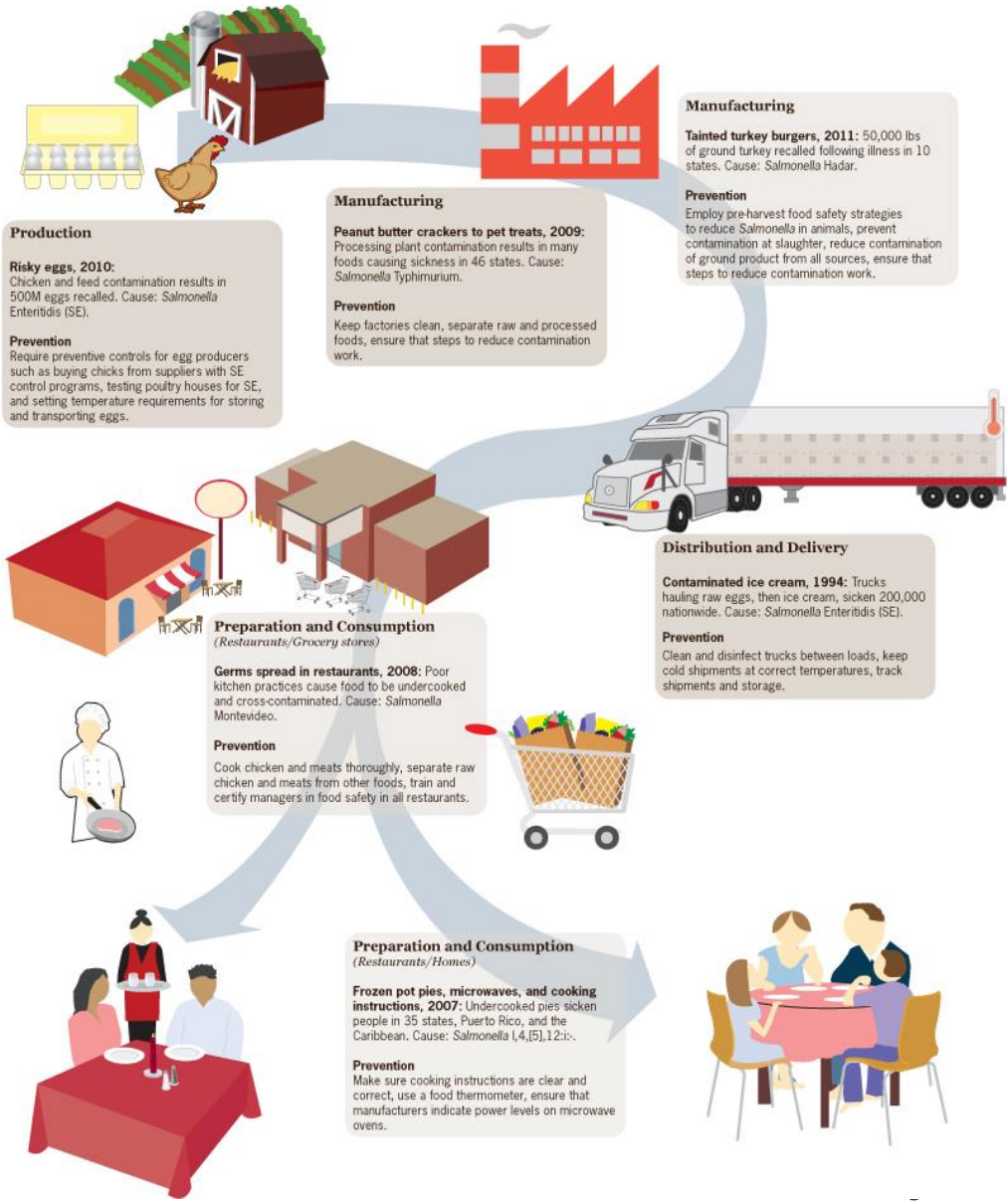
Cold-chain System and Food Safety in Korea

SangWoo Cho, Ph.D.
R&D Center of Pulmuone Co., Ltd.
2019. 09. 27.

Definition of Cold Chain System

The term cold chain or cool chain denotes the series of actions and equipment applied to maintain a product within a specified low-temperature range from harvest/production to consumption. A cold chain is a temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of refrigerated production, storage and distribution activities, along with associated equipment and logistics, which maintain a desired low-temperature range. It is used to preserve and to extend and ensure the shelf life of products, such as fresh agricultural produce, seafood, frozen food, photographic film, chemicals, and pharmaceutical drugs.

From: Wikipedia

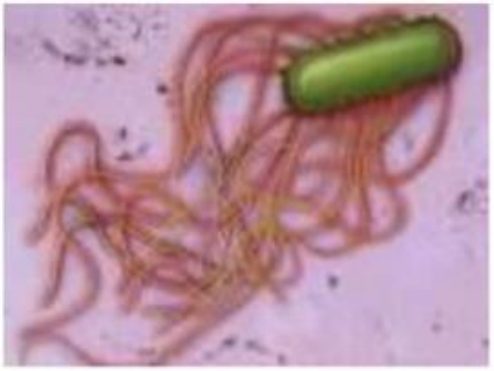


Necessity of cold chain

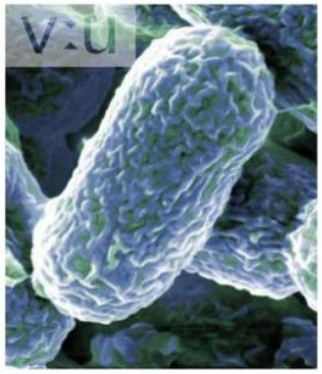
◆ Keep food fresh and extend the shelf life to reduce food waste

◆ Prevent growth of pathogenic bacteria and food poisoning

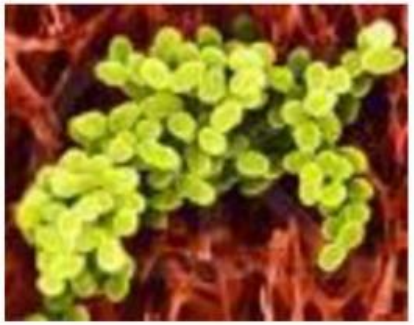
Salmonella



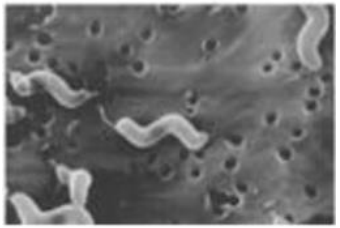
E. coli O157:H7



Staphylococcus aureus



Campylobacter jejuni



Global cold chain market

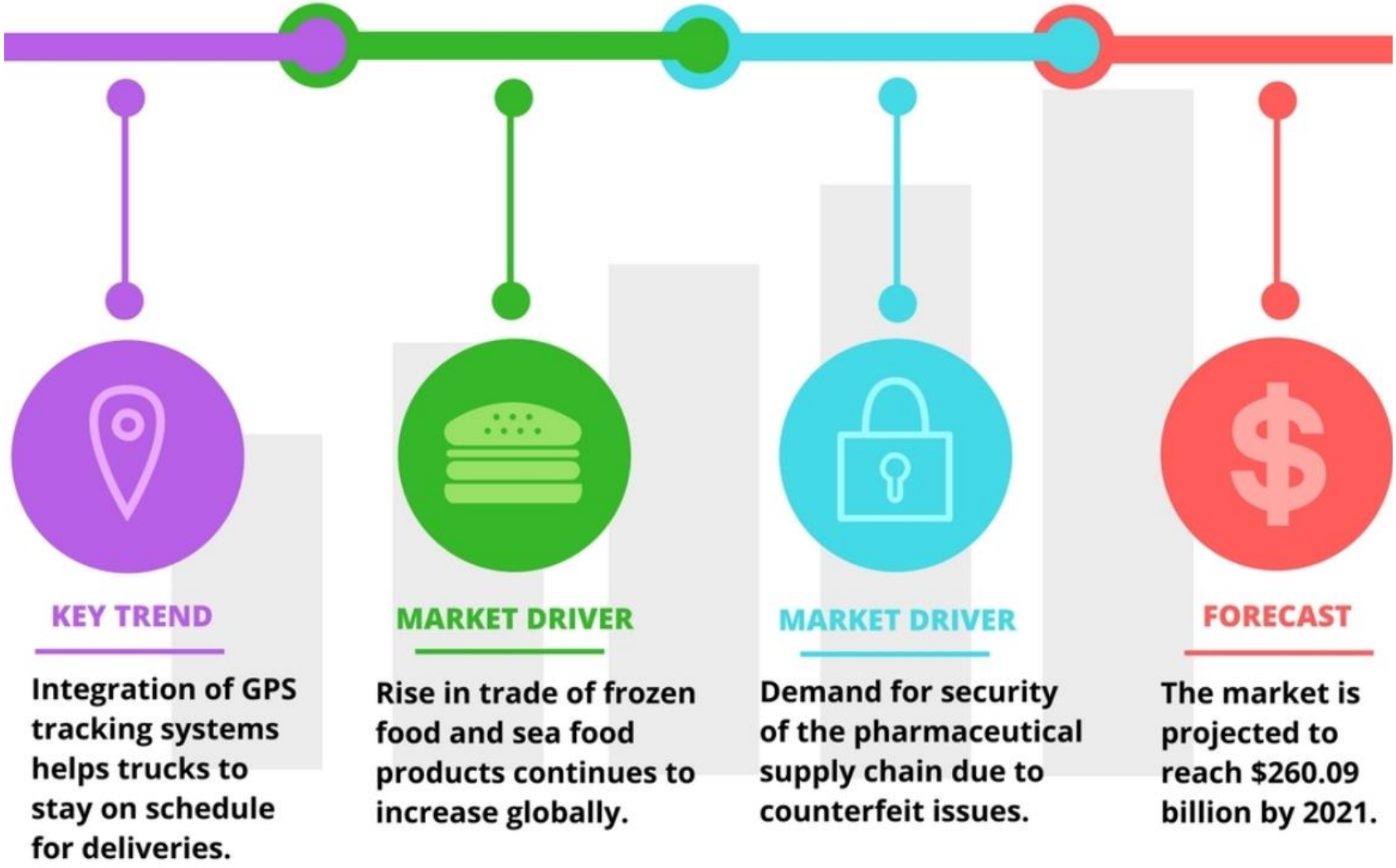
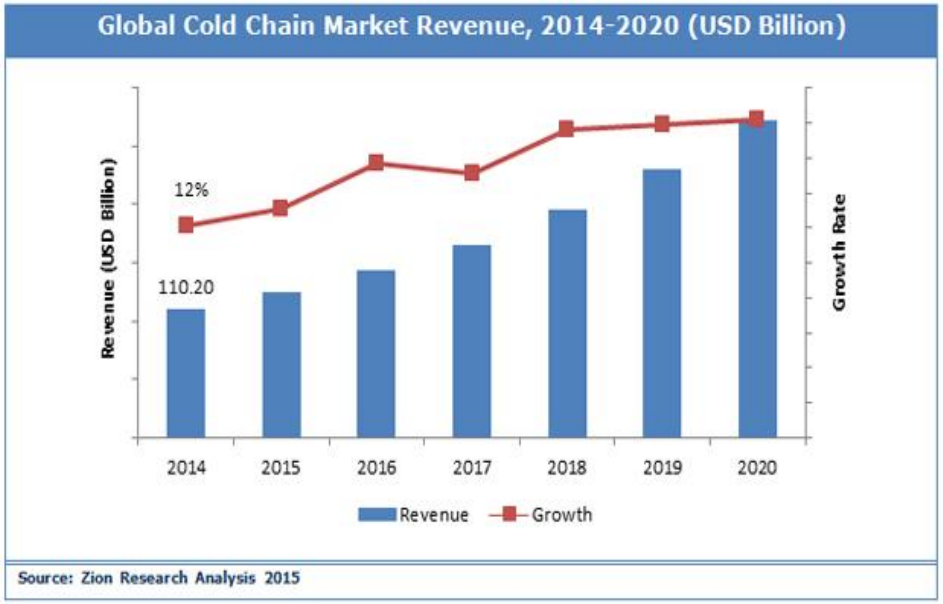
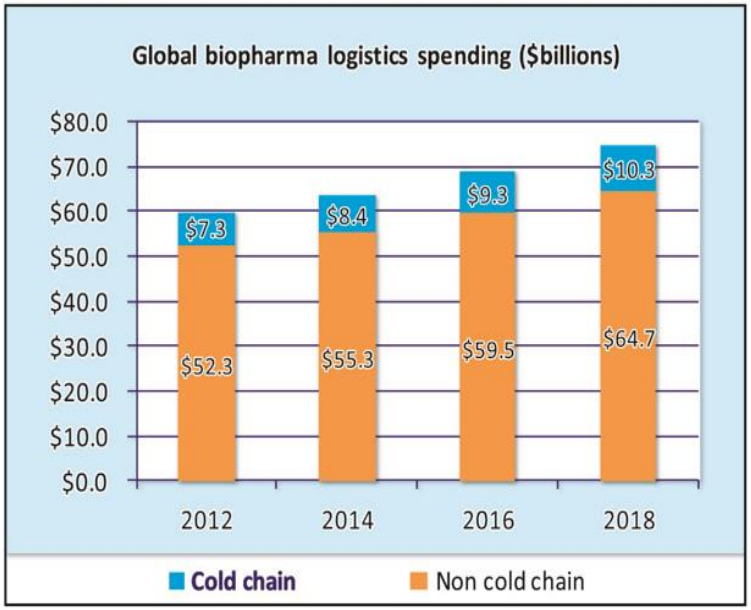


Image from: Global Cold Chain Market - Drivers and Forecasts by Technavio

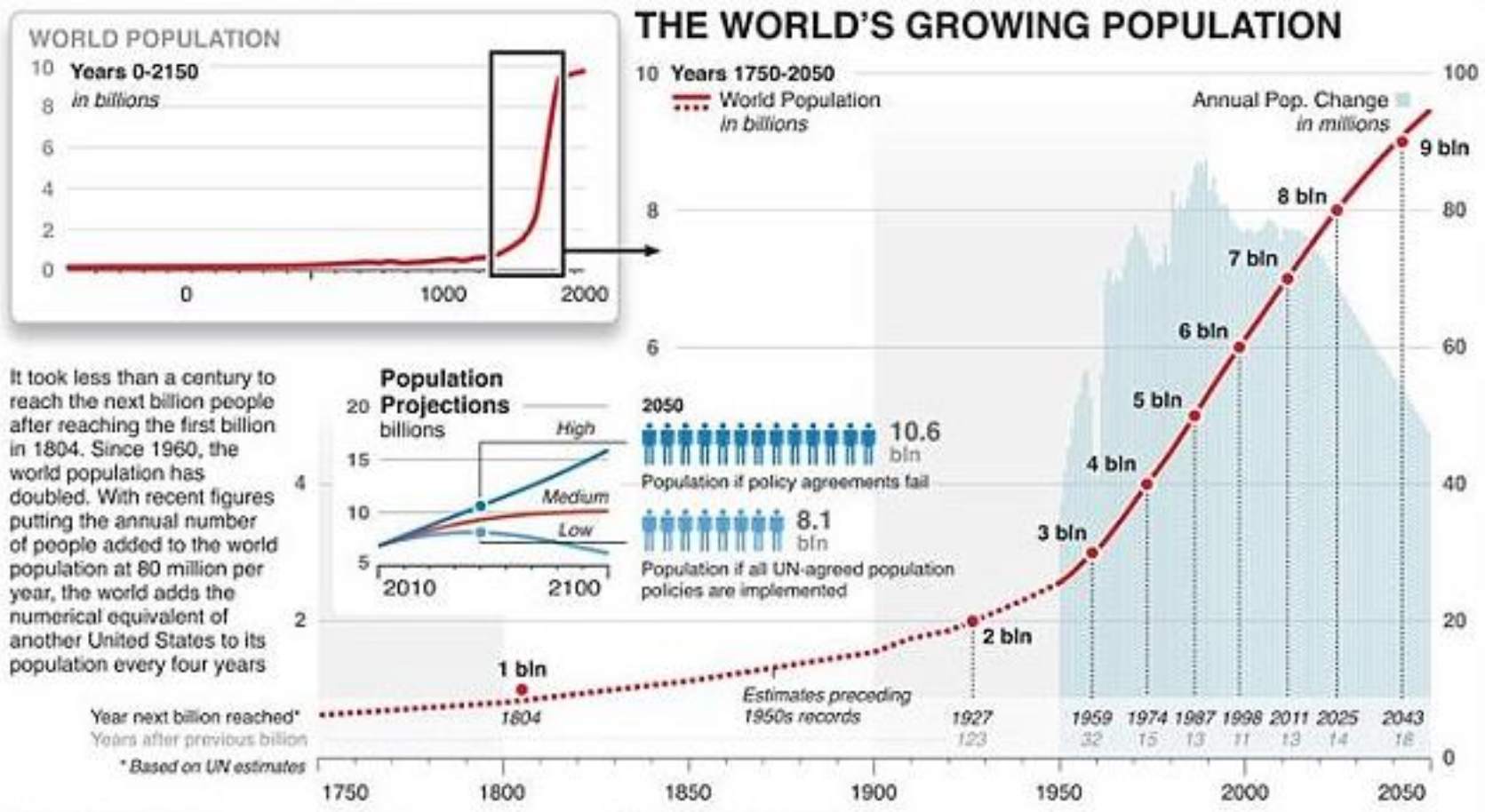
◆CAGR cold chain industry into 2019 = 16%.

- Perishable food distribution = $250 billion.
- Biopharma industry = $10 billion;
  Esp. in Asia = $1.2 billion.





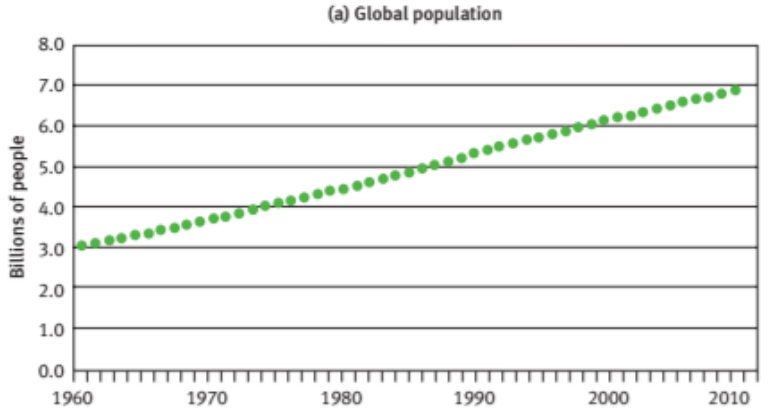
◆Since the Industrial Revolution, the world's population has been exploding.

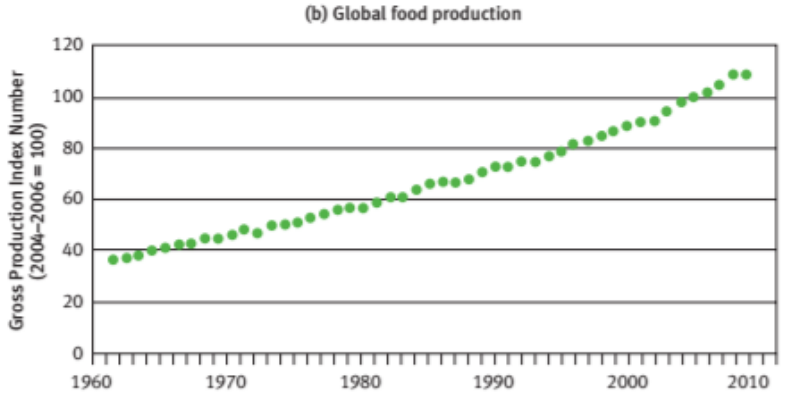


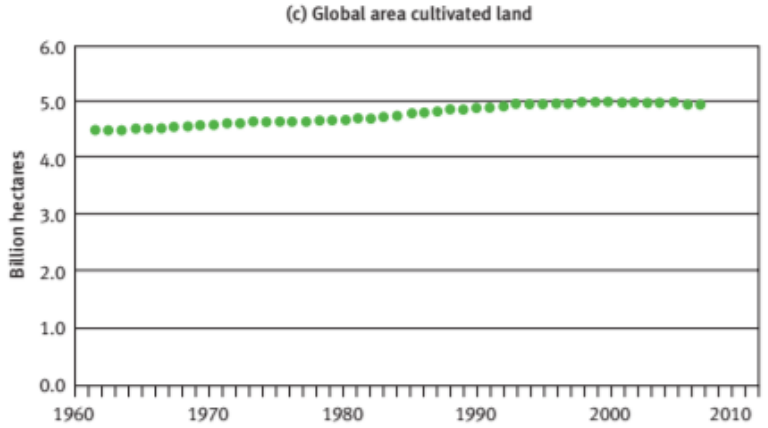
Source: http://www.dailymail.co.uk/news/article-2053652/UK-population-hit-70m-2027.html

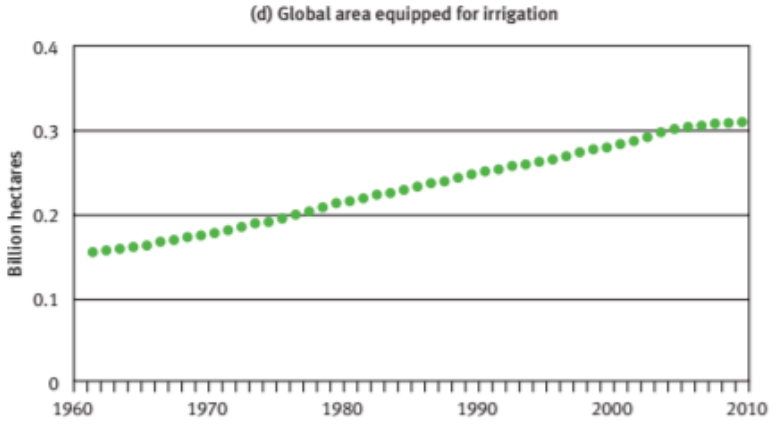
How about the cultivating area for food?

◆ The area for food supply is not enough in the future!









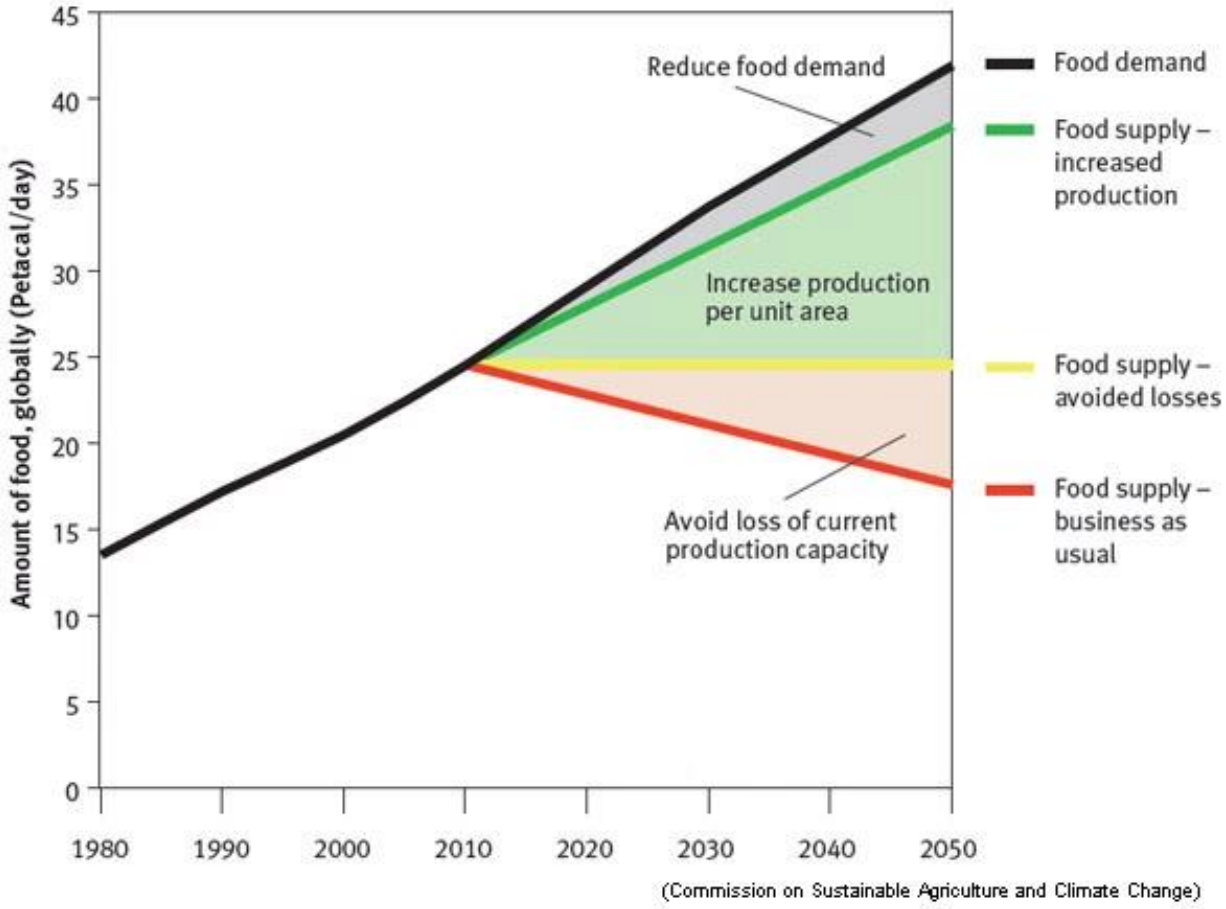
➢ Cultivating area based on year 1960~2007, FAO

➢ FAOStat. http://faostat.fao.org

Source: https://cgspace.cgiar.org/bitstream/handle/10568/35589/climate_food_commission-final-mar2012.pdf?sequence=1

Then what do we do?

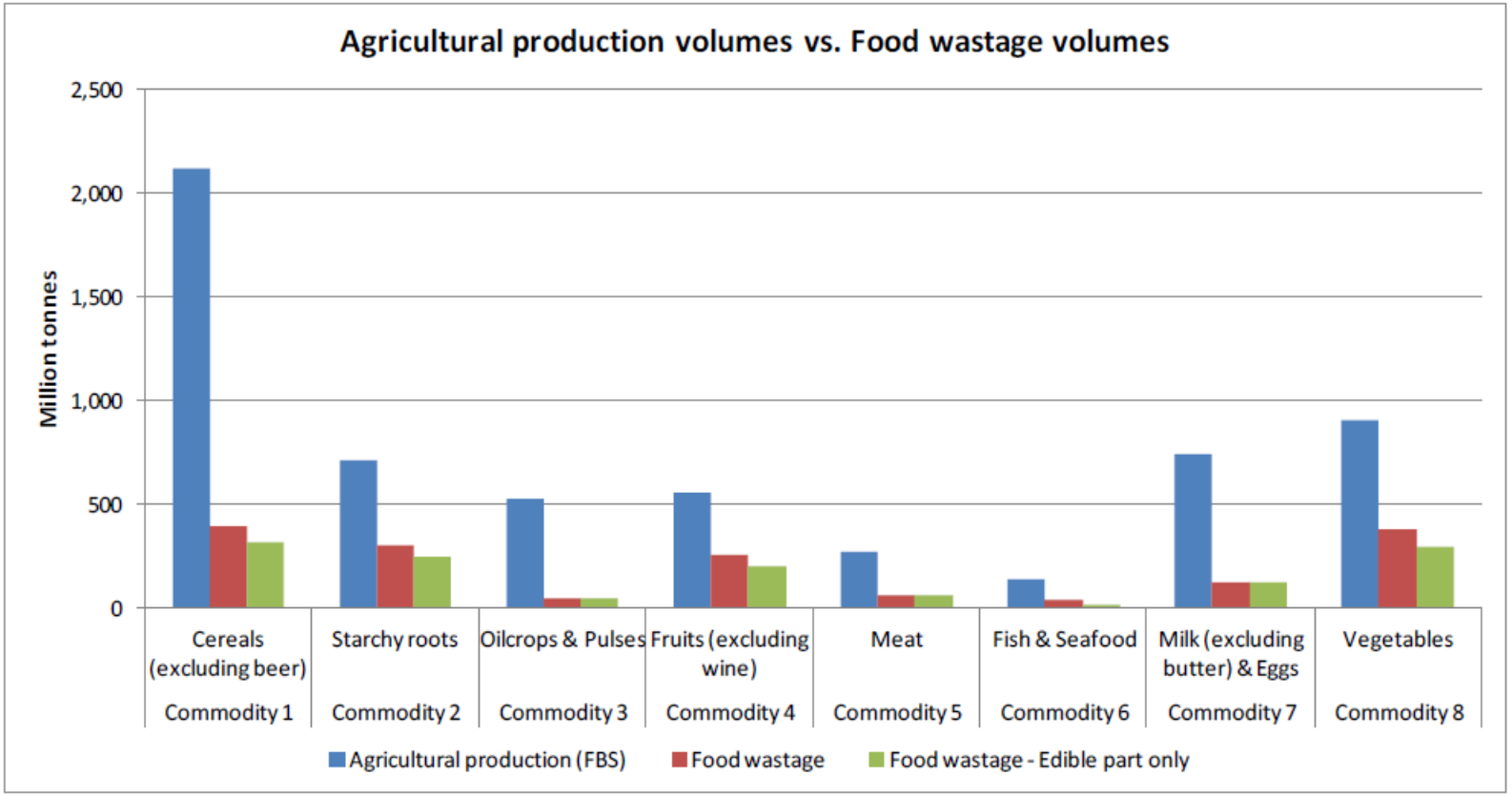
- Food production is expected to fall short of population growth rate.
  - ✓ Eat less and eat better
  - ✓ Improve food production yield for a given cropland: smart farming
  - ✓ Reduce food waste: expanding infrastructure in less developed countries



(Commission on Sustainable Agriculture and Climate Change)

World Food Production and Waste

- In 2007, about 1.6 billion tons of primary foods were discarded and disappeared.
- The edible part is about 1.3 billion tons.
- About one third of food is discarded.

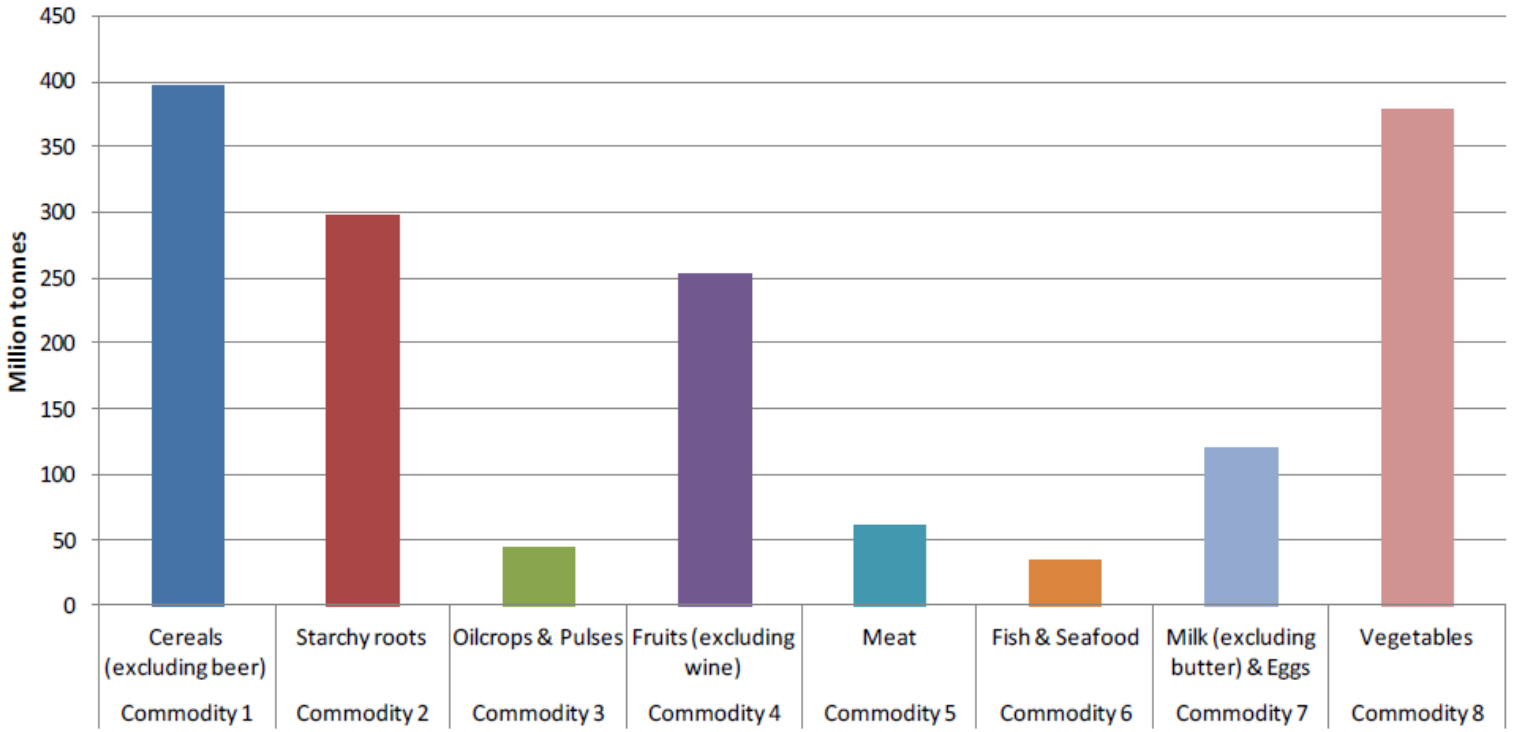


Source: http://www.fao.org/docrep/018/ar429e/ar429e.pdf

Waste categories

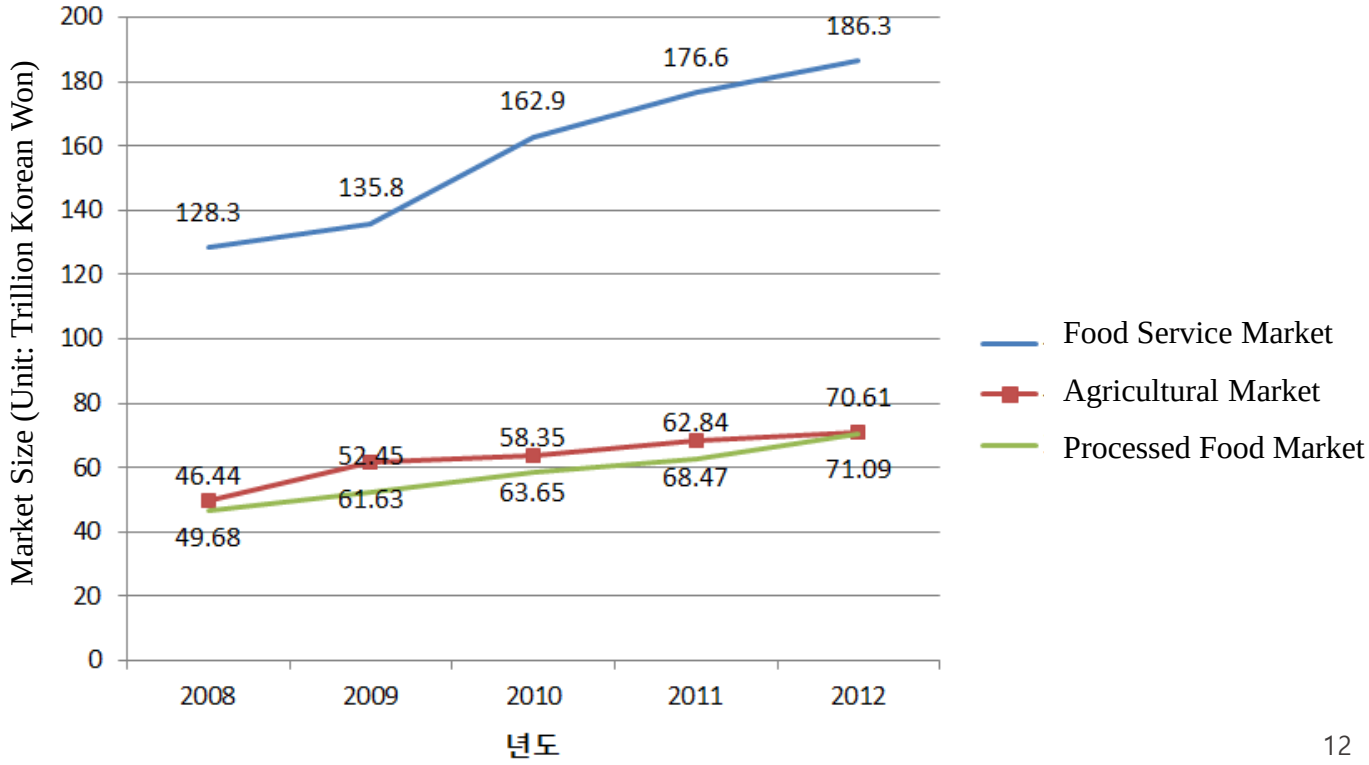
◆ Major contributors to food wastage volumes

- Cereals (25%) > Vegetables (24%) > Starchy roots (19%) > Fruits (16%)
- Plants (85%) vs. Animals (15%)



Food market size in Korea

- In 2012, about 330 billion USD.
- Annual average growth rate;
  - Agricultural market 5.3%,
  - Processed food market 11.0%,
  - Food service market 9.9%
- The market for fresh food was about 160 billion UDS that is 48% of total food market size.
  - Cold chain system is important in order not to waste fresh foods.



Effect of storage temperature on shelf life of foods

The shelf life of 5 major cold storage foods (tofu, fish cake, jelly, kimbap, triangle gimbap) was extended by 45 ~ 87% and 87 ~ 171% when stored at 7 ℃ and 5 ℃, respectively.

Effect of shelf life elongation of major cold storage foods

Storage Temperature / Food	10℃	7℃	5℃
Tofu	13.52 days	19.84 days (146%)	26.39 days (195%)
Fishcake	23.82 days	34.88 days(146%)	47.56 days (199%)
Agar jelly	20.40 days	29.67 days (145%)	38.21 days (187%)
Gimbab*	1.45 days	2.47 days (170%)	3.93 days (271%)
Triangle Gimbab	3.16 days	5.93 days (187%)	7.68 days (243%)
Average of major 5 foods	12.47 days	18.56 days (159%)	24.76 days (201.8%)

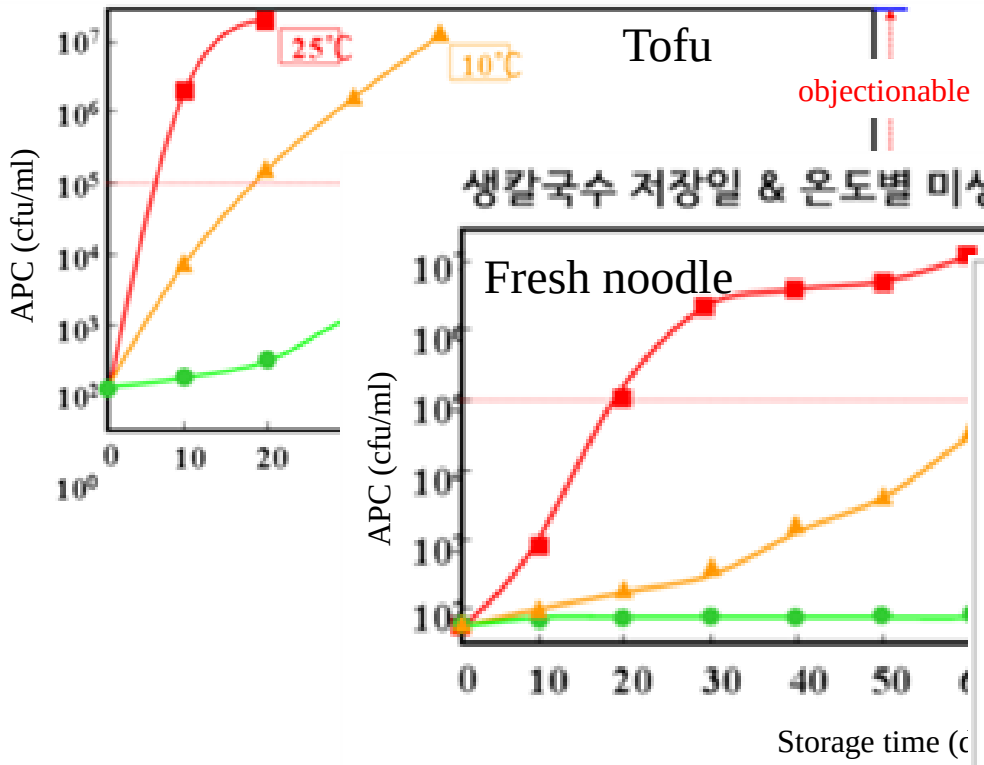
** A Korean traditional RTE foods made with steamed rice, vegetables and chopped meat that is wrapped with dried green seaweed sheet*

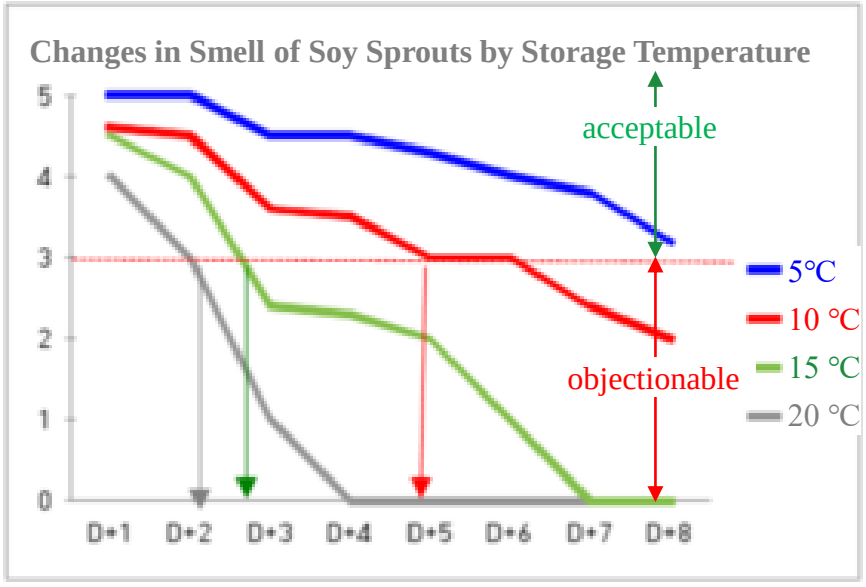
Source: A Study on the Management Plan of Foods for Refrigerated Display, Sangdo Ha, ChungAng Univ., 2007

Effect of storage temperature on shelf life of foods

As a result of storing our main products: tofu, fresh noodles, and bean sprouts by temperature, as the temperature increases, the growth rate of general bacteria increases rapidly, resulting in poor quality and inferior merchandise.
In general, when stored at 5 ℃, the freshness was twice as effective as when stored at 10 ℃.

Change of APC by Storage Temperature by Refrigerated Foods





How cold should perishable food be?

Pulmuone

Food pathogens have optimal conditions for growth, and there is also a minimum temperature at which growth stops. Most food poisoning bacteria stop growing when they are less than 5 ℃.

TABLE A-1
LIMITING CONDITIONS FOR PATHOGEN GROWTH

PATHOGEN	MIN. A_w (USING SALT)	MIN. pH	MAX. pH	MAX. % WATER PHASE SALT	MIN. TEMP.	MAX. TEMP.	OXYGEN REQUIREMENT
BACILLUS CEREUS	0.92	4.3	9.3	10	39.2°F 4°C	131°F[1] 55°C	facultative anaerobe[4]
CAMPYLOBACTER JEJUNI	0.987	4.9	9.5	1.7	86°F 30°C	113°F 45°C	micro-aerophile[2]
CLOSTRIDIUM BOTULINUM, TYPE A, AND PROTEOLYTIC TYPES B AND F	0.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe[3]
CLOSTRIDIUM BOTULINUM, TYPE E, AND NON-PROTEOLYTIC TYPES B AND F	0.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe[3]
CLOSTRIDIUM PERFRINGENS	0.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe[3]
PATHOGENIC STRAINS OF ESCHERICHIA COLI	0.95	4	10	6.5	43.7°F 6.5°C	120.9°F 49.4°C	facultative anaerobe[4]
LISTERIA MONOCYTOGENES	0.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe[4]
SALMONELLA SPP.	0.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe[4]
SHIGELLA SPP.	0.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS GROWTH	0.83	4	10	20	44.6°F 7°C	122°F 50°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS TOXIN FORMATION	0.85	4	9.8	10	50°F 10°C	118°F 48°C	facultative anaerobe[4]
VIBRIO CHOLERAE	0.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe[4]
VIBRIO PARAHAEMOLYTICUS	0.94	4.8	11	10	41°F 5°C	113.5°F 45.3°C	facultative anaerobe[4]
VIBRIO VULNIFICUS	0.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe[4]
YERSINIA ENTEROCOLITICA	0.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe[4]

Source: Fish and Fishery Products, hazards and Controls Guidance, 4th Ed., 2019, FDA

Danger zone for the PHFs

When food is removed from refrigeration, the temperature of the food gradually increases and can reach the temperature associated with the growth range specific to particular pathogens.
Traditionally, the rule of thumb for foods that will support microbial growth has been no more than 4 hours in the danger zone (41°F (5°C) to 135°F (57°C)).

Source: HARPC for Human Food: Draft Guidance for industry, FDA

Leaving food out too long at room temperature can cause bacteria (such as S*taphylococcus aureus, Salmonella Enteritidis, Escherichia coli* O157:H7, and *Campylobacter*) to grow to dangerous levels that can cause illness. Bacteria grow most rapidly in the range of temperatures between 40 °F and 140 °F, doubling in number in as little as 20 minutes. This range of temperatures is often called the "Danger Zone.“

Never leave food out of refrigeration over 2 hours.

Source: Food Safety Education, USDA

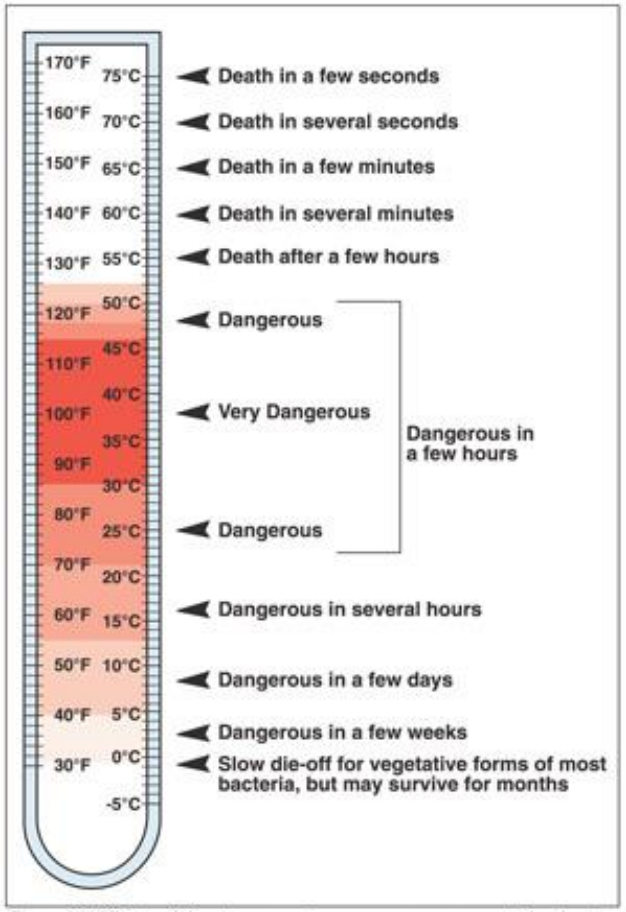


Figure 2. Effects of time-temperature exposures on vegetative bacteria in moist foods, including "danger zones."

Temperature specification for the PHFs in each country

- Most developed countries manage below 5 ℃.
- The UK is divided and managed according to the characteristics of the product.
- To reduce food poisoning hazards and maintain food quality, the refrigeration temperature needs to be operated below 5 ℃ because the growth inhibition temperature of *Sallmonella*, a typical food poisoning bacterium is 5.2 ℃.

Temperature specifications of food categories

Country / Foods							
Refrigerated	0~10°C	≤ 10°C		≤ 5°C	≤ 4°C	≤5°C	≤ 8°C
Frozen	≤ -18°C	≤ -15°C	≤ -18°C ≤ -28°C	≤ -20°C	≤ -18°C	냉동상태 유지	≤ -12°C ≤ -18°C
RTE	≤ 5°C ≥ 60°C	-	-	≤ 5°C	-	≤ 5°C	≤ 8°C
Fresh fruits	≤ 5°C	≤ 10°C		≤ 5°C	식품별	≤ 5°C	≤ 8°C
Milk & Dairy	0~10°C	≤ 10°C	2~6°C	≤ 7°C	≤ 4°C	≤ 5°C	≤ 10°C
Meat & Meat Products	-2~10°C -2~5°C	≤ 10°C	0~4°C	≤ 4°C 가금육	≤ 4°C	≤ 5°C	≤ 7°C
Eggs	0~15°C	≤ 8°C	0~4°C	≤ 7°C	≤ 4°C	≤ 5°C	≤ 4°C
Fishery	≤ 5°C	≤ 10°C	0~4°C	≤ 4°C	≤ -1°C	≤ 5°C	≤ 0°C

Source: Investigation on the storing and distributing temperatures of foods and their evidences in major foreign countries, MS Chung, ChungAng Univ., 2017

New trend in Korean Food Industry

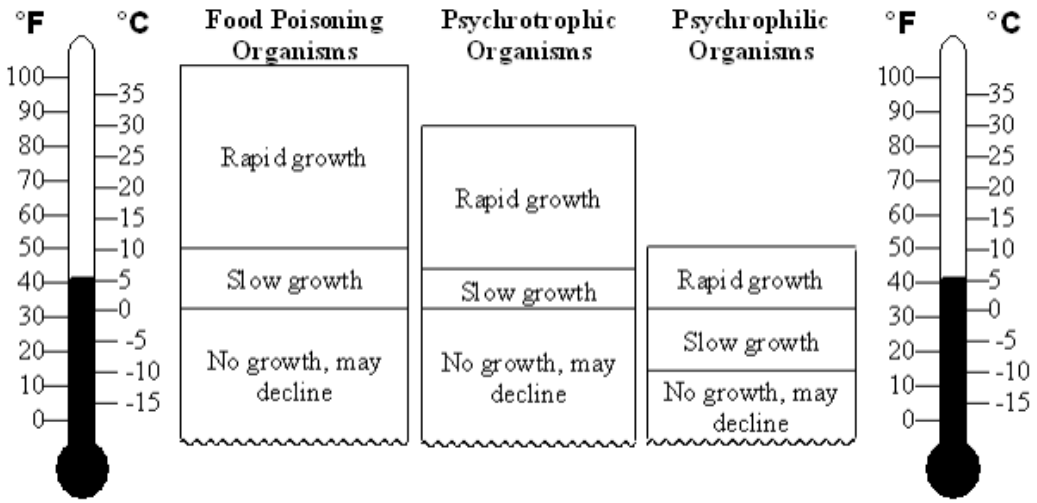
- ◆ Delivery of fresh food is increasing due to on-line shopping.
- ◆ Demand for early morning delivery continues to increase due to the increase in single-person households and dual-family homes.
  - Preferred Early Morning Delivery Items: Fresh Foods, HMR*
- ◆ Difficulties exist in refrigeration temperature during fresh delivery.
  - Difficulty in Temperature Control of Refrigerated Vehicles
  - Destruction of cold chain when loading and unloading fresh food
  - Aging of Refrigerated Vehicles

Distributors Jump into Dawn Delivery of Fresh Food

업체	특징
Market Kully	업계 최초 진출. 지난 3월 월매출 100억, 회원수 60만 명 돌파, '샛별배송' 주 7일로 확대
tmon	신선 · 냉장 · 냉동식품 1600여종 운영. 올 상반기 신선식품 매출 성장률 397%
BGF	SK플래닛 자회사 '헬로네이처' 300억원 투자해 지분 50%+1주 확보, 경영권 인수
GS Retail	GS프레시 통해 서울 지역에 간편식 · 신선식품 등 5000여 개 상품 오전 1~7시에 배송
HanKook Yakult	기존 유제품 새벽배송망 활용해 자체 가정간편식 브랜드 '잇츠온' 새벽 정기배송 서비스
Lotte	롯데프레시센터 통해 신선식품 새벽배송. 과일 품질 안 좋으면 100% 교환 · 환불
ShinSeaGye	프리미엄 신선식품 브랜드 'Just Fresh' 론칭. '쓱배송 굿모닝' 시범 서비스 운영 중

In the case of frozen foods…

All food poisoning bacteria cannot grow below -10 degrees. Therefore, if there is no problem with the quality of the food, the storage temperature of frozen food needs to be reconsidered the current standard.



*Note: *Listeria monocytogenes* has the characteristics of a psychrophilic organism, but is a food poisoning organism.

Note however that the ATP Agreement** requires that temperatures in international transport should be no higher than:

Ice cream	-20°C
Frozen or quick (deep)-frozen fish, fish products, molluscs and crustaceans and all other quick (deep)-frozen foodstuffs	-18°C
All frozen foodstuffs (except butter)	-12°C
Butter	-10°C

* Follow the procedures outlined in Annexes IV and V
** Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage (drawn up by the Inland Transport Committee of the United Nations Economic Committee for Europe): for detailed references see Appendix

Guidance for the frozen foods delivery in Korea

[그림 2. 택배 배송물 냉동식품 스티커 예시]

Guidance for the frozen foods delivery

Packaging Stage

- Fully frozen below -18 ℃
- Recommended workplace temperature below 15 ℃
- Styrofoam box more than 2cm thick
- Refrigerant is recommended to use dry ice
- Meticulously sealed packaging
- Frozen food identification sticker

Delivery Stage

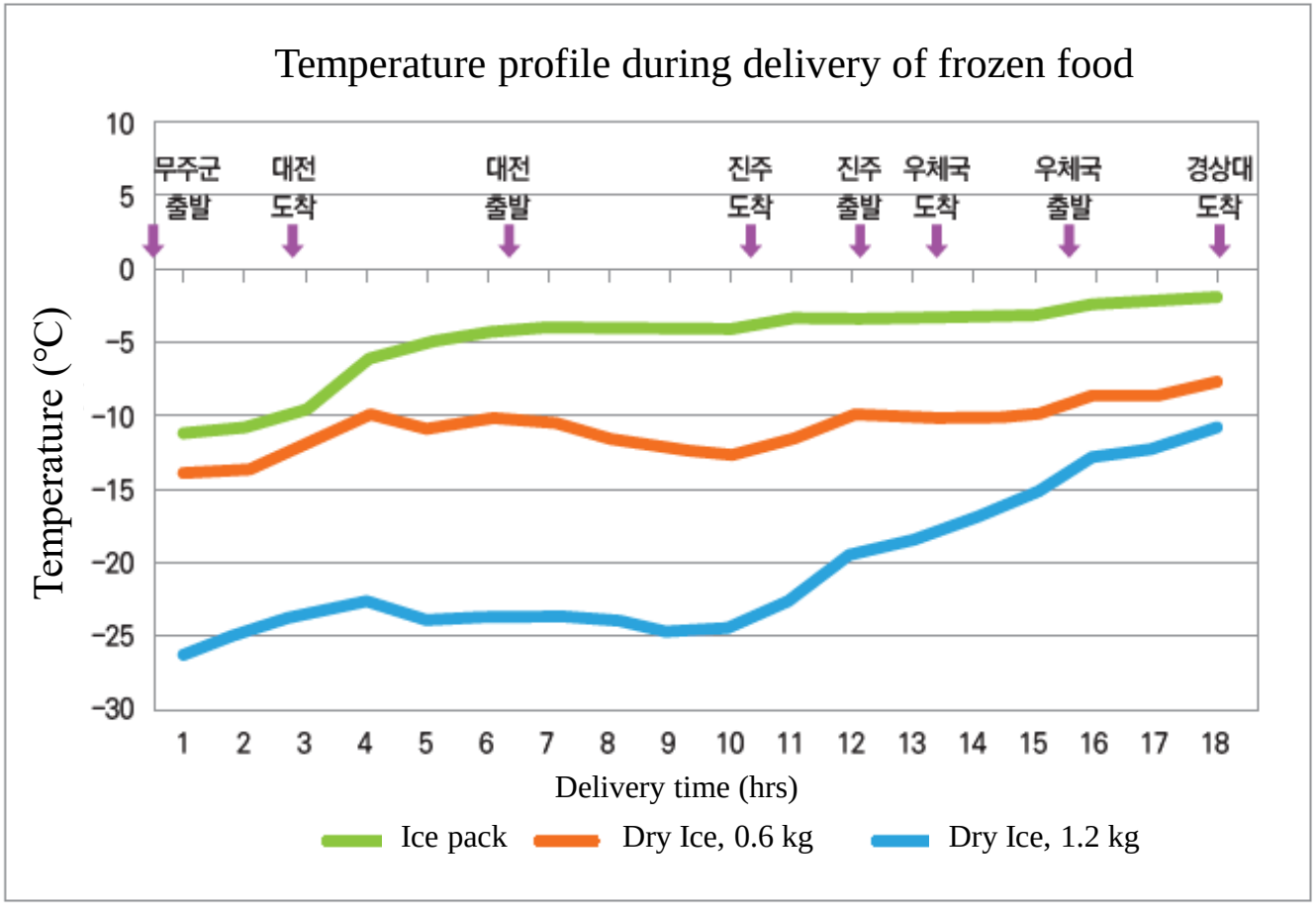
- Receive and collect frozen foods first
- Minimize exposure to outside air when getting on or off
- Be careful not to damage it by loading it on the top
- Same day or next day delivery recommended
- Do not accept if next day delivery is difficult

Receiving Stage

- Sending sns message to help consumers get back quickly
- Guide consumers to check box and contents after receipt
- Store frozen foods promptly and ingest them as soon as possible.

Guidance for the frozen foods delivery: temperature profile

Since the cold storage effect of frozen food parcel delivery usually lasts for 24 hours after the product is shipped to consumers, it is difficult to secure the quality and safety of frozen foods. Refrigerant used for frozen food parcel delivery is recommended to use dry ice, as it has better cooling effect than gel ice pack.



- Ensure that the Time-Temperature Recorders (TTR) of the transport vehicle on receipt of food from the supplier do not exceed the following criteria (Source: Supplier Compliance Manual, 2015).
  - RTE Seafood, shellfish, dairy products and agricultural products: Air temperature in the vehicle for transportation 4.4 ℃ not to exceed 4 hours.
  - Meat and poultry vehicles: The internal air temperature does not exceed 45 7.2 ℃ for more than 4 hours.
  - Ambient temperature not exceeding 1 hour at temperatures above 21 ℃.
  - Ambient temperature not to be left for more than 4 hours at temperatures below 1.7 ℃ for produce and -3.9 ℃ for uncooked meat or poultry.

Take away

- As a result of the Fourth Industrial Revolution, the cold chain industry is developing in various ways, with high growth of 16% annually.

- The benefits of cold chains in the food industry can reduce food waste by increasing the shelf life of fresh food. In the case of major 5 kinds of refrigerated foods in Korea, the shelf life is extended about twice when stored at 5 ℃, which is lower than 10 ℃ specified by the Food Sanitation Law.

- Increasing on-line purchases and early morning deliveries make it can be difficult to comply with legal standards for frozen and refrigerated temperatures during the distribution stages. However, in order to protect the safety of fresh food from pathogens, substantial cold chains must be secured. To do this, the on-line order delivery should be operated with the criteria of suppressing the growth of pathogens by maintaining the minimum temperature handling manual for refrigerated food.

Thank you for listening!

For Me
For Earth

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

ILSI
Focal Point
in China

Risk assessment of glutamic acid and glutamates in China

Junshi Chen

China National Center for Food Safety Risk Assessment

ILSI
Focal Point
in China

Outline

1.Background

2. Objectives

3.Project Design

4.Preliminary Results

ILSI
Focal Point
in China

Background

Food additives

Glutamic acid and glutamates are approved as flavor enhancer food additives by many countries, e.g. China, EU, USA, Japan, South Korea, Australia, etc.
Total global production of monosodium glutamate (MSG) is about 3.3 million tons per year, and the total demand is about 3 million tons. 90% of the world total production of MSG is in Asia. China, Japan and South Korea are the world largest MSG producers.

Protein constituents (binding form)

Glutamic acid occurs as one of the non-essential amino acids, which binds with other amino acids in proteins, and this binding form accounts for about 20% of the total protein intake.

Natural sources (free form)

Natural free form glutamate occurs in many foods, including meat, fish, poultry, breast milk and vegetables.

ILSI Focal Point in China

Background

Authorised uses and use levels

Country	Food additives	Authorised uses and use levels
CAC	glutamic acid +sodium glutamate +potassium glutamate +calcium glutamate +magnesium glutamate +ammonium glutamate	Be authorized at quantum satis (QS) at 16 kinds foods.
EU	glutamic acid +sodium glutamate +potassium glutamate +calcium glutamate +magnesium glutamate +ammonium glutamate	Be authorised at QS in salt substitutes, seasonings and condiments, and at the MPL of 10,000 mg/kg or 10,000 mg/L in 67 kinds of foods.
USA	sodium glutamate +potassium glutamate +ammonium glutamate	Do not exceed the reasonable amount required to achieve the desired physical, nutritional, and other effects.
Australia & New Zealand	glutamic acid +sodium glutamate +potassium glutamate +calcium glutamate +magnesium glutamate +ammonium glutamate	Be authorised at QS, and do not exceed the reasonable amount required to achieve the desired effects.
Japan	glutamic acid +sodium glutamate +potassium glutamate +calcium glutamate +magnesium glutamate +ammonium glutamate	Calcium glutamate cannot be used in special foods for meals, and there is no limitation about glutamic acid and other glutamates.
China	glutamic acid +sodium glutamate	Monosodium glutamate is authorized at QS in foods. L-glutamic acid is authorized to use as synthetic spices in foods

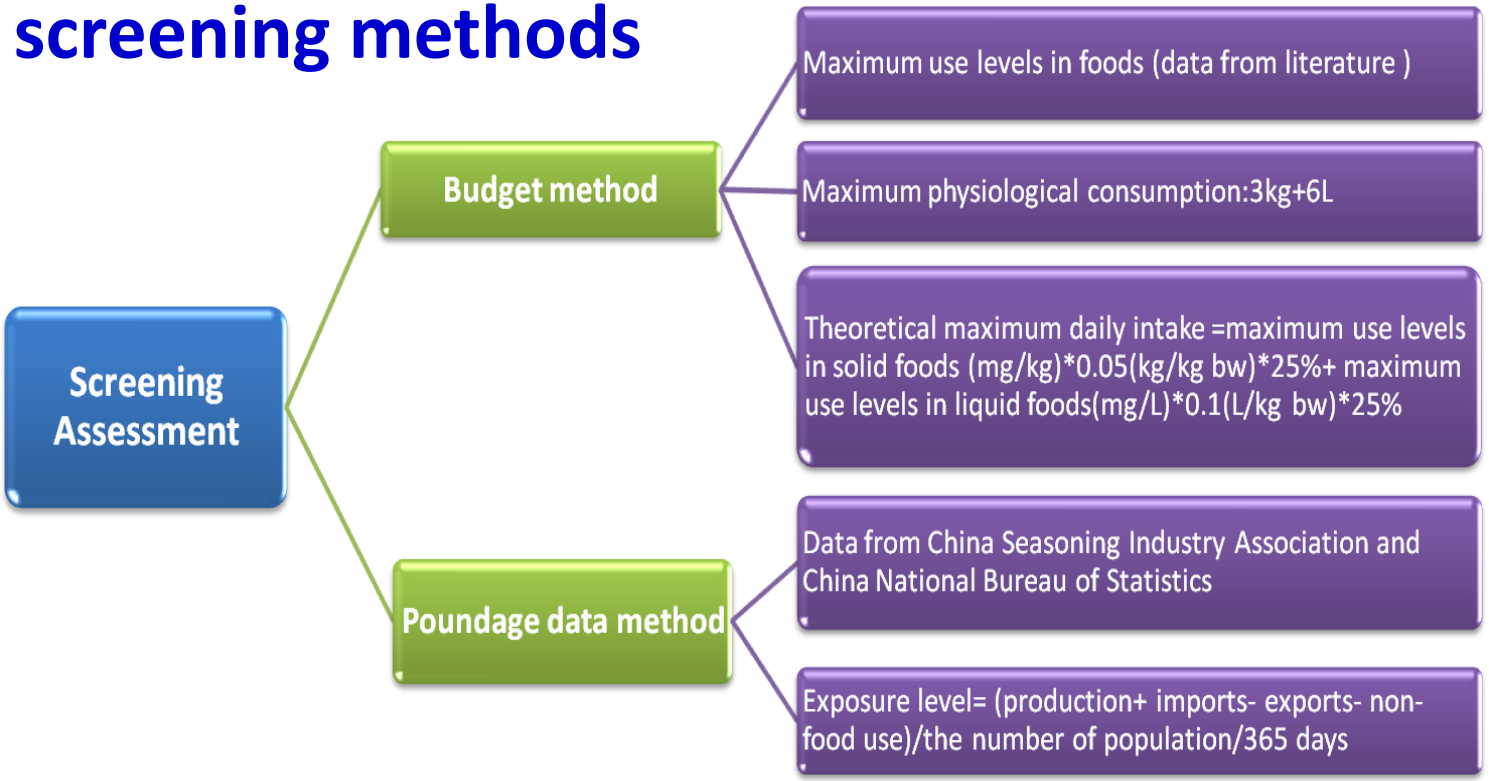
Health-based Guidance Value (HBGV) of Glutamates

Organization	Year	Group ADI
JECFA	1970 1973	0-120 mg/kg BW
	1987 2004	ADI not specified
EFSA	1990 2015	ADI not specified
	2017	0-30 mg/kg BW
FSANZ	2003	ADI not specified

ILSI
Focal Point
in China

Background

Preliminary exposure assessment in Chinese population – screening methods



Daily intake of glutamic acid

1,614 mg/kg BW

Daily intake of glutamic acid

59.71 mg/kg BW

Further exposure assessment is needed and included in the priority list of national risk assessment projects in China (conducted by CFSA).

ILSI
Focal Point
in China

Objectives

1. To evaluate the scientific basis of EFSA ADI for glutamic acid and glutamates;
2. To collect information on the use of glutamic acid and glutamates as food additives in China;
3. To assess the exposure level of dietary glutamic acid and glutamates in Chinese population, as well as the contribution rates of natural and added glutamic acid and glutamates as food additives;
4. To provide scientific support to risk management of glutamic acid and glutamates in foods in China.

ILSI
Focal Point
in China

Project Design

- **Data sources**
  - Collect existing data
  - Focus on filling key data gaps
- **Framework for risk assessment**
  - Hazard identification
  - Hazard characterization
  - Exposure assessment
  - Risk characterization

Project Design

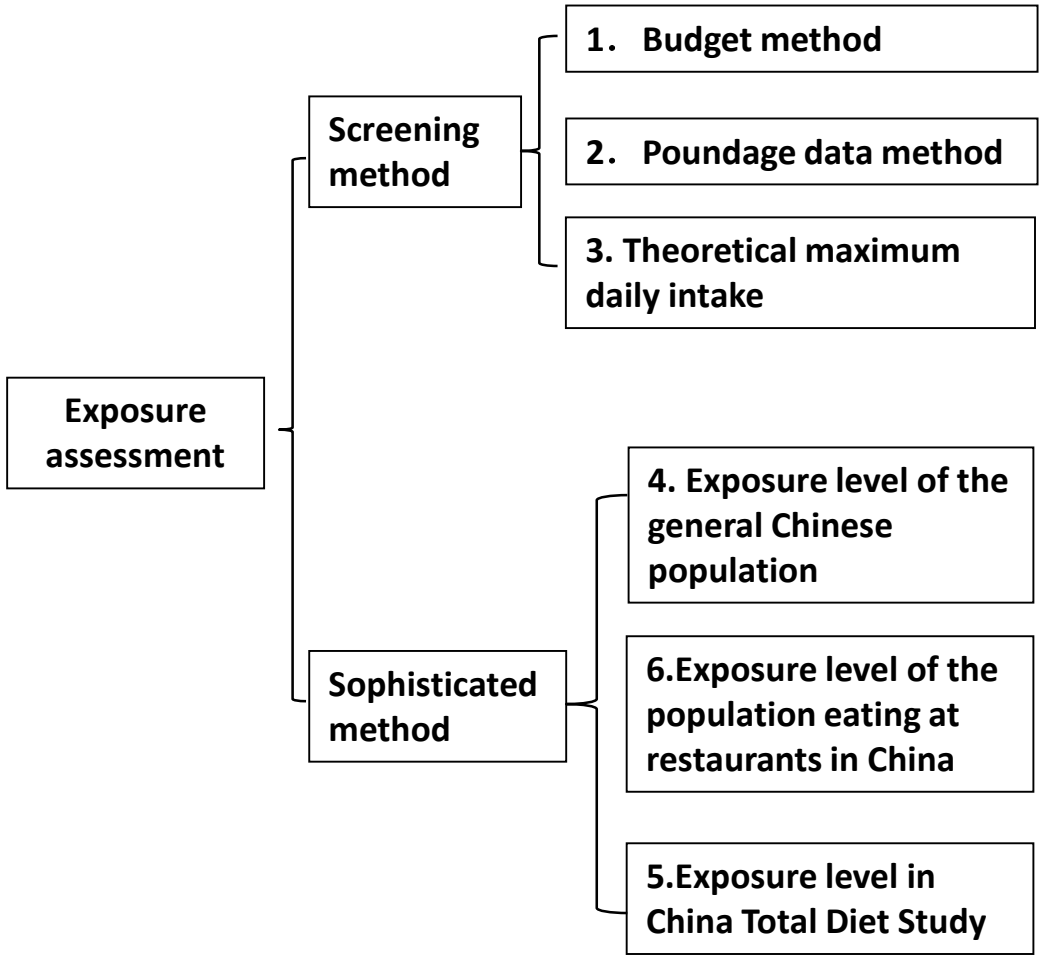
Hazard identification and hazard characterization

Toxicological data collection	Reliability evaluation of toxicological data	Relevance evaluation of toxicological data	Systematic review and meta-analysis	Review the scientific basis of ADIs
◈ ADME ◈ Acute toxicity ◈ Genetic toxicity ◈ Reproduction toxicity ◈ Chronic toxicity ◈ Carcinogenicity ◈ Neurotoxicity ◈ …	**Focus on neurotoxicity and developmental neurotoxicity** ◈ Animal studies: neurotoxicity and developmental neurotoxicity ◈ Population epidemiological studies: neurotoxicity and developmental neurotoxicity ◈ Risk assessment report of international agencies: key literatures used to establish the HBGV value			Review and discuss the results of systematic review of neurotoxicity of MSG and proposal of ADI from the Working Group.
◈ CFSA ◈ Southern Medical University	◈ Jiangsu Center for Disease Control and Prevention	◈ Beijng Center for Disease Control and Prevention	◈ Huazhong University of Science and Technology	◈ National Expert Committee on Food Safety Risk Assessment ◈ China National Toxicology Plan ◈ Panel group ◈ Working group
Finished	Finished	Finished	Finished	On going

ILSI
Focal Point
in China

Project Design

Exposure Assessment



Background exposure level
(background concentration in foods × food consumption)
+
Exposure level by processed foods
(use level/ concentration in processed foods × processed food consumption)
+
Exposure level by cooking condiments
(use level/ concentration in condiments × condiment consumption)

Project Design

ILSI Focal Point in China

Data Collection for Exposure Assessment

Concentration data

Consumption data

Use levels of glutamates in processed foods

Concentration of glutamates in foods

Concentration traceability analysis of glutamates in typical foods

Use levels of glutamates in processed foods from GNPD data			Food Category（based on National Standard GB2760）	Data sources
Food category	**N**	**%**		
Meat products	5,644	29.45	Prepared and cooked meat products	◆ Chinese Flavoring Association ◆ China Food Science and Technology Association ◆ China Food Industry Association ◆ China Baked Food and Sugar Products Industry Association ◆ China Federation of Commerce
Condiments	4,610	24.06	Condiments	
Cereal products	4,167	21.75	Cereal products	
Nuts	1,071	5.59	Nuts	
Processed fruits	7,26	3.78	Processed vegetables	
Cooked aquatic products	5,77	3.01	Cooked aquatic products	
Baked foods	488	2.55	Baked foods	
Egg products	137	0.71	Remanufacturing eggs	
Processed fruits	54	0.28	Processed fruits	
Infant foods	42	0.22	Infant foods	
Others	1,648	8.60	Soy products	
total	**19,164**	100.00		
GNPD global product information database			The Report on MSG Production and Sales in China	China Biological Fermentation Industry Association

896 products
maximum use level
regular use level

ILSI
Focal Point in China

Project Design

Data Collection for Exposure Assessment

Concentration data

Consumption data

Use levels of glutamates in processed foods

Concentration of glutamates in foods

Concentration traceability analysis of glutamates in typical foods

Food Category	N	Detection Method
Cereal foods and their products	819	CFSA detection method for glutamic acid and glutamates in foods: ultra-high performance liquid chromatography - tandem mass spectrometry. The detection method was verified by Chin National Center for Food Quality Supervision and Inspection, China National Research Institute of Food and Fermentation Industries, and China National Institute of Food and Drug.
Vegetables and their products	781	
Meat and its products	785	
Aquatic products	602	
Eggs and their products	298	
Beans and their products	296	
Nuts and their products	117	
Baked foods	328	
Condiments	604	
Puffed foods	95	

4725 food samples
9 food categories
48 food subcategories

Project Design

Data Collection for Exposure Assessment

Concentration data

Consumption data

Use levels of glutamates in processed foods

Concentration of glutamates in foods

Concentration traceability analysis of glutamates in typical foods

- **The concentrations of stable carbon isotope in glutamates was used to estimate the ratio of natural and added glutamates in foods.**
- **Food samples with high content of glutamates (such as soy sauce, soybean paste and oyster sauce) were selected.**

Project Design

ILSI Focal Point in China

Data Collection of Exposure Assessment

Concentration data

The survey in Chinese restaurants was conducted in 7 provinces in China. 1 city and 1 county in each province were selected with a total of 14 survey sites. In each survey site, 9 restaurants of different sizes were selected, and the food categories, the product information, and the use levels of all condiments as well as the number of people eating in every restaurant were investigated for three days by the weighing method and the three-day accounting method.

Consumption data

- Food consumption data of population in China in 2016-2017;
- Condiment consumption data in Chinese restaurants in 2018.

ILSI
Focal Point
in China

Preliminary Results

Hazard assessment (Neuro-toxicity)

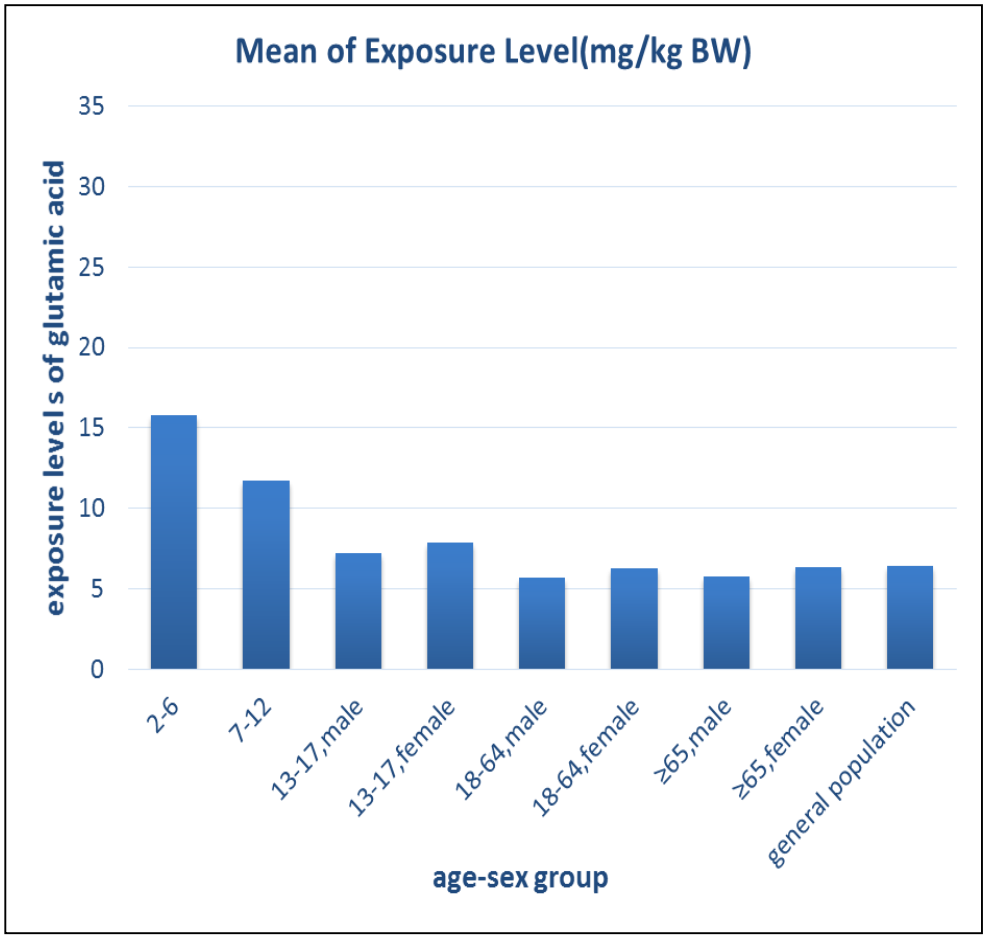
1. Dose-effect relationship in neurotoxicity of MSG was not found in systematic review of current literatures.
2. There is no adequate evidence to support the ADI established by EFSA in 2017 (30 mg/kg BW).

ILSI
Focal Point
in China

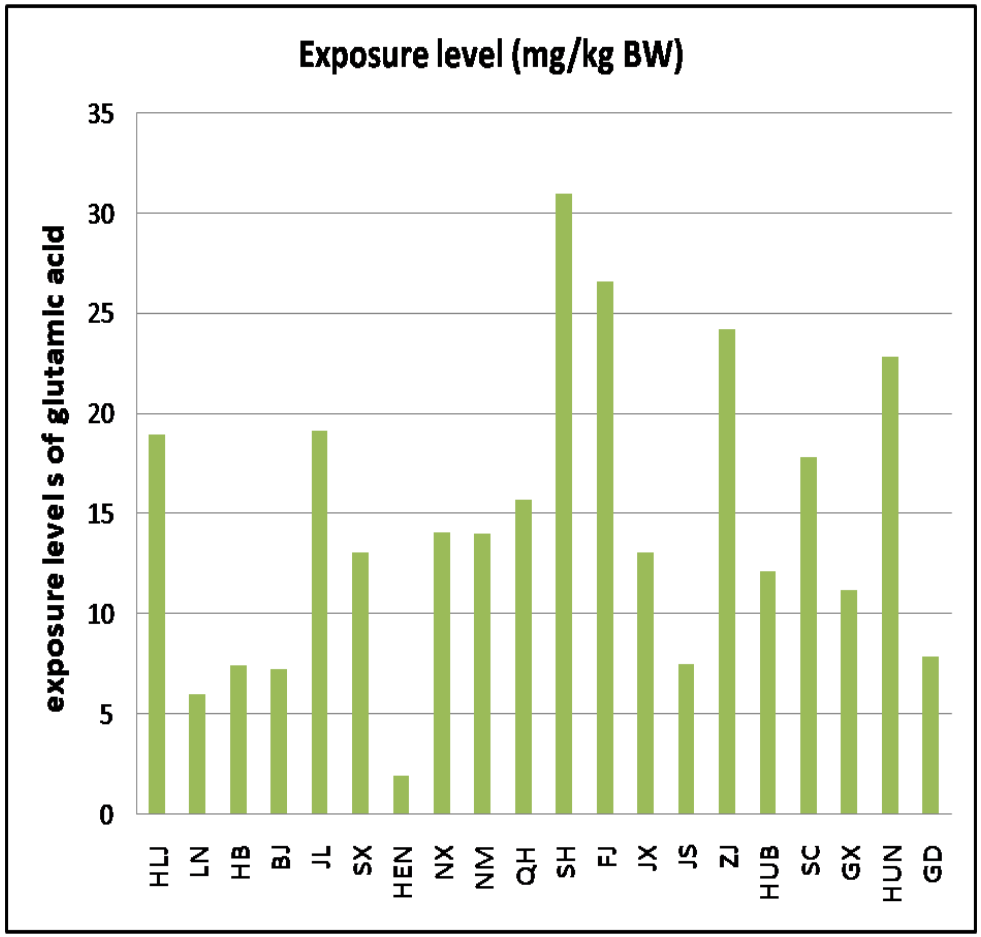
Preliminary Results

Exposure assessment

Exposure level based on individual data



Exposure level from Total Diet Study



ILSI
Focal Point
in China

Next Step

1. Submit data to EFSA;
2. Develop ADI for glutamic acid and glutamates (independent);
3. Estimate intakes of glutamic acid and glutamates in different sub-populations and exposure scenarios;
4. Distinguish dietary intake of glutamic acid and glutamates as food additive and as natural-occurring ingredient;
5. Draft scientific findings and opinion for peer review.

ILSI
Focal Point
in China

Thank you !

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

11th BeSeTo Meeting

Ministry of Food and Drug Safety

Microbiome and Food Safety

Hyo-Sun KWAK

Ministry of Food and Drug Safety, KOREA

2019. 9.26~27

CONTENTS

The need for NGS

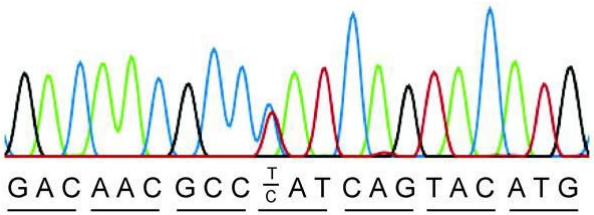
Ministry of Food and Drug Safety

Next Generation Sequencing

NGS: high throughput sequencing technology
Produce massive amount of sequence information

20 – 10,000X coverage
Digital
Massively parallel
Like "Millions of Sanger reactions"

Sanger Sequencing



2X coverage
Analog

NGS Platforms

ThermoFisher
Ion Proton & PGM

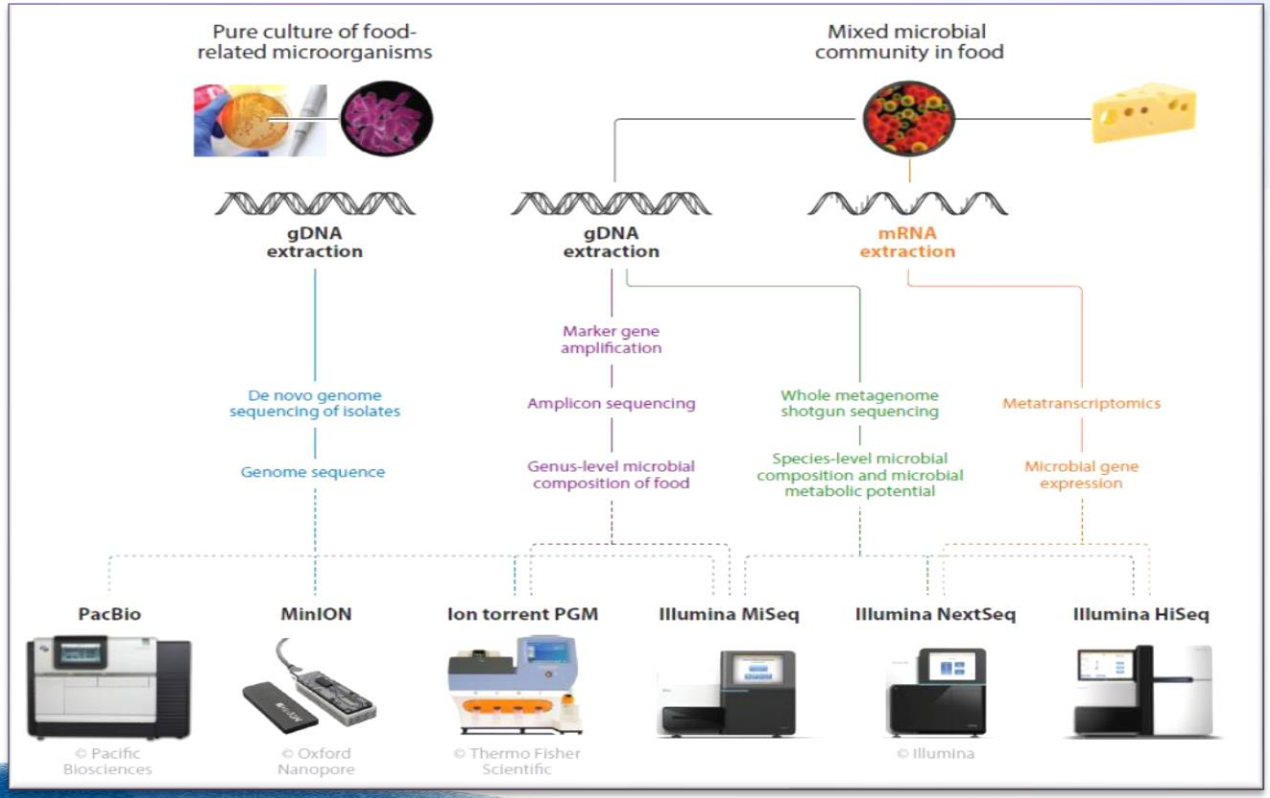
Illumina
HiSeq, NextSeq & MiSeq

PacBio
RSII & Sequel

Oxford Nanopore
MinION & GridION

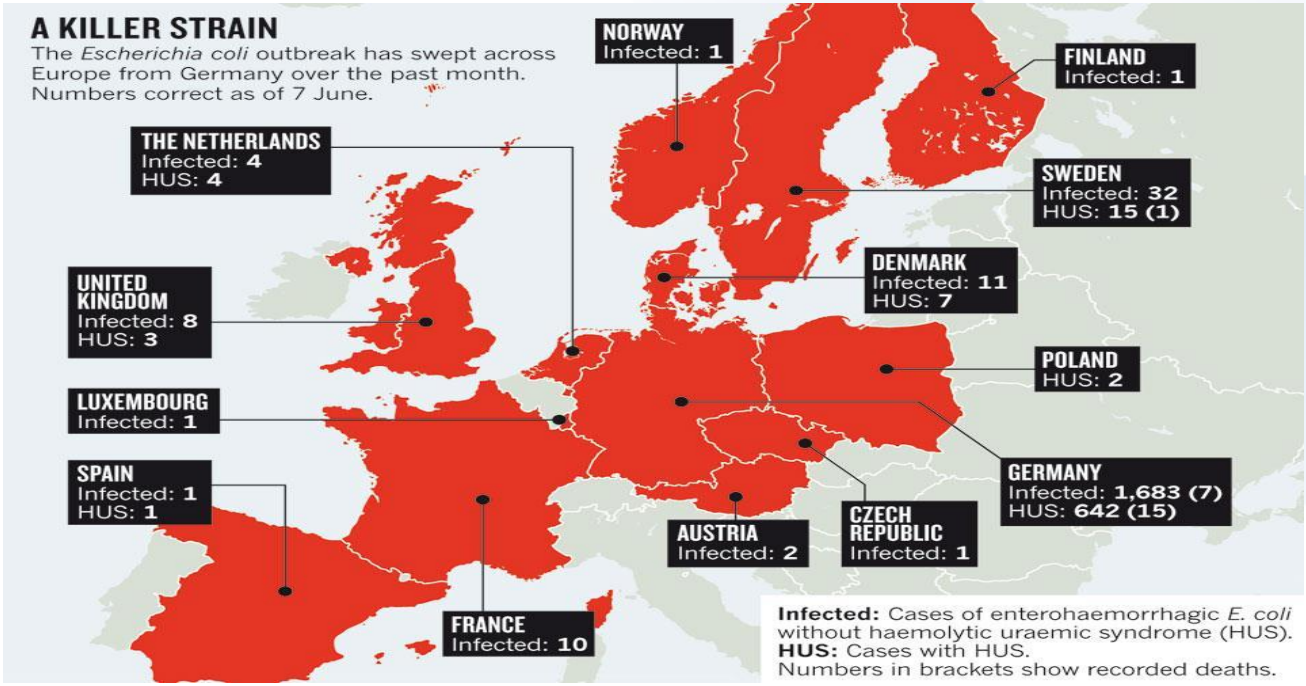
NGS application in Food Microbiology

- **Whole genome sequencing** is the process of determining the complete DNA sequence of an organism's genome at a single time.
- **Metagenome Sequencing** is the process of finding genetic materials from environmental or food samples to analyze microbial community.



Walsh et al., 2017

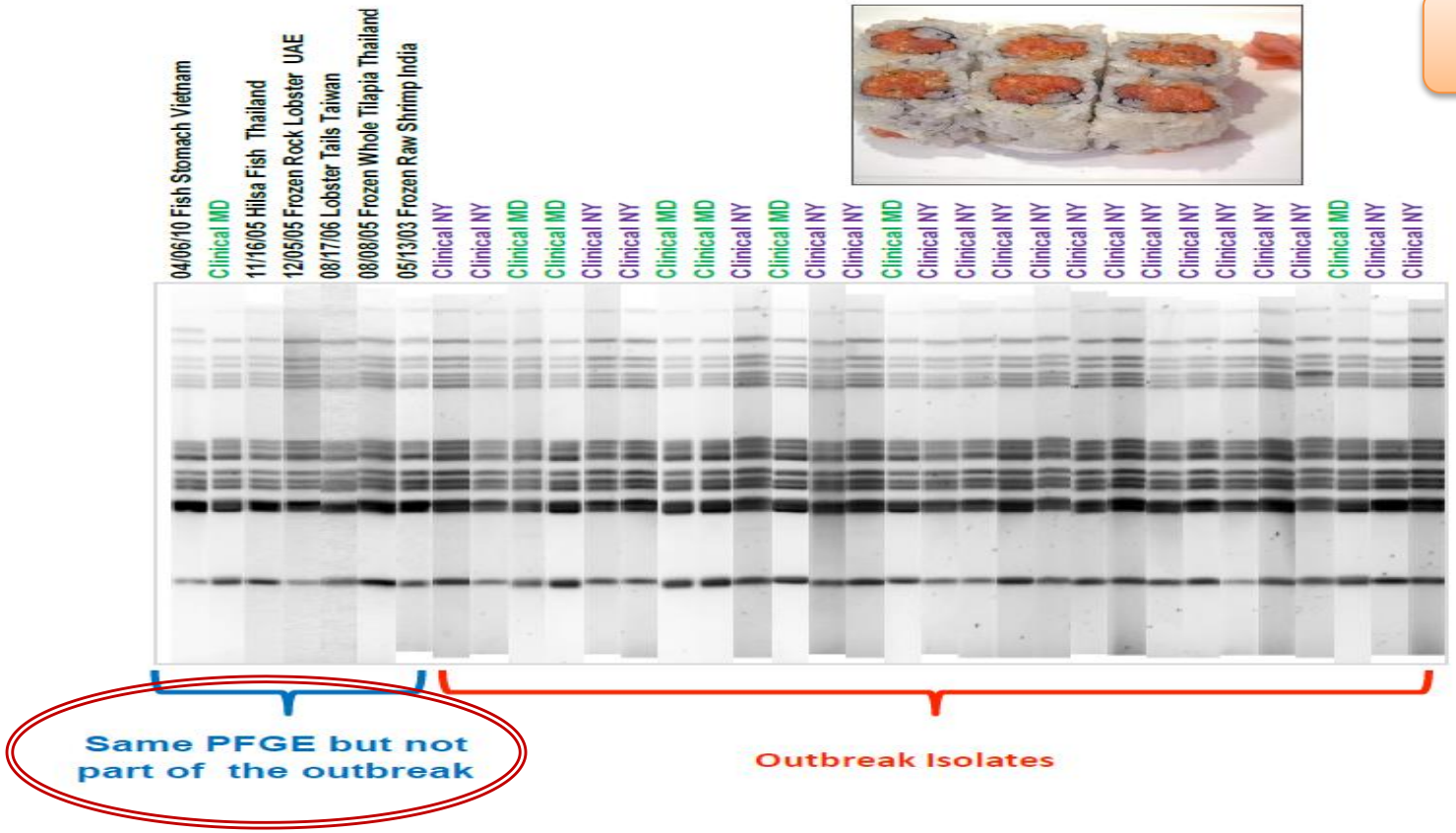
E. coli O104 outbreak in Germany (2011)



- ✓ 53 dead, 4,500 hospitalized, fenugreek seeds imported from Egypt
- ✓ Delayed and misleaded investigation caused damage estimated 1.3 billion USD
- ✓ Paid 236 million USD to other EU countries for the damage of E. coli outbreak
- ✓ The novel *E. coli* O104:H4 was confirmed by NGS technology
- ✓ *E. coli* mutant has combined characteristics of EHEC and EAEC

Salmonella Barelly outbreak (2012)

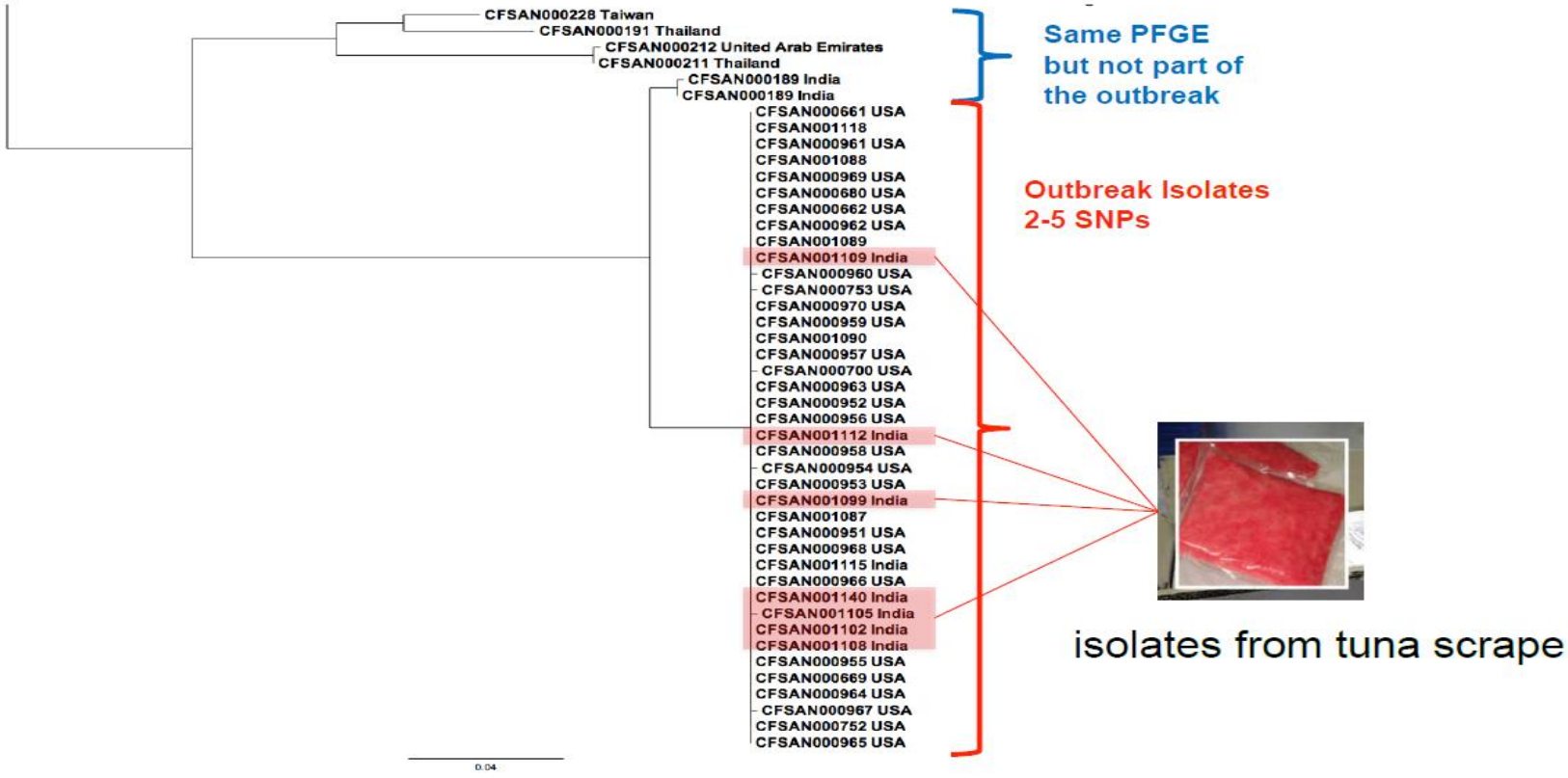
24 states
410 patients



- ✓ PFGE result showed homology with unrelated Salmonella strains previously isolated from Thailand, Taiwan and India.
  → it was difficult to find the food of responsible with PFGE

SNP analysis

SNP phylogeny for *S.* Bareilly strains

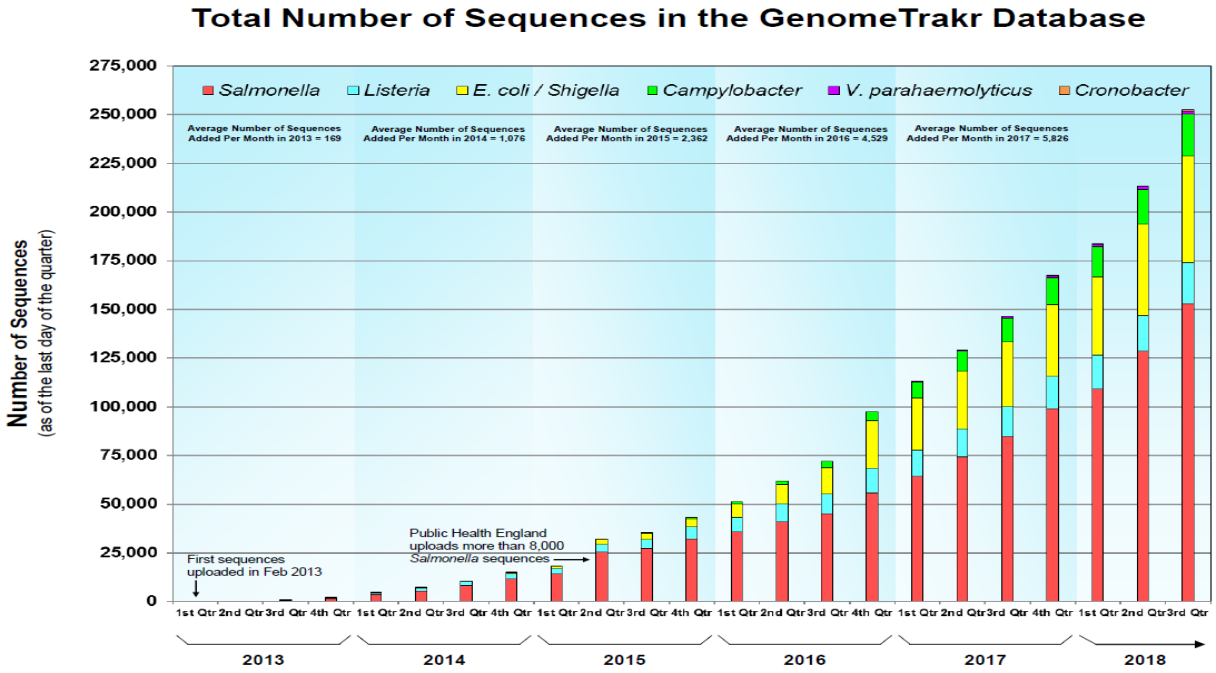


- ✓ US FDA find out the tuna scrape was the food of responsible for the Salmonella outbreak
- ✓ 6 strains with the same PFGE pattern but not part of the outbreak categorized differently by WGS

The paradigm shift

- (US) Whole Genome Sequencing technology is used for quick and accurate outbreak investigation ('13~) : Develop and run GenomeTrakr network
- The UK ('14~, FSA), China ('09~, BGI): collect and apply WGS in food safety management

  * FSA: Food Safety Agency, ** BGI: Beijing Genome Institute



FDA GenomeTrakr (252,000 WGS)

Establishment NGS analysis system

- ✓ Foodborne Pathogen Resource Center
- ✓ WGS
- ✓ Metagenome
- ✓ Genome DB
- ✓ Analyzing program

Ministry of Food and Drug Safety

Foodborne pathogen resources center

(Korea Culture Collection for Foodborne Pathogen)

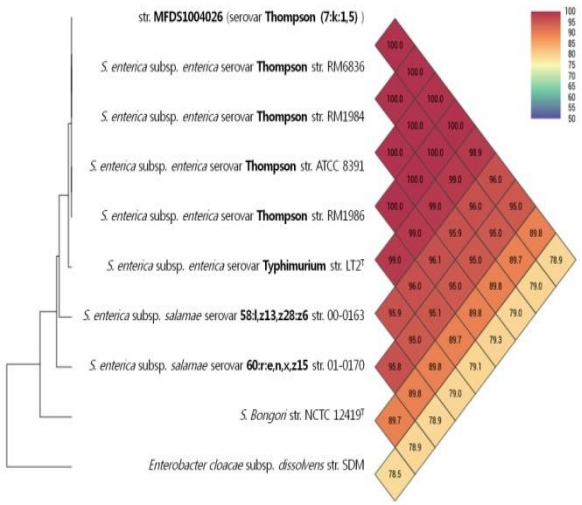
- ✓ We built FP resource center to collect and systematically store foodborne pathogens from outbreak and surveillance program
- ✓ The collected strains can be used for various analysis including WGS and MG analysis

Whole genome Lab

Metagenomics lab

WGS

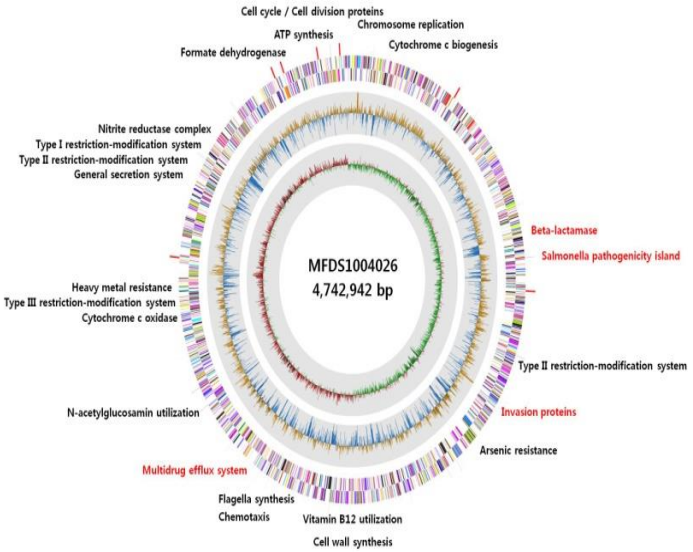
- Collect whole genome of foodborne pathogen
- All WGS information is stored in DB for homology analysis
- WGS: identify virulence factors (genes), resistome, etc



<Average nucleotide identification (ANI)>

COG	Description	Genes	%
J	Translation, ribosomal structure and biogenesis	176	4.09%
K	Transcription	322	7.48%
L	Replication, recombination and repair	181	4.20%
D	Cell cycle control, cell division, chromosome partitioning	39	0.91%
O	Posttranslational modification, protein turnover, chaperones	178	4.13%
M	Cell wall/membrane/envelope biogenesis	272	6.32%
N	Cell motility	73	1.70%
P	Inorganic ion transport and metabolism	242	5.62%
T	Signal transduction mechanisms	154	3.58%
C	Energy production and conversion	300	6.97%
G	Carbohydrate transport and metabolism	398	9.25%
E	Amino acid transport and metabolism	373	8.66%
F	Nucleotide transport and metabolism	91	2.11%
H	Coenzyme transport and metabolism	149	3.46%
I	Lipid transport and metabolism	84	1.95%
Q	Secondary metabolites biosynthesis, transport and catabolism	56	1.30%
R	General function prediction only	0	0.00%
S	Function unknown	1,217	28.27%
Total		4,305	100%

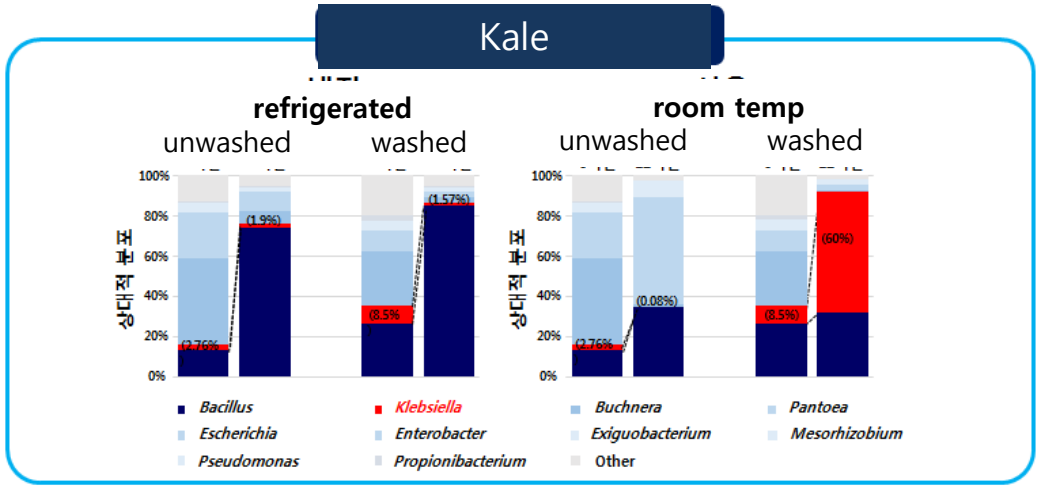
<COG and CDSs>



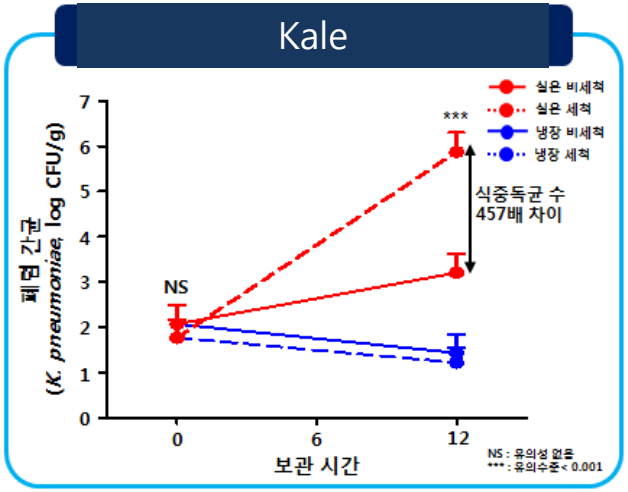
<Genome Map>

Metagenome analysis

◆ Microbial community analysis of various food commodities for quality control
- The containing species of lactic acid bacteria
  * Confirmation of compliance with labeling and quality control of probiotics and fermented milk products
- Application of microbial community analysis to microbiological quality control of foods



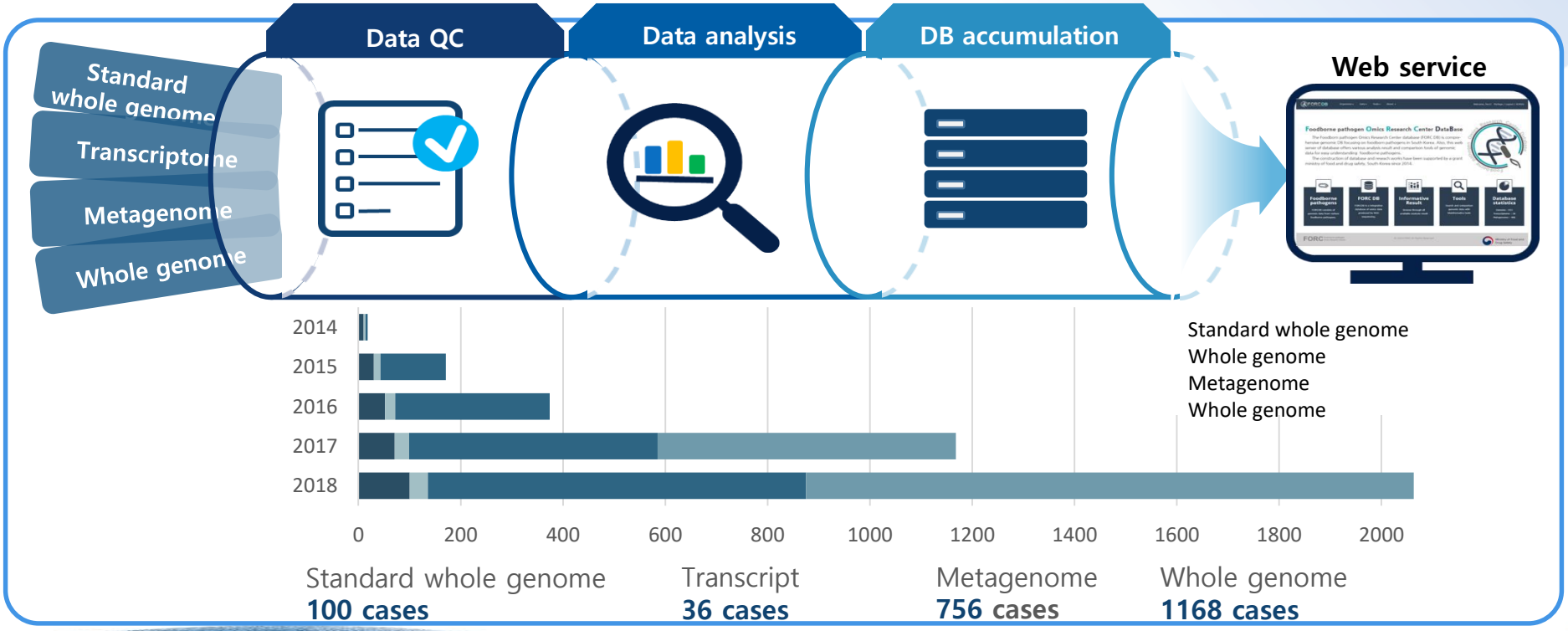
Proportion of bacteria



# of bacteria

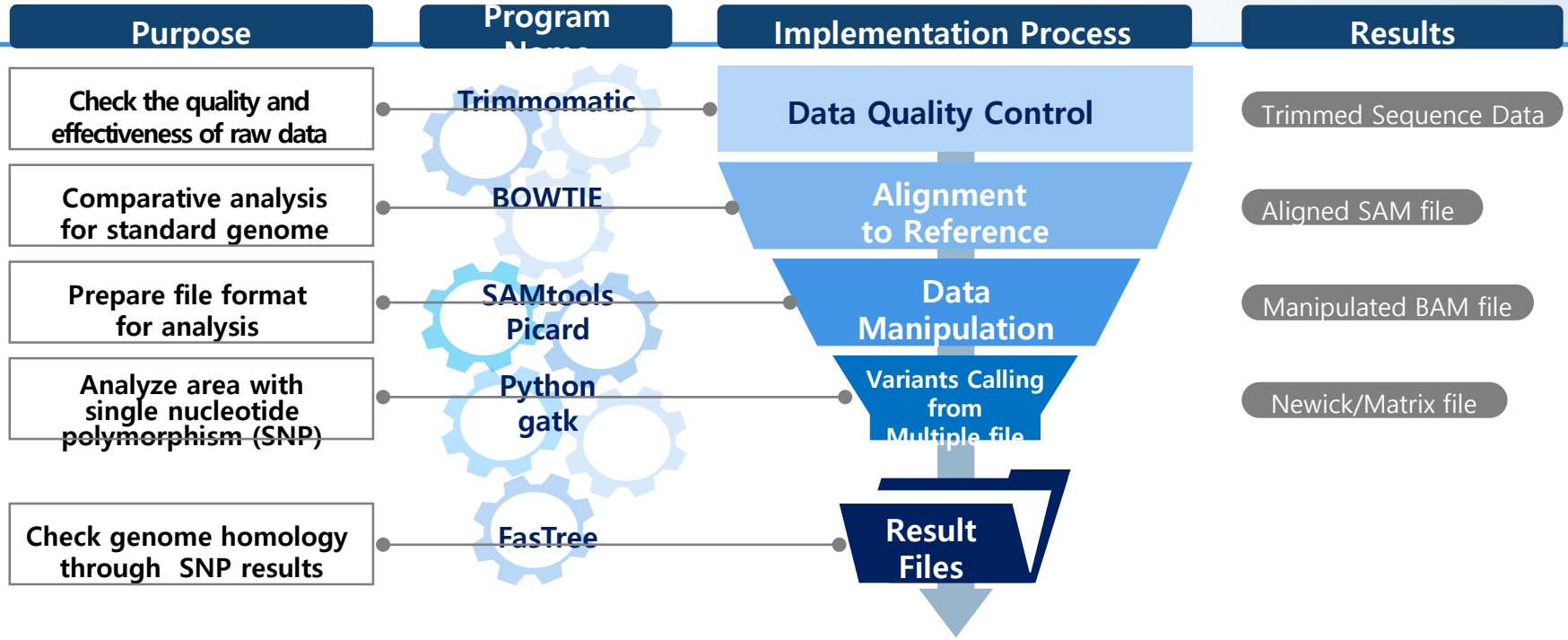
Establishment of Genome DB

- Establishment of genome DB: identify and analyze genome-level information on foodborne Pathogens.
- WGS including high quality standard WG, transcriptome, metagenome are stored
- At the end of 2019, about 3000 genome information will be collected



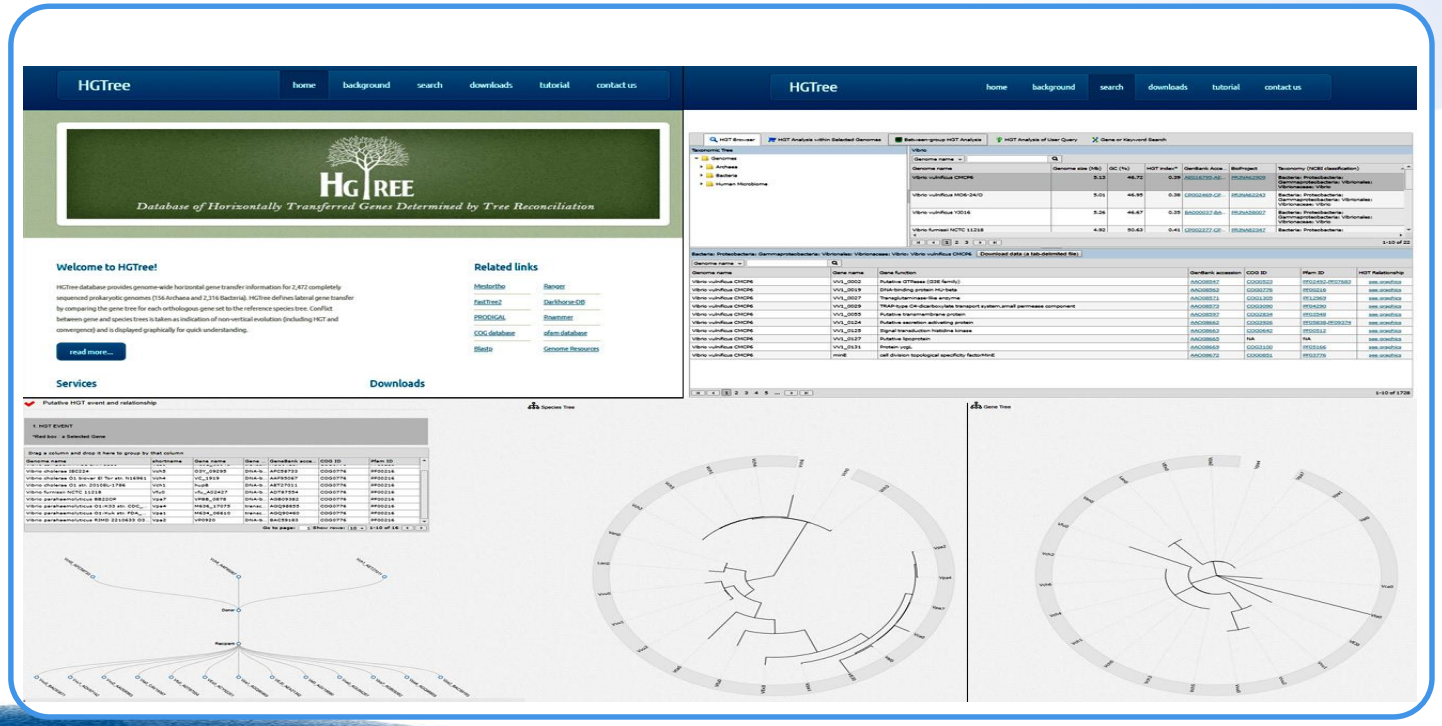
Analysis program – MFDS SNPing

- SNP-based genome homology analysis
- Development of pipeline for comparative analysis on foodborne pathogen genome information to be utilized for exact identification of causes for foodborne outbreak.
- Web based, minimize the steps of work flow, easy use (for non-expert)



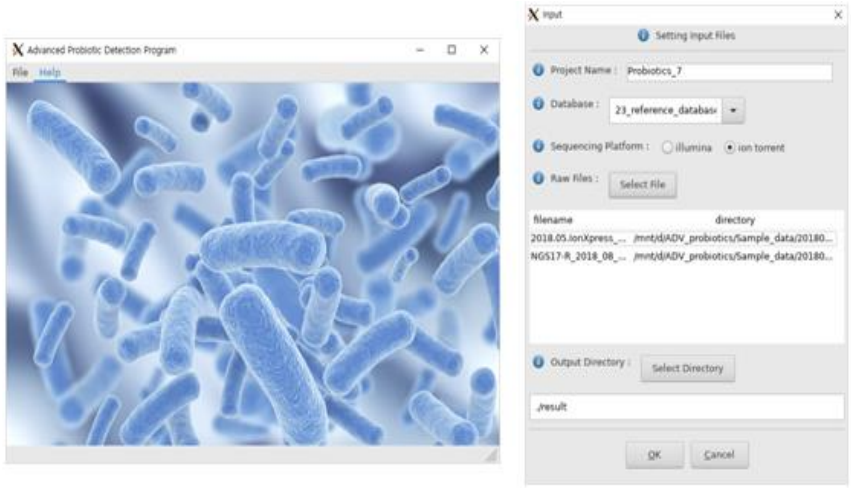
Analysis program – HGTree

- Horizontal gene transfer database
- Analyzes the acquisition of virulence and/or antibiotic resistance genes through different microbial species
- Database with horizontal gene transfer in between 2,472 microbial genomes

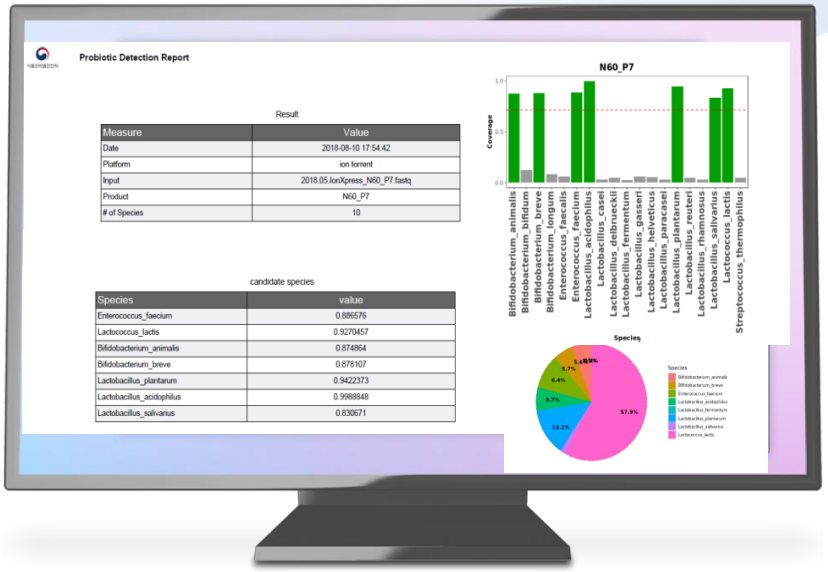


Analysis program – Metagenome

- Pipeline to observe the composition of the lactic acid bacterial species and their ratio in food
  - Accurate identification of lactic acid bacteria by comparing and analyzing microbial genome information



< Metagenome analysis program>

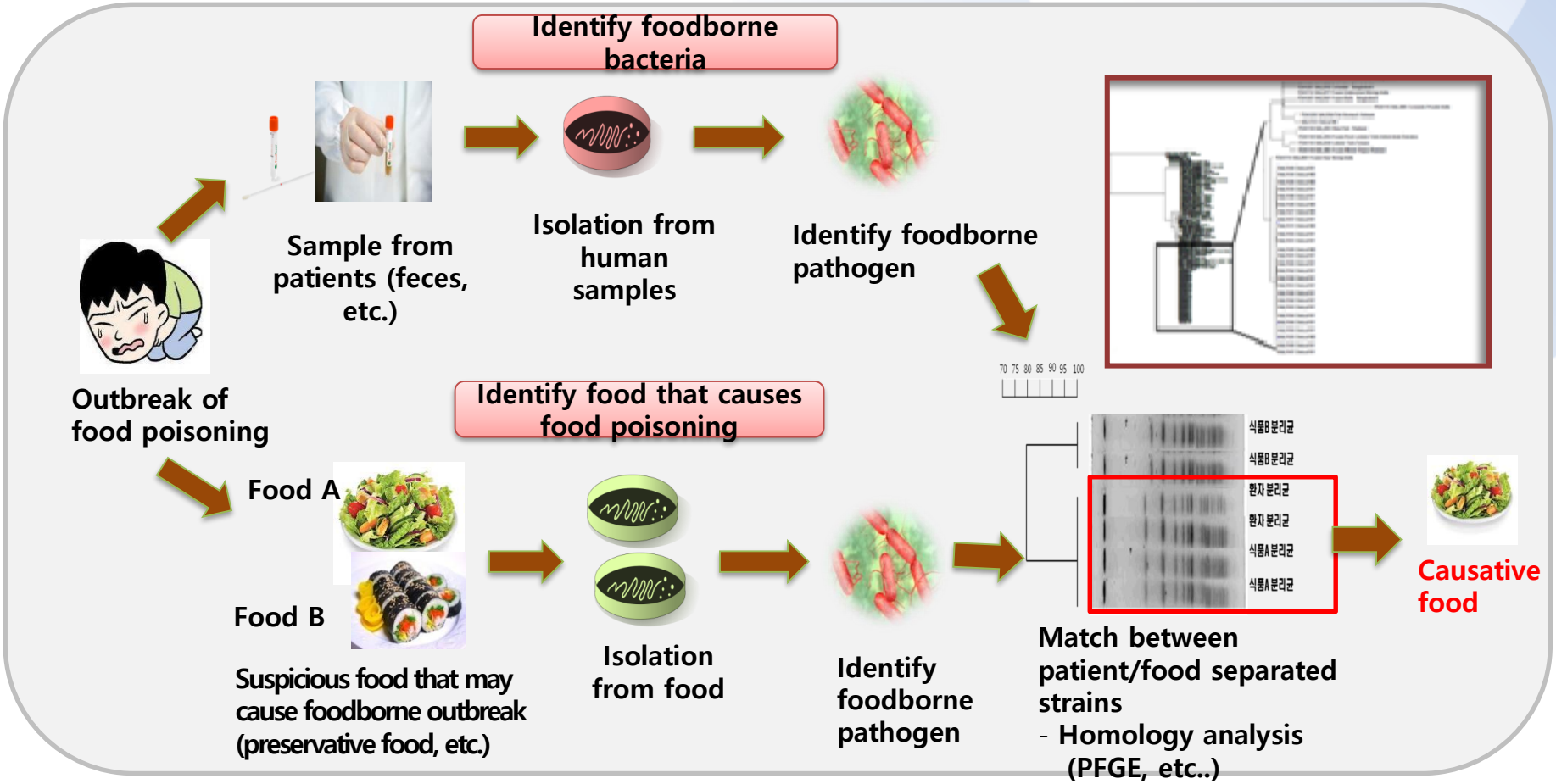


< Analyzed result>

WGS for outbreak investigation

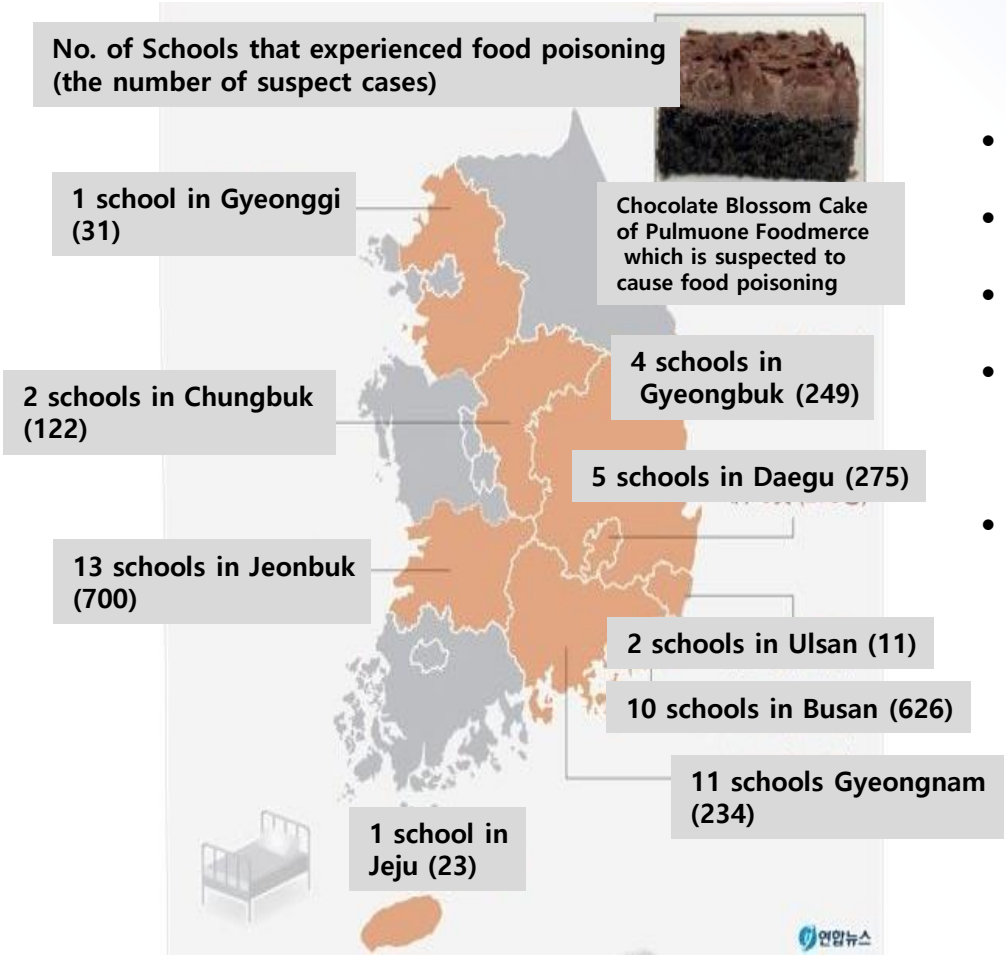
Ministry of Food and Drug Safety

Process of Foodborne Outbreak Investigation



The genetic homology of pathogen isolated from patients and food samples are confirmed through PFGE → PFGE & WGS

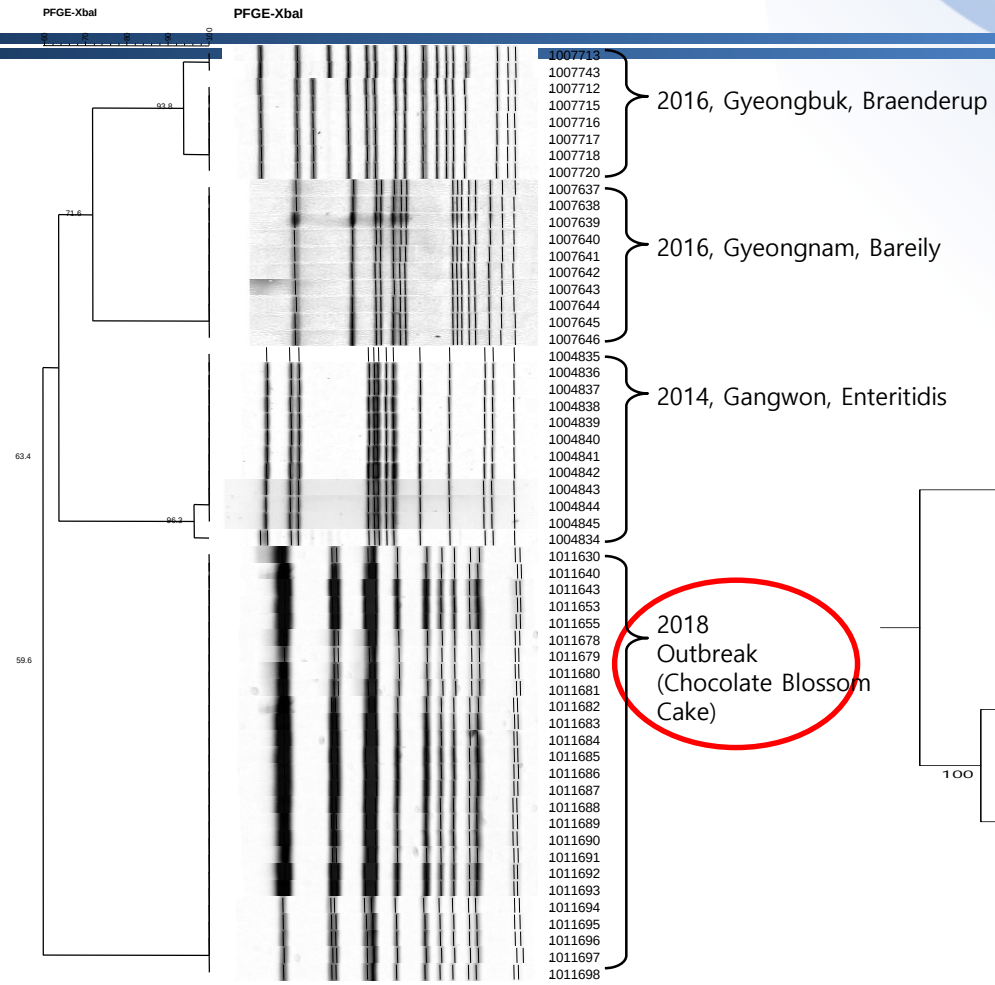
Salmonella Thompson outbreak (2018)



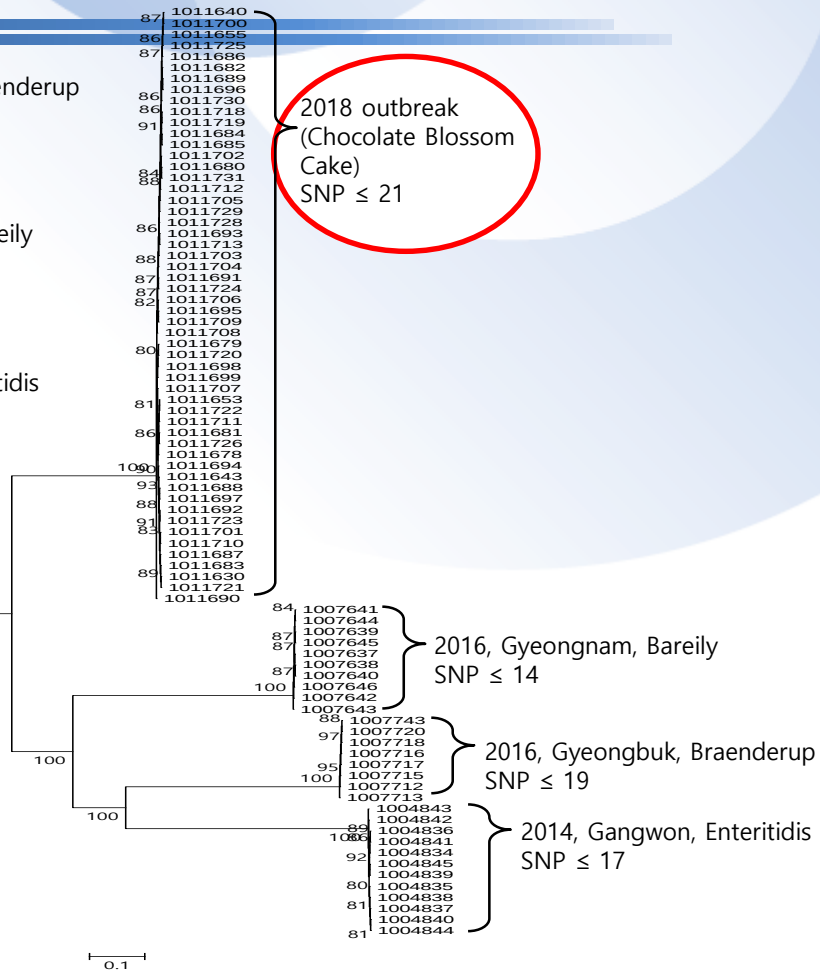
- dateL Sep. 2018
- No. of patients: 2,207
- Causative agent: *S.* Thompson
- Responsible food: chocolate cake

- *S.* Thompson identified in patients, preserved foods, raw and processed liquid egg whites, and the environment (whippers)

A. PFGE Analysis



B. Genome Analysis



The same PFGE pattern and WGS result were identified within Salmonella isolated from patients and chocolate cake product, raw and processed materials and environment.

Metagenome for probiotic products

Ministry of Food and Drug Safety

US FDA, NGS need for quality control of probiotic product

Culture-Independent Metagenomic Surveillance of Commercially Available Probiotics with High-Throughput Next-Generation Sequencing

Jennifer N. Patro, Padmini Ramachandran, Tammy Barnaba, Mark K. Mammel, Jada L. Lewis, Christopher A. Elkins

Division of Molecular Biology, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, Laurel, Maryland, USA

ABSTRACT Millions of people consume dietary supplements either following a doctor's recommendation or at their own discretion to improve their overall health and well-being. This is a rapidly growing trend, with an associated and expanding manufacturing industry to meet the demand for new health-related products. In this study, we examined the contents and microbial viability of several popular probiotic products on the United States market. Culture-independent methods are proving ideal for fast and efficient analysis of foodborne pathogens and their associated microbial communities but may also be relevant for analyzing probiotics containing mixed microbial constituents. These products were subjected to next-generation whole-genome sequencing and analyzed by a custom in-house-developed k-mer counting method to validate manufacturer label information. In addition, the batch variability of respective products was examined to determine if any changes in their formulations and/or the manufacturing process occurred. Overall, the products we tested adhered to the ingredient claims and lot-to-lot differences were minimal. However, there were a few discrepancies in the naming of closely related *Lactobacillus* and *Bifidobacterium* species, whereas one product contained an apparent *Enterococcus* contaminant in two of its three lots. With the microbial contents of the products identified, we used traditional PCR and colony counting methods to comparatively

available products containing multiple microbes to ensure consumer safety.

Received 29 February 2016 **Accepted** 9 March 2016 **Published** 30 March 2016

Citation Patro JN, Ramachandran P, Barnaba T, Mammel MK, Lewis JL, Elkins CA. 2016. Culture-independent metagenomic surveillance of commercially available probiotics with high-throughput next-generation sequencing. mSphere 1(2):e00057-16. doi:10.1128/mSphere.00057-16.

Editor Garret Suen, University of Wisconsin, Madison

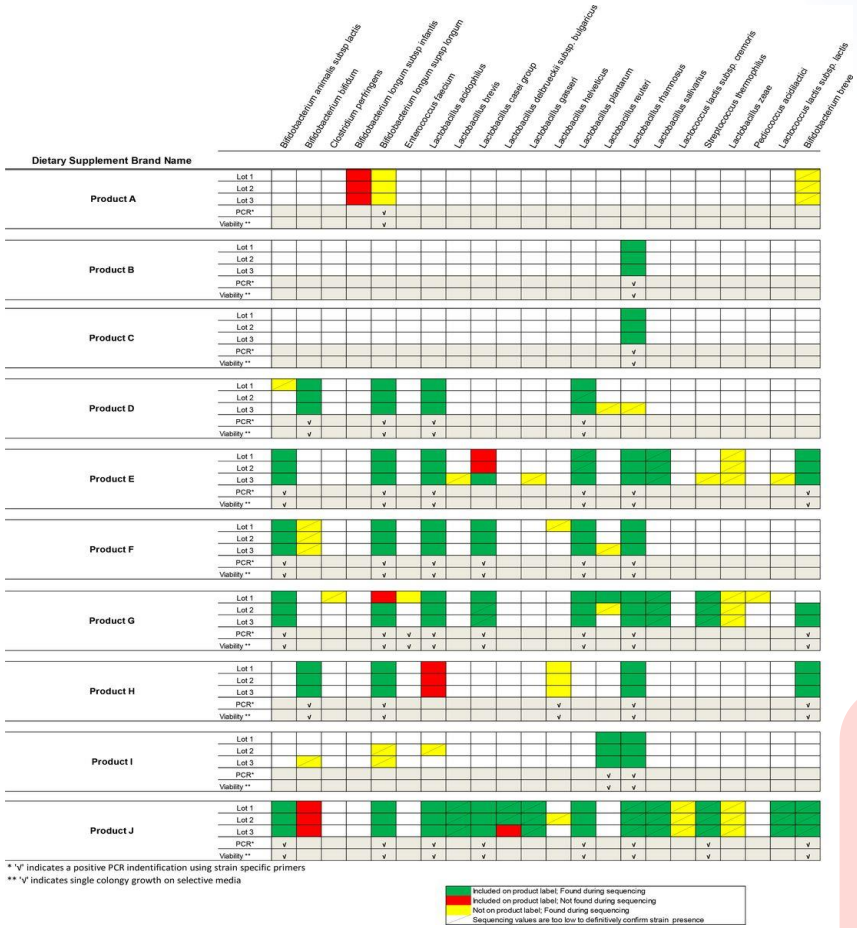
Address correspondence to Christopher A. Elkins, chris.elkins@fda.hhs.gov.

J.N.P. and P.R. contributed equally to this work.

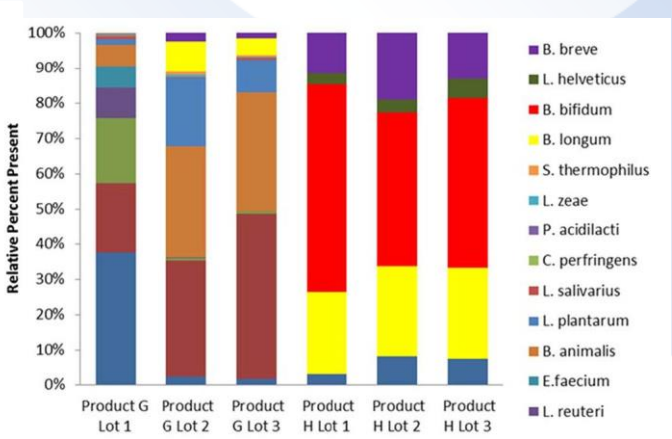
Sequencing of probiotics sold in US market

FDA emphasized the need for the introduction of NGS for metagenomic surveillance on probiotic products.

Researches on the test of LAB by metagenomic sequencing and analysis



A. It is notable that some of the indicated LAB and bifidobacteria ingredients from 5 probiotic products were not detected



B. The relative abundance of each bacterium in a product also shows the inconsistency in different lot of the same product

- This study gave us a good reason why we need to test and control the quality of the commercial probiotic products.
- The NGS clearly demonstrated its utility for quickly analyzing commercially available products containing multiple microbes to ensure consumer safety.

mSphere, 2016, 1(2):e00057-16

US FDA, researches on probiotic products

FDA developing next-gen toolbox for probiotic products

By Stephen Daniells+

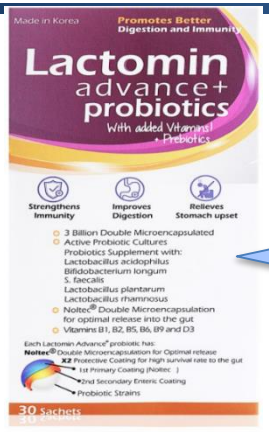
16-May-2016

Last updated on 03-Jun-2016 at 17:12 GMT

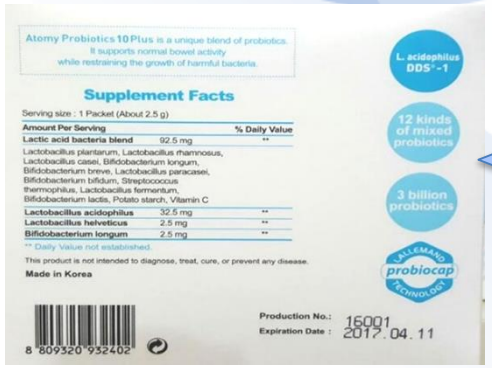
Related tags: Probiotics, DNA microarray, FDA, GMPs, IPA World Congress + Probiota Americas

The US Food and Drug Administration is developing a next-generation toolbox for analyzing live microbial products, including DNA microarrays, metagenomic sequencing and analysis, and a whole genome database development.

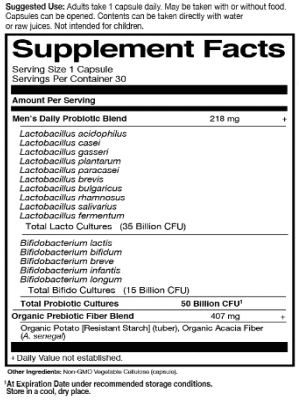
Labelling probiotic products



Lactobacillus acidophilus,
Bifidobacterium longum,
Lactobacillus plantarum,
Lactobacillus rhamnosus



Lactobacillus plantarum,
Lactobacillus rhamnosus,
Lactobacillus casei,
Lactobacillus paracasei,
Lactobacillus fermentum,
Bifidobacterium longum,
Bifidobacterium breve
Bifidobacterium bifidum,
Bifidobacterium lactis,
Streptococcus thermophilus



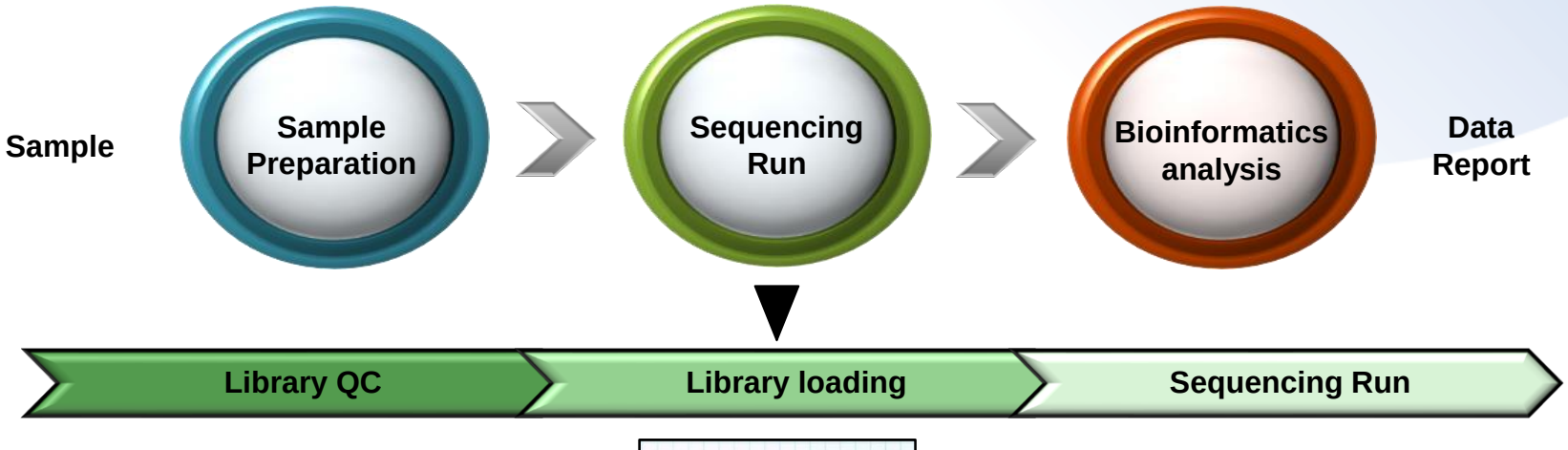
Lactobacillus acidophilus,
Lactobacillus casei,
Lactobacillus gasseri,
Lactobacillus plantarum,
Lactobacillus paracasei,
Lactobacillus rhamnosus,
Lactobacillus fermentum,
Lactobacillus bulgaricus,
Lactobacillus salivarius,
Bifidobacterium longum,
Bifidobacterium breve,
Bifidobacterium bifidum,
Bifidobacterium lactis,
Bifidobacterium infantis

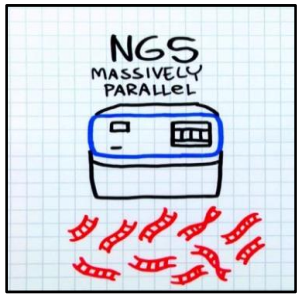
Streptococcus thermophilus
Lactobacillus acidophilus,
Bifidobacterium lactis,
Lactobacillus rhamnosus,
Bifidobacterium longum,
Bifidobacterium bifidum

With the conventional culture based detection, it is impossible to identify the variety of microbial species contained in probiotic products
→ However, microbial species can possibly be identified by NGS technology

Metagenome for probiotic products

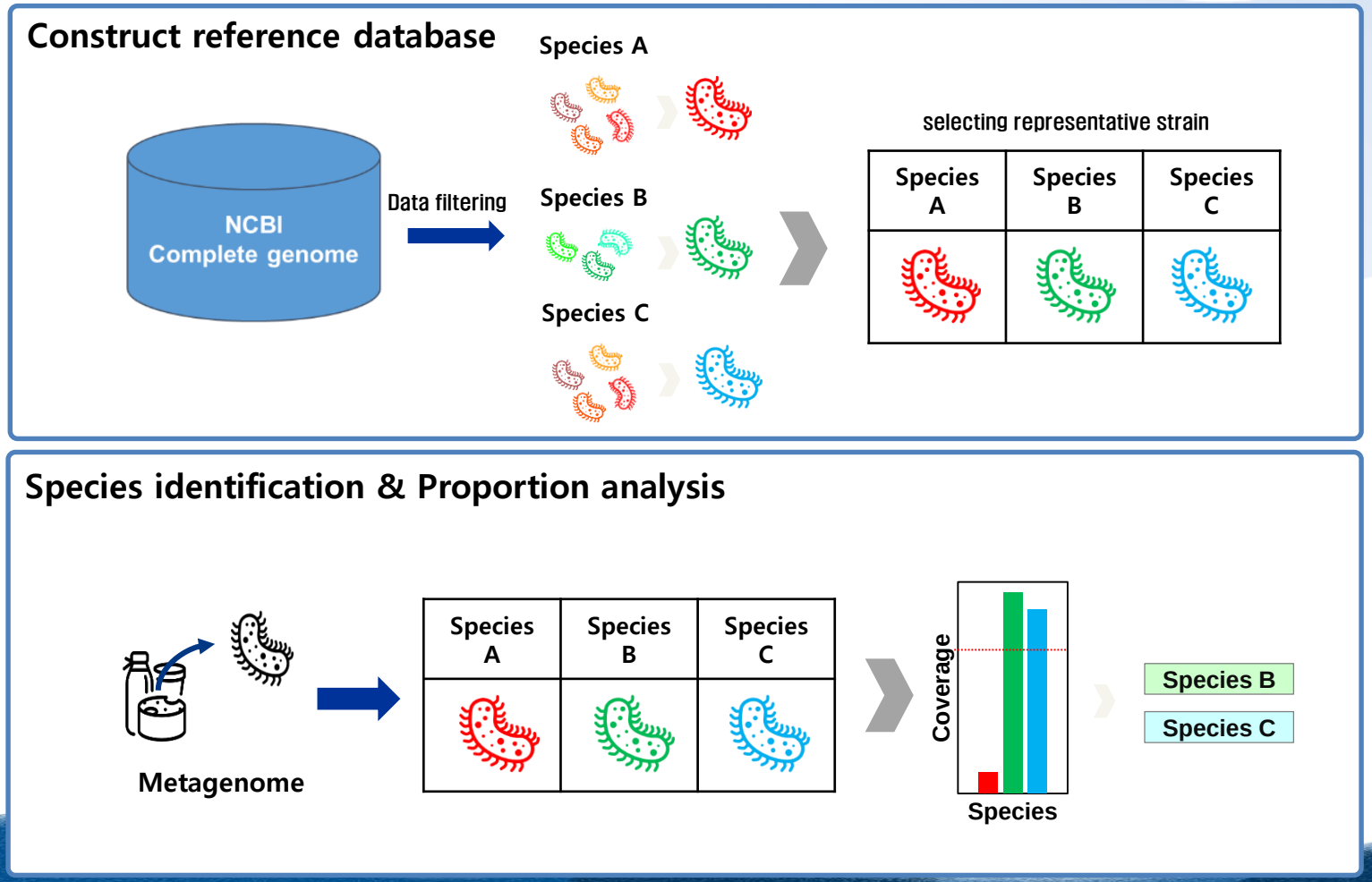
- Add NGS based metagenome analysis for the standard test method
- Propose to submit WGS information of each bacterial strain for certifying probiotic products



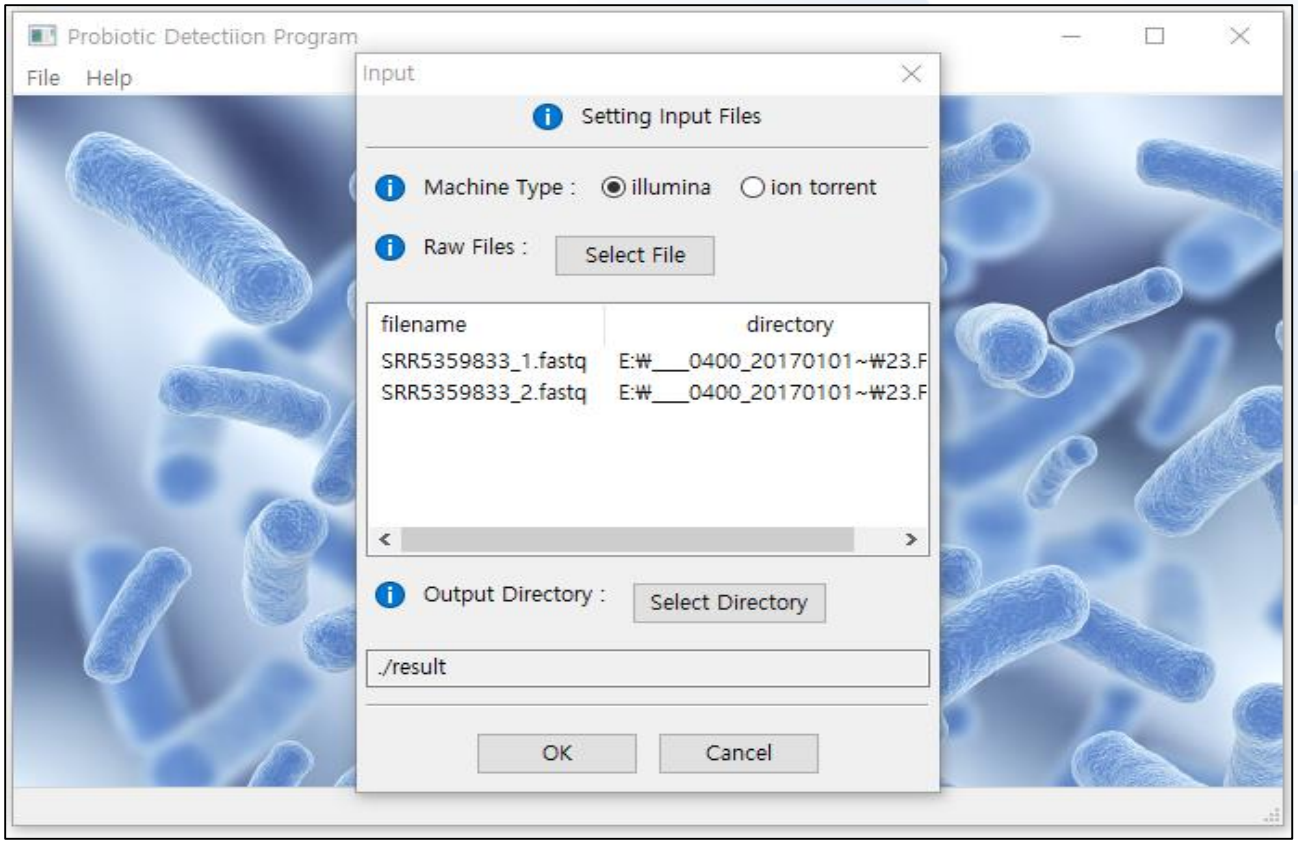


Metagenome pipeline

The development of the pipeline is working in two steps which are building a reference genome database and a software for detecting LAB and calculating ratio of each species



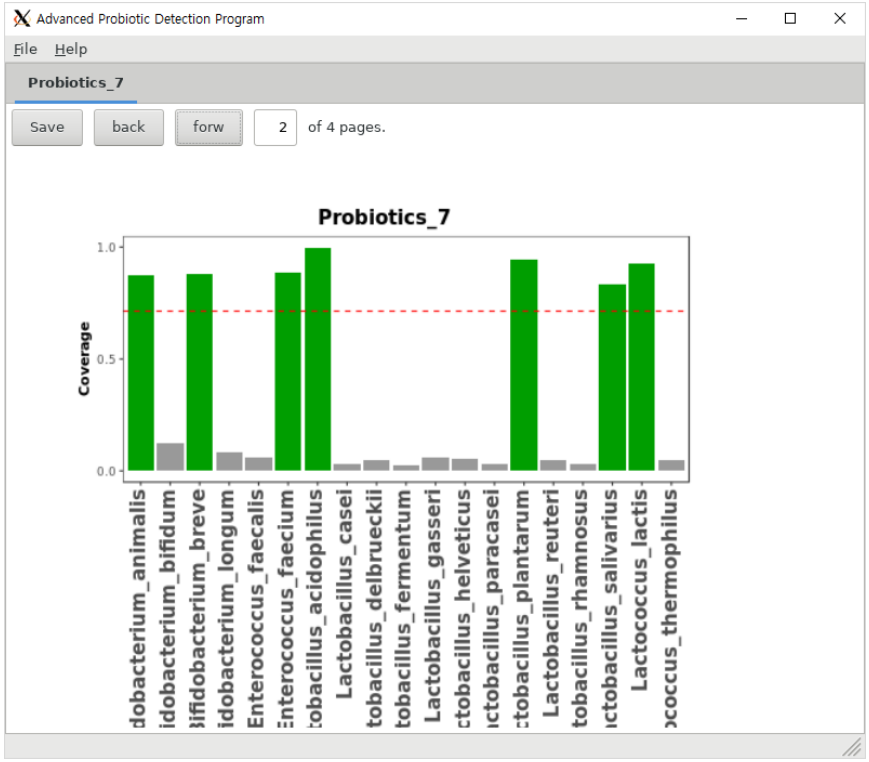
Automated analysis



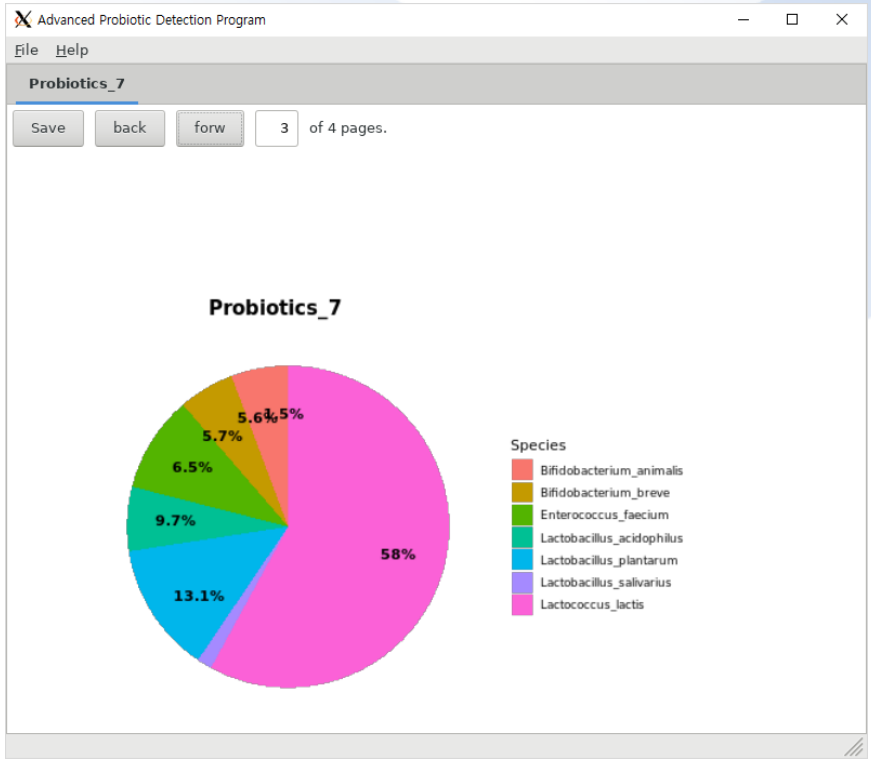
Pipeline has been developed to automate the input of metagenome data and verify the results.

Analyzed result

Identification of species

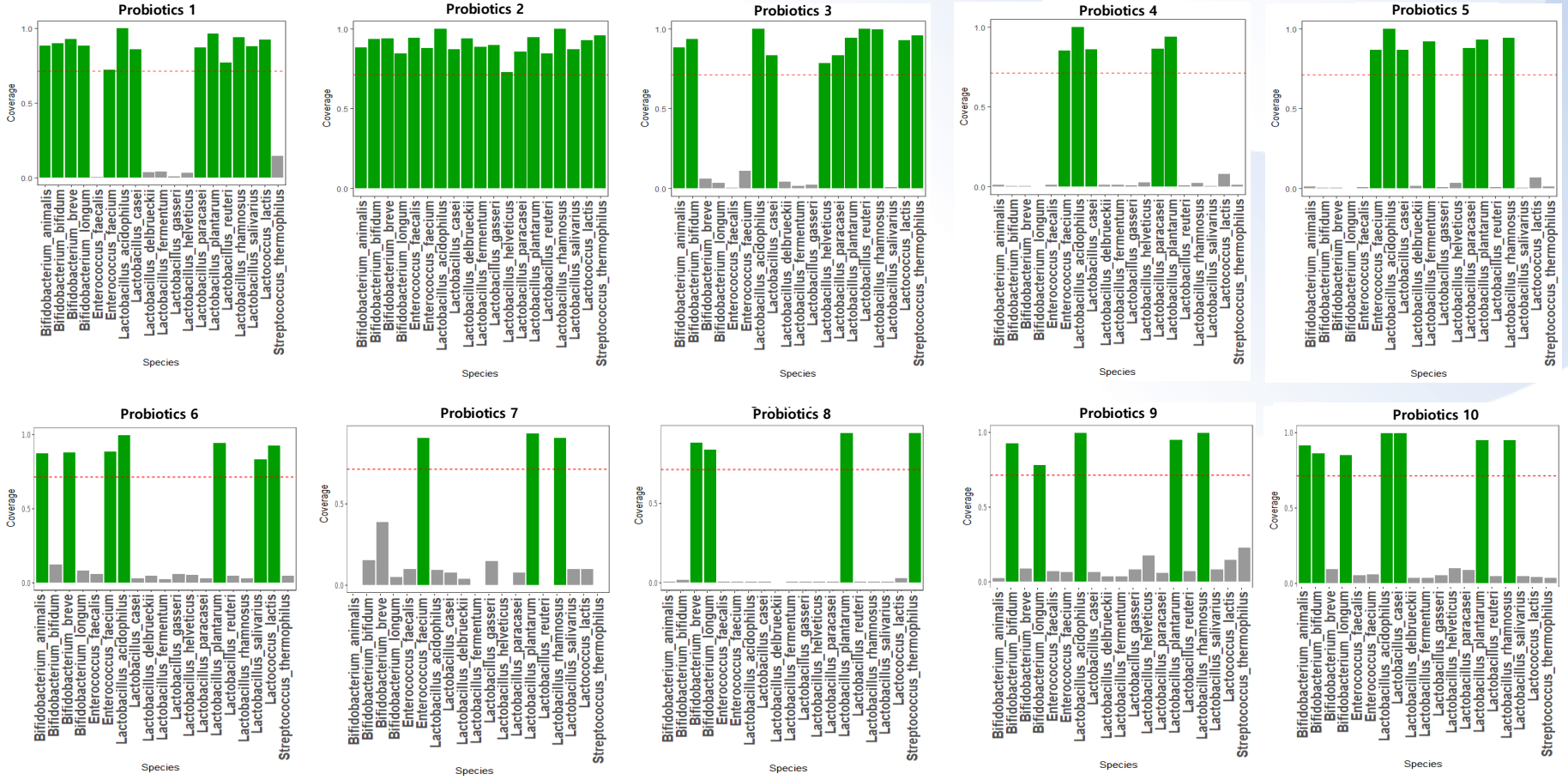


Ratio of LAB species



This pipeline enables the identification of lactic acid bacteria contained in probiotic products and proportions of lactic acid bacterial spices.

Real product applications



➢ From this pilot test on 10 commercially available probiotic products, we could check our pipeline has higher accuracy and it is more user friendly than other software.

Future plan

Ministry of Food and Drug Safety

Major goals

- ✓ continuing collection of WGS information
- ✓ Develop pipeline for serotype analysis
- ✓ Collaborating research with US FDA
- ✓ Expanding metagenome DB for LAB
- ✓ Establishment of fb-pathogen genome network

Foodborne Pathogen Genome Network

Genome DB | **Analysis system**

WGS data Standardize & Transfer

- Isolates from outbreak
- Isolates from contaminated food/environment
- Foreign Genome DB (DDBJ, NCBI, EMBL-EBI — INSDC, International Nucleotide Sequence Database Collaboration)

GUI-based Analysis Reports

- Identification of causes of foodborne disease
- SNPing and Clustering

Genome characterization

- Comparative genomic analysis
- Virulence marker search
- Domestic vs Foreign isolates comparison

MFDS and regional offices

Relevant organizations (National Institute of Fisheries Science, National Institute of Animal Science)

Health and Environment Research Institute

Domestic researchers

- ✓ This network is intended to collect WGS data on foodborne bacteria isolated from outbreak and contaminated food/environment by MFDS and relevant organizations.
- ✓ It is expected to obtain various analysis results in one place and short time
- ✓ It will be written and published in English, It will be available for everyone in 2021

Acknowledgement

MINISTRY OF FOOD AND DRUG SAFETY
National Institute
of Food and Drug Safety Evaluation

Food Microbiology Division, MFDS

C&K genomics

Bioinformatics analysis : Woori Kwak, Donghyeok Seol

Thank You

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

Healthy China 2030 Vision to Action

Sugar Related Policies and Regulations Update

Jennie Zheng, Tate & Lyle, Sep. 26

Content

- Healthy China 2030 landscapes
- The overall objectives related with sugar
- Government Actions
- Society Actions
- Personnel Actions
- Food producers' commitment

Healthy China 2030 landscapes

~~from Guidance to Executive Actions

❖ from vision to action

Healthy China Programme 2030

- Guide Reasonable Diet

National Nutrition Programme

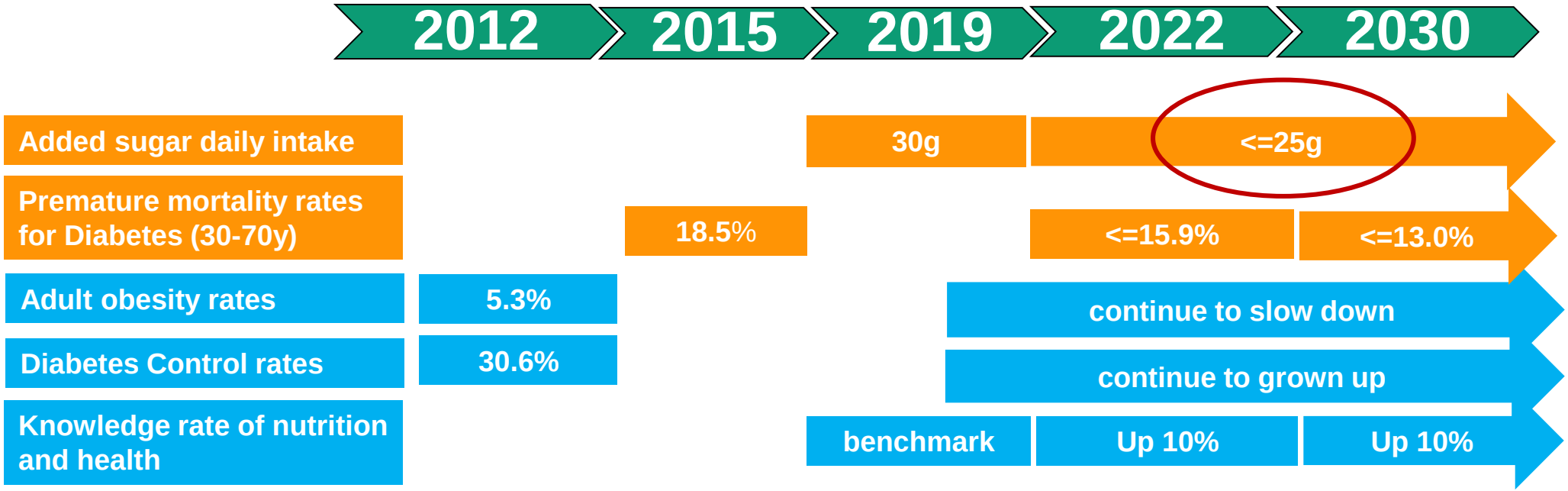
- Eating balance
- Reduce Sugar, Oil, Salt

Healthy China Actions

- Actions for Reasonable diet

2015 → 2016 → 2017 → 2019 → 2022 → 2030

The overall objectives related with Sugar



Anticipatory objective
Advocacy objective

Government Action 1: Regulation approach

~~Strengthen Nutrition Regulation from top-to-down

2019 → **2020** → **2022** → **2030**

Nutrition Regulation

- Speed up sugar labeling regulation release
- Set up added sugar intake guidance for Children as soon as possible

Nutrition and Health Standard

- Limit high sugar product commercialization
- Promote Low sugar or none sugar product
- Develop Nutrition driven food industry

Government Action 2: Visual-target approach

~~~Label/Packaging

2017 | 2018 | 2019 | 2020 | 2022 | 2030

Nutrition Information Panel in 2011. Reinforce low sugar or none sugar claim

Nutrition Information Panel is under drafting and plan to add sugar Label

Voluntary FOP nutrition label in May 2018, reinforcing the adoption

Voluntary Health Choice logo Oct 2018, reinforcing the adoption,

Start the trial for Sugar label in food service industry

Add sugar daily intake warning label on sugar packaging

图 1 “健康选择”标识（LOGO）

图 2 “聪明选择”标识（LOGO）

Sugar<11g/100g	Health Choice example	FOP example	NIP example

Society Action: Recipe innovation approach

~~~Sugar replacement

2019 → **2020** → **2022** → **2030**

Food manufactures

- Use natural sweet substitutes or sweeteners to replace Glucose in the recipe
- Scientific based glucose reduction during food processing
- strengthen “low sugar” or “none sugar” claim on packaging

Whole Society

- specific counters for low-sugar foods in supermarket or stores
- Limit to commercialize high sugar content beverage and snacks in schools.
- Reduce to serve sugar containing beverage and food in canteen

Personnel Action: Habit Initiative approach

~~~Consume less sugars

2019	2020	2022	2030

General Population	• limit added sugar consumption • Less sugar containing beverage/desert consumption • Improve capability to identify low/none- sugar food through nutrition label
Primary and middle school students	• Avoid high sugar containing food consumption
Aging people	• Reduce calorie intake 400-500 kcal/day • Choose Low GI food
Obesity and Diabetes population	• Reduce energy intake • Choose beverage or food containing natural sweet substitutes or sweeteners instead
~~~

Food producers' commitment 01

---Nestle : Further decrease sugars

2019 | 2020 | 2030

- Cutting sugars in cocoa and malt beverage products, with the detail approaches:
- Increasing fiber while reducing sugar
- without added sucrose

Nestlé Good Food, Good Life

By 2020

Reduce the sugars we add in our foods and beverages by 5% to support individuals and families in meeting global recommendations.

●●○ In progress

Our result: 0.8% of sugar removed from our foods and beverages*.

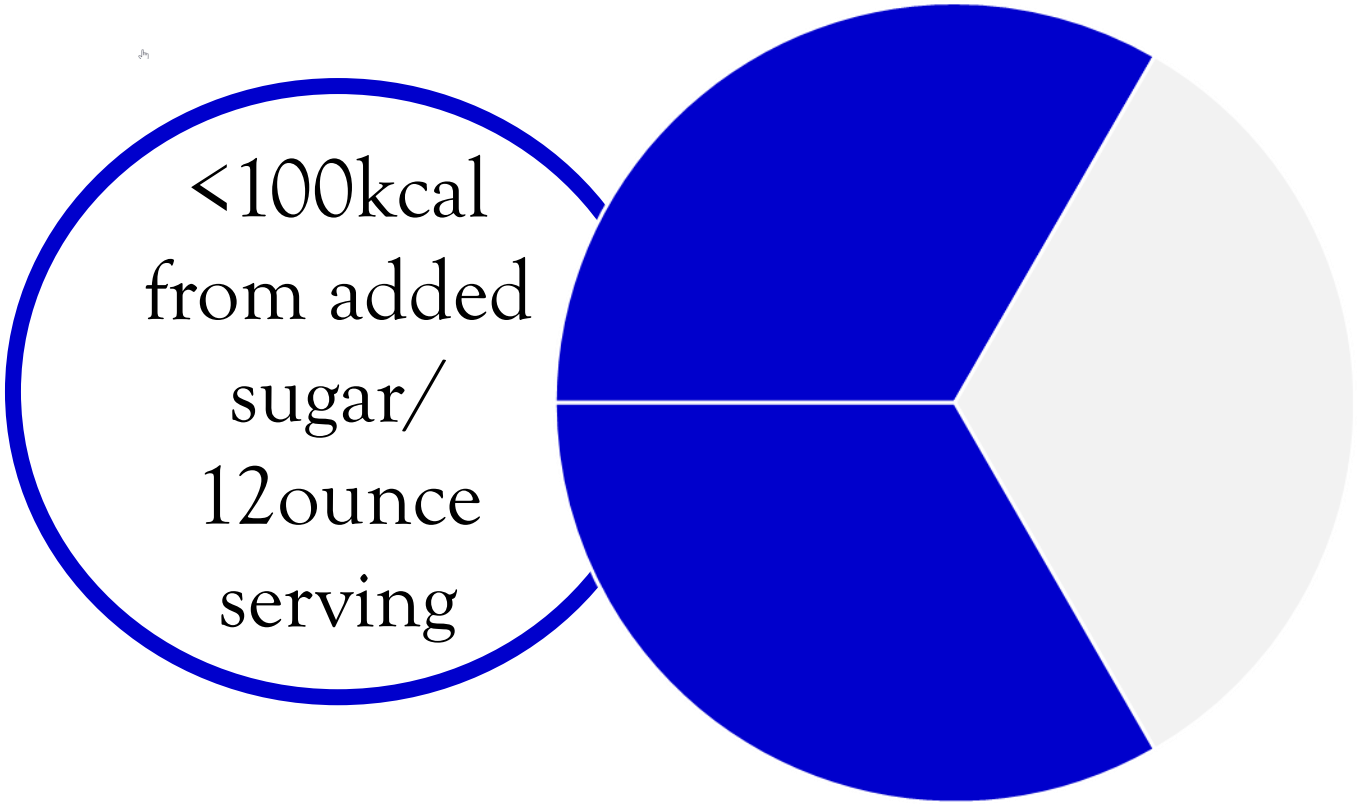
Food producers' commitment 02

---Pepsico : "2025 objective"

2019 → 2025 → 2030

pepsi

Global Beverage Portfolio Volume



Summary

- Added sugar daily intake <25g by 2030
- Government top to down sugar regulation
- Reinforce sugar labeling from every aspects
- Food manufactures continue to reduce sugar in the recipe
- Chinese population start to consume less sugar
- Food producers' set up each commitment for sugar reduction

THANKS AND QUESTIONS

Jennie Zheng,
Regulatory and Scientific Affairs Manager, Greater China
Tate & Lyle, Sep. 26, Penang
Jennie.zheng@tateandlyle.com

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

The Circumstances Surrounding Sugar in Japan

Merina Sugimori

Coca-Cola (Japan) Company

Disclosure

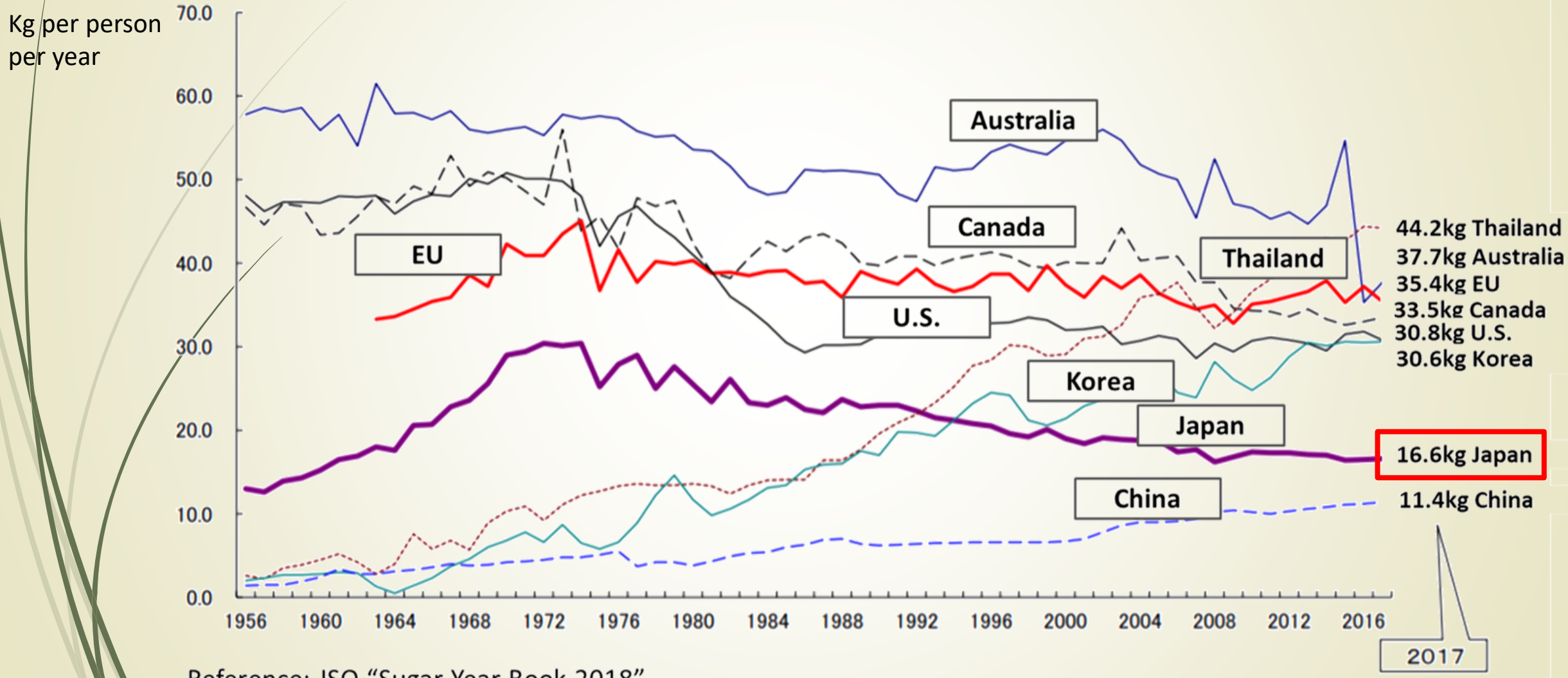
I have no actual or potential conflict of interest in relation to this presentation.

Agenda

- Overview
- Administrative views on sugar in Japan
- Positioning of sugar in terms of nutrition
- Sugar labeling regulation
- Types of sweeteners
- Sugar with health functions
- Conclusion

Overview

Annual sugar intake by country



Reference: ISO “Sugar Year Book 2018”

*The amount of sugar in terms of raw sugar

Overview

WHO sugar recommendations

- WHO guideline (2015) strongly recommends adults and children reduce their daily intake of free sugars to less than 10% of their total energy intake to prevent obesity and tooth decay
- A further reduction to below 5% or roughly 25 grams (6 teaspoons) per day would provide additional health benefits.

Administrative views on sugar

Ministry of Health, Labour and Welfare

- The ministry which determines Dietary Reference Intakes (DRIs)
- The target amount of sugar is not determined in DRIs
- Also, Sugar tax is NOT introduced
- However, sugar is recognized as a food which can be harmful if it is taken excessively
  - ✓ The standards of “no sugar” and ”reduced sugar” are determined (described later)
  - ✓ Some types of foods with functions are required to explain that it doesn’t lead to excessive intake of sugar

Administrative views on sugar

Ministry of Agriculture, Forestry and Fisheries

- MAFF conducts “Ariga-To（ありが糖）” campaign

  Arigato（ありがとう）＝Thank you

  To （糖） ＝Sugar

- The major purposes of this campaign are:
  - ✓Support the stable supply of high quality sugar
  - ✓Encourage the culture of foods which contain sugar, especially traditional Japanese cuisine and sweets
  - ✓Promote Japanese foods containing sugar to inbound tourists

Positioning of sugar in terms of nutrition

Carbohydrates（炭水化物）

Saccharides（糖質）

Starch, sugar alcohols,
oligosaccharides etc.

Sugars（糖類）

Free sugars
(monosaccharides, disaccharides)

**Dietary Fiber
（食物繊維）**

Cellulose, inulin,
Indigestible dextrin etc.

Sugar labeling regulation

- Energy: 4kcal/g
- Labeling standards

Appropriate intake of sugar labeling

- ✓ **No sugar**
  <0.5g/100g or <0.5g/100ml
- ✓ **Low sugar**
  <5g/100g or <2.5g/100ml
- ✓ **Reduced sugar**
  >5g/100g or >2.5g/100ml reduction as well as >25% relative difference

"No sugar added" labeling

- ✓ **No sugar added**
  Neither any types of sugars including honey nor sugar equivalents such as dry fruit are not used

*In addition to meet each standard, sugar amount labeling is also required

Sugar with health functions

Two functional food categories, FOSHU (Food for Specified Health Uses) and FFC (Foods with Function Claims) admit some kinds of sugars as active ingredients respectively.

Types of sugar	Functions	Category
Isomaltulose (disaccharide)	Improve tooth health	FOSHU
	Moderate the rise of blood sugar level after meal	FFC
Rare sugars - psicose, sorbose, tagatose,allose (monosaccharide)	A sweetener with lesser rise of blood sugar level than sugar	FFC

Conclusion

- Sugar intake of Japan is relatively low, one of the reasons is because more people are health conscious
- DRIs for sugar is not determined nor sugar tax is not introduced while sugar is recognized as a food which can be harmful if it is taken excessively
- The labeling standards are determined to encourage the appropriate sugar intake
- Some sugars are admitted to claim health functions

THANK YOU!!

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

Sugar Related Policies and Regulations in SEA Region

Pauline Chan
Director
Scientific Programs
ILSI SEA Region

ILSI
Southeast Asia Region

Sugar reduction in SEA

- With the rising prevalence of NCDs in SEA Region, health authorities in many regional countries are taking actions to promote healthy lifestyles including healthy diets
- One of the strategies used is the reduction of sugar in the diet
  - Education to cut down sugar consumption
  - Encouragement of product reformulations
  - Sugar tax

ILSI Southeast Asia Region

Product reformulation

- Healthier Choice Logo programs have been implemented in several countries to improve the content of food products, including the reduction of sugar content
  - Singapore
  - Malaysia
  - Thailand
  - *Brunei*
  - *Indonesia* (September 2019)*

ILSI Southeast Asia Region

Singapore-Healthier Choice Logo

- Singapore
  - Implemented in 1998
  - Currently consists of 14 categories and 105 subcategories

Beverages

Sub-category	Fat (g/100g)	Saturated Fat (g/100g)	Trans Fat (g/100g)	Sodium (mg/100g)	Total sugar (g/100g)	Added Sugar (g/100g)	Tag for HCS
Malted or chocolate drink[1,2]	≤ 2	(a)	≤ 0.1	≤ 120	-	≤ 6[3]	Lower in Sugar {Lower in Saturated Fat} {Trans Fat Free} {Lower in Sodium}
3-in-1 or 2-in-1 coffee/tea beverages [1]	≤ 1	-	≤ 0.1	-	≤ 5	-	Lower in Saturated Fat {Trans Fat Free} { Lower in Sugar} {No Added Sugar}
Soluble Coffee/Tea *(including coffee bags with no added fat)*	No Added Fat	-	-	-	-	No Added Sugar	No Added Sugar
Sweetened drinks[1,2]							Lower in Sugar [4] No Added Sugar [5] Sugar Free [6]
• Non-carbonated drinks/ Asian drink	-	-	-	-	≤ 6g	-	
• Isotonic drinks	-	-	-	-	≤ 6g	-	
• Juice drinks (at least 10% fruit juice)	-	-	-	≤40mg	≤ 6g	-	
• Carbonated drinks	-	-	-	-	≤ 7g	-	
Water (Still or Carbonated)	-	-	-	≤ 20mg	0	0	No Added Sugar [5] Sugar Free [6]

ILSI Southeast Asia Region

Singapore – Healthier Choice Logo

Desserts NEW

Sub-category	Calories/ serving	Fat (g/100g)	Saturated Fat (g/100g)	Dietary Fibre (g/100g)	Sodium (mg/100g)	Total Sugar (g/ 100g)	Tag for HCS logo
Local Soup Desserts[a] NEW							
• Clear soup desserts e.g. cheng tng, green bean soup, tau suan, red bean soup, etc.	≤ 200	-	-	≥3.0	-	≤ 6.0	Lower in Sugar
• Soup desserts containing cream[b] e.g. black sesame paste, almond paste, walnut paste, pulut hitam, bobo chacha, chendol, etc.	≤ 200	≤ 2.5	≤ 1.5	≥3.0	-	≤ 6.0	Lower in Sugar {Lower in Saturated Fat}
Jellies REVISED e.g. grass jelly, aiyu jelly, fruit jelly, etc	-	-	-	≥3.0 NEW	-	≤11 REVISED	Lower in Sugar
Pudding REVISED e.g. mango pudding, almond pudding, etc	-	≤ 1.5	(c)	≥3.0 NEW	≤ 120	≤11 REVISED	Lower in Sugar {Lower in Sodium} {Lower in Saturated Fat}

Sub-category	Fat (g/100g)	Sugar (g/100g)	Sodium (mg/100g)	Tag for HCS
Juice[1]				
Vegetable[2] (100%)	-	≤12.5	≤ 120	Lower in sodium {Lower in Sugar}
Fruit[3] (at least 60% fruit juice[d])	-	≤12.5	-	No Added Sugar
Fruit and Vegetable Juice[3]	-	≤12.5	≤120	No Added Sugar

Sub-category	Calories/ serving	Fat (g/100g)	Saturated Fat (g/100g)	Dietary Fibre (g/100g)	Sodium (mg/100g)	Total Sugar (g/ 100g)	Tag for HCS logo
Local and seasonal cakes NEW e.g. nian gao, mooncakes, pineapple tarts, nonya kueh, tapioca kueh, etc.	-	≥ 25% fat reduction compared to reference food[d]		≥3.0	-	≥ 25% sugar reduction compared to reference food[d]	Lower in Sugar {Lower in Saturated Fat}

ILSI Southeast Asia Region

Singapore-Healthier Choice Logo

Sub-Category	Energy (kcal/ serving)	Fat (g/100g)	Saturated Fat (g/100g)	Trans Fat (g/100g)	Sodium (mg/100g)	Dietary fibre (g/100g) Revised #	Total Sugar (g/100g)	% of Whole-grains*
Whole-grains								
• Rice (unpolished)				All acceptable				100
• Mixed rice[1]				All acceptable				≥ 20
• Wholegrains[1]				All acceptable				100
Flour, wholemeal	-	-	-	-	No added sodium	≥ 5	-	100
Flour, self-raising	-	-	-	-	≤ 350	≥ 5	-	100
Instant Oats / Oatmeal [2]	-	-	-	-	No added sodium	-	No Added Sugar	100
Breakfast cereal, cereal bars, cereal and fruit bars (ready-to-eat) – Adult's cereal [3]	-	≤ 4[(b)]	-	-	≤ 400	≥ 4	≤25[(a)]	≥ 25
Children's Cereal	-	≤ 3.3	-	-	-	≥ 4	≤35	≥ 25
Cereal Mix[4]	-	≤ 2	-	≤ 0.1	≤ 120	-	≤ 8	≥ 25[(f)]
Pasta	-	≤ 2[(c)]	-	-	≤ 120	≥ 3	-	100

Soy products								
• Soy milk / beverage[1]	≤ 2[(c)]	-	≤ 40	≤ 6	≥ 60			
Cultured milk drink/ yoghurt drink[1]	≤ 1	-	-	≤ 7[(a)]	-	-	Lower in Saturated F	{Lower in Sugar}
Hamburger, hotdog type	-	≤ 5[(b)]	-	≤ 0.1	≤ 450	≥ 3	-	≥ 10
Buns, rolls (filled) Cream, jam, fruits, custard, savoury	-	≤8[(b)]	-	≤ 0.1	≤ 400	≥ 2	≤ 15	≥ 10
Steamed buns								
• Filled (e.g"Pau")	-	≤ 8[(b)]	-	-	≤ 250	-	≤ 18	≥10[(e)]
• Unfilled (e.g "Mantou")	-	≤ 8[(b)]	-	-	≤ 250	-	≤ 15	≥15[(e)]
Cakes, muffins	-	≤ 22	-	≤ 0.2 [(g)]	≤ 300	≥ 3[(h)]	≤ 24	≥ 10[(e)]
Biscuits and crackers	≤ 250[(d)]	≤ 25	≤ 10	< 0.5	≤ 420	-	≤ 24	≥ 30[(e)]

Dairy Products

Sub-Category	Fat (g/100g)	Sodium (mg/100 g)	Total Sugar (g/100g)	Added Sugar (g/100g)	Calcium ^ (mg/100 ml)	Dietary Fibre (g/100g) NEW	Tag for HCS
Liquid milk (plain)	≤ 1.5	-	-	-	≥ 130	-	Lower in Saturated Fat {Higher in Calcium}
Liquid milk (flavoured)[1]	≤ 1.5	-	-	≤ 6[(a)]	≥130	-	Lower in Saturated Fat {Higher in Calcium} {Lower in Sugar}

ILSI Southeast Asia Region

Malaysia- Healthier Choice Logo

- The HCL was officially launched in April 2017 and the guidelines were revised in June 2019
  - Existing 41 HCL categories remained
  - 2 New HCL Categories added:
    - Cereal Group: Cereal Drinks + Bread
    - Beverages: Mixed Vegetable & Fruits Juice + Botanical Drink (Powder)
  - Standardization nutrient criteria between "Healthier Choice Logo Malaysia" & "Sugar-Sweetened Beverages Tax
    - Drinks: Total Sugars ≤5.0g/ 100ml
    - Flavoured Milk: Total Sugars ≤7.0g/ 100ml
    - Fruit & Vegetable Juices: Total Sugars ≤12.0g/ 100ml

ILSI Southeast Asia Region

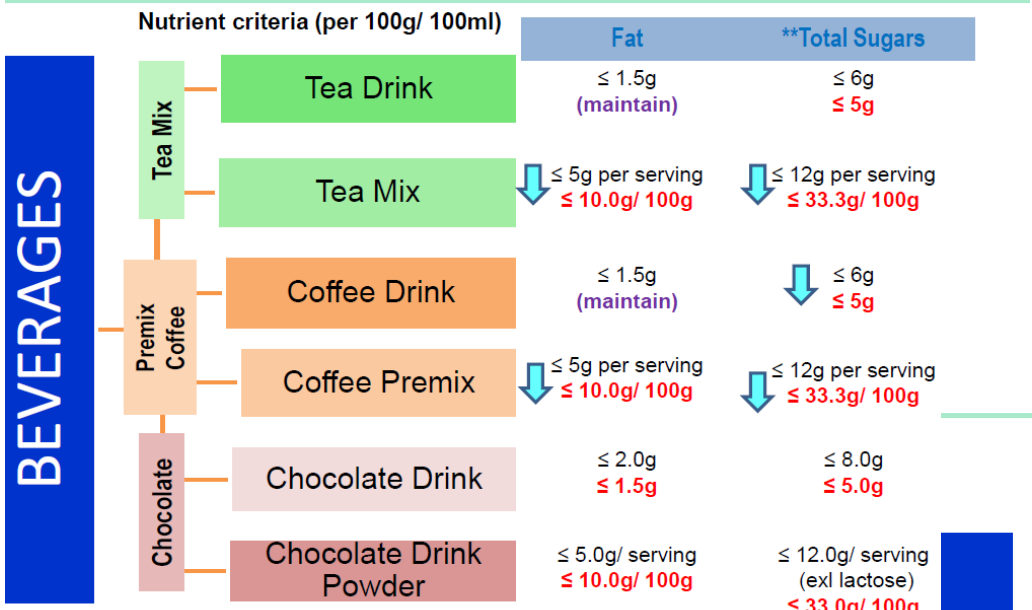
Malaysia- Healthier Choice Logo

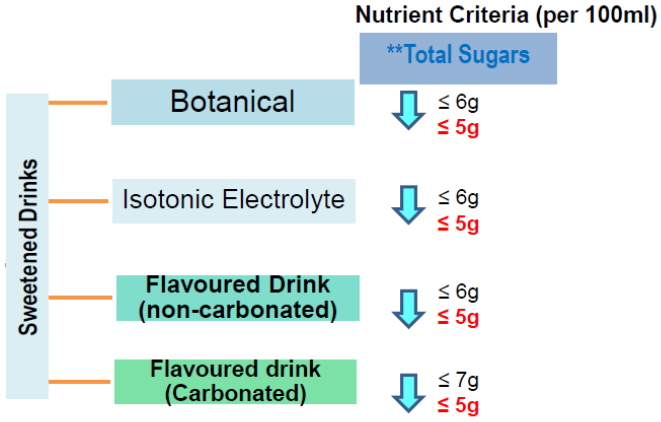
- The HCL was officially launched in April 2017 and the guidelines were revised in June 2019
  - Products with permitted sweetening substances will be considered for HCL authentication
  - Introduction of Additional Criteria (AC): it gives extra value for HCL products

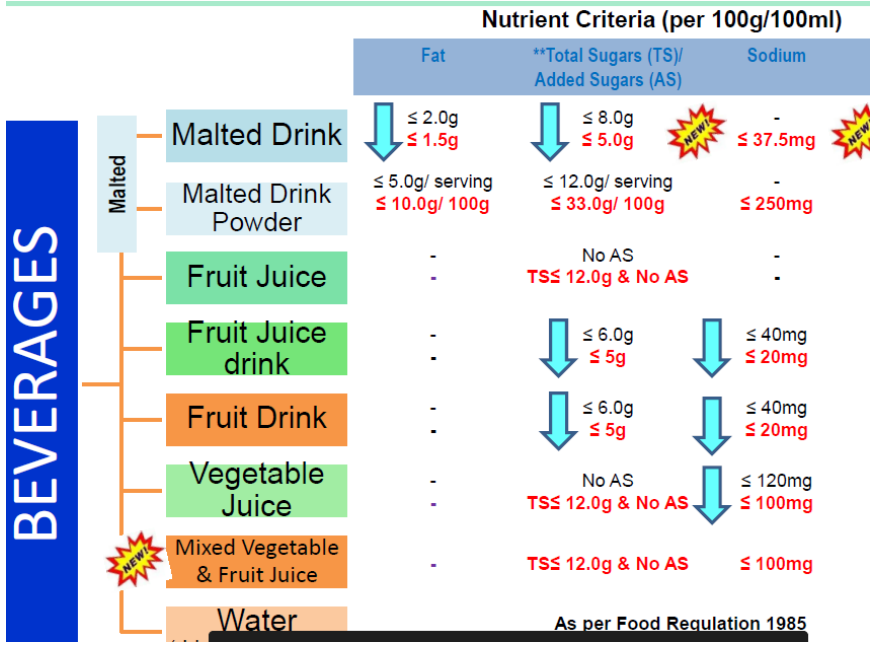
NUTRIENTS	FOOD (SOLID) VALUE PER 100g	DRINK (LIQUID) VALUE PER 100ml
Vitamin A	120 µg	60 µg
Vitamin E	1.5mg	0.75mg
Vitamin D	0.75 µg	0.375 µg
Vitamin B1	0.21 mg	0.105 mg
Vitamin B2	0.24 mg	0.12 mg
Vitamin B6	0.3 mg	0.15 mg
Folic Acid	30 µg	15 µg
Vitamin B12	0.15 µg	0.075 µg
Vitamin C	9.0 mg	4.5 mg
Calcium	120 mg	60 mg
Iron	2.1 mg	1.05 mg
Dietary Fiber	3.0 g	1.5 g

ILSI Southeast Asia Region

Malaysia- Healthier Choice Logo







Source: Ms Fatimah Sulong, Nutrition Division, MOH Malaysia

Malaysia- Healthier Choice Logo

	Fat Content	Sodium	Total Sugars	Fiber	Whole grains
Plain Meal/ Oatmeal	- -	No added (maintain)	≤ 25g No Added	≥ 6g (maintain)	100% (maintai
Breakfast Cereal (adult)	≤ 3g (maintain)	≤ 400mg (maintain)	≤ 25g ≤ 20g	≥ 3g ≥ 6g	≥ 25% (maintai
Breakfast Cereal (children)	≤ 3g	≤ 400mg	≤ 30g	≥ 3g	≥ 25%
Prepared Cereal Food	≤ 11g ≤ 10g	≤ 632mg ≤ 250mg	**≤ 42g ≤ 33g	≥ 3g (maintain)	-
NEW! Cereal Drink	≤ 1.5g/ 100ml	≤ 37.5g/ 100ml	≤ 5.0g/ 100ml	≥ 0.45g/100ml	-

Sub-Categories of Breakfast Cereal for Children & Adults has been combined & shared for same nutrient criteria

Nutrient Criteria (per 100g/ 100ml)

	Fat	Calcium	**Total Sugars (TS)	Sodium
Fresh milk (liquid)	As per Food Regulation 1985 (Standard 82) (maintain)			
Cultured Milk/ Fermented Milk	≤ 1.5g (maintain)	- -	≤ 8.0g (exl lactose) ≤ 7.0g (Exl Lactose)	NEW! Probiotic: >10^6 CFU/ml
Yoghurt Drink	≤ 1.5g (maintain)	NEW! ≥ 60mg	≤ 8.0g (exl lactose) ≤ 5.0g (Exl Lactose)	
Yoghurt	≤ 2.0g (maintain)	- -	≤ 10.0g (exl lactose) ≤ 7.0g (Exl Lactose)	
Processed Cheese	≤ 15.0g -	≥ 240mg (maintain)	- -	NEW! - ≤ 830mg

Biscuits	≤250 kcal/ s ≤500 kcal/ 100g	TF≤ 25g, SAFA≤ 10g, TFA≤ 0.5g *TF≤ 20g	≤ 420mg ≤ 400mg	≤ 24g ≤ 20g
NEW!			00mg	≤ 5g

Nutrient Criteria (per 100g)

Soy sauce: Light & dark	Sodium: ≤ 4500mg ≤ 3000mg	Total Sugars: - NEW! ≤ 16.0g	

	Energy	Fat	Total Sugars (TS)	Sodium
Salad dressing	≤ 380Kcal ≤ 350Kcal	SFA≤ 5.0g, TFA≤ 1.0g Total Fat ≤ 5.0g	≤ 20.0g ≤ 11g	≤ 750mg (maintain)
Peanut Butter	NEW! Protein: ≥ 25g	SFA≤ 10.0g, TFA≤ 0.5g -	≤ 30.0g ≤ 15.0g	≤ 400mg (maintain)

Nutrient Criteria (per 100g/ 100ml)

Milk Substitute	Fat	Calcium	**Total Sugars (TS)	Protein
RTD Soy Bean Milk	≤ 2.0g -	≥ 60mg (maintain)	≤ 6.0g ≤ 5.0g	NEW! - ≥ 2.5g
Soy Bean Milk (Powder)	- -	- ≥ 400mg	- ≤ 33.3g	- ≥ 16.7g

Source: Ms Fatimah Sulong, Nutrition Division, MOH Malaysia

Thailand- Healthier Choice Logo

Product group	Criteria
Beverage	Fruit juice & Vegie juice (not include 100% juice) - Total sugar ≤6g/100ml Soda drink& Flavor drink - Total sugar ≤6g/100ml Cereal drink - Total sugar ≤6g/100ml Soy milk - Total sugar ≤6g/100ml

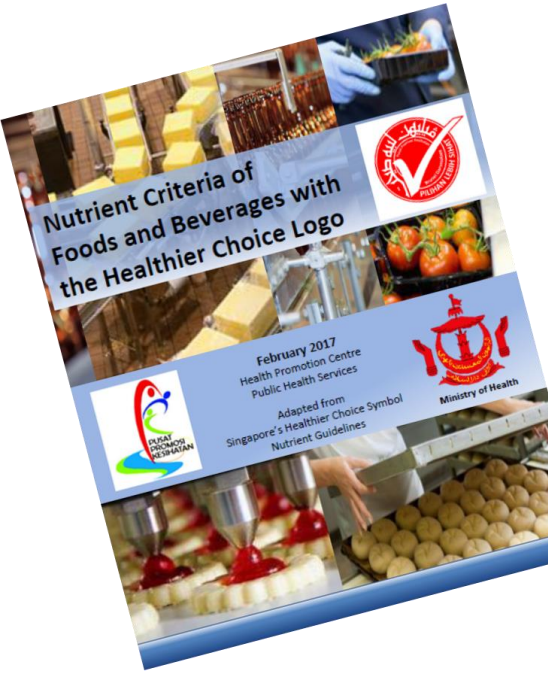
ILSI Southeast Asia Region

Thailand- Healthier Choice Logo

Product group	Criteria
Beverage	Coffee - Total sugar ≤6g/100ml - Total fat ≤ 1% Tea - Total sugar ≤6g/100ml - Total fat ≤ 0.6% Chocolate drink - Total sugar ≤6g/100ml - Total fat < 1%

ILSI Southeast Asia Region

Brunei- Healthier Choice Logo



	(g/100g)	Fat (g/100g)	Fat (g/100g)	(mg/100g)	sugar (g/100g)	Sugar (g/100g)	Choice Logo and nutrition claim
Water (still or carbonated)	-	-	-	≤20mg	0	0	Sugar Free No Added Sugar
Malted or chocolate drink	≤2		≤0.1	≤120	≤8 (including lactose)	-	Lower in sugar Lower in Saturated Fat Trans Fat Free Lower in sodium
3-in-1 or 2-in-1 coffee/tea beverages	≤1	-	≤0.1	-	≤5	-	Lower in Saturated Fat Trans Fat Free Lower in Sugar No Added Sugar
Sweetened drinks • Non-carbonated drinks/ Asian drink	-	-	-	-	≤6	-	
• Isotonic drinks	-	-	-	-	≤6	-	
• Juice drinks (at least 10% fruit juice)	-	-	-	≤40mg	≤6	-	
• Carbonated drinks	-	-	-	-	≤6	-	

Sub-Category	Energy (kcal/ serving)	Fat (g/100g)	Saturated Fat (g/100g)	Trans Fat (g/100g)	Sodium (mg/100g)	Dietary fibre (g/100g)	Total Sugar (g/100g)	% of Whole-grains
Wholegrains								
• Rice (unpolished)	All acceptable							100
• Mixed rice	All acceptable							≥ 20
• Wholegrains	All acceptable							≥ 20
Flour, wholemeal	-	-	-	-	No added sodium	≥ 5	-	100
Flour, self-raising	-	-	-	-	≤ 350	≥ 5	-	100
Instant Oats / Oatmeal	-	-	-	-	No added sodium	-	No Added Sugar	100
Adult's Cereal, breakfast cereals, cereal bars, cereal bars		≤ 4	-	-	≤ 400	≥ 4	≤ 25	≥ 25
Children's Cereal		≤ 3.3	-	-	-	≥ 4	≤ 35	≥ 25
Cereal beverages	-	≤ 2	-	≤ 0.1	≤ 120	-	≤ 8	≥ 25
Pasta	-	≤ 2	-	-	≤ 120	≥ 3	-	100

ILSI Southeast Asia Region

Brunei- Healthier Choice Logo

Sub-category	Fat (g/100g)	Sodium (mg/100g)	Total Sugar (g/100g)	Added Sugar (g/100g)	Calcium (mg/100ml)	Healthier Choice Logo and nutrition claim
Liquid milk (plain)	≤ 1.5	-	-	-	≥ 130	Lower in Saturated fat Higher in Calcium
Liquid milk (flavored)	≤ 1.5	-	≤ 10 (including lactose)		≥ 130	Lower in Saturated fat Higher in calcium Lower in Sugar

Sub- category	Fat (g/100g)	Sugar (g/100g)	Sodium (mg/100g)	Healthier Choice Logo and nutrition claim
Juice (No added sugar allowed) • Vegetable juice	-	≤12.5	≤120	Lower in sodium Lower in sugar
• Fruit juice (at least 60% fruit juice)	-	≤12.5	-	No Added Sugar
Fruit and vegetable Juice	-	≤12.5	≤120	No Added Sugar

ILSI Southeast Asia Region

Sugar reduction tax in SEA

- Sugar-sweetened beverage (SSB) tax is also currently being implemented in several SEA countries
  - Malaysia
  - Brunei
  - Philippines
  - Thailand

ILSI Southeast Asia Region

Sugar reduction tax in Malaysia

- Malaysian government has implemented sugar tax which took effect on July 1, 2019
  - The excise duty rates were gazetted in May 2019 and affected manufacturers were given a transition period to adapt and reformulate their existing products
    - SSB/Drinks + flavoured milk, soy milk, coffee and tea beverages, isotonic, etc): Total Sugars ≥5.0g/ 100ml
    - UHT milk based beverages: Total Sugars ≥ 7.0g/ 100ml
    - Fruit & Vegetable Juices: Total Sugars ≥ 12.0g/ 100ml
    - Non alcoholic beer: ≥ 5.0g/ 100ml
  - Exercise tax of MYR 0.4 (USD 0.097)/L

ILSI Southeast Asia Region

Sugar reduction tax in Brunei

- Implemented since 1 April 2017
  - SSB : ≥ 6 g of total sugar/100 ml
  - Soymilk beverages: ≥ 7 g of total sugar/100 ml
  - Malted/chocolate drinks: ≥ 8 g of total sugar/100 ml
  - Coffee-based or flavoured drinks: ≥ 6 g of total sugar/100 ml
  - Milk based beverage, fruit and veg juice are exempted from tax
  - Exercise tax: BND 0.40 (USD 0.29)/L

ILSI Southeast Asia Region

Sugar reduction tax in Philippines

- Since 1 January 2018
- All SSBs of any types (liquid, powder, concentrate, etc) need to pay tax
  - Including sweetened tea, juice dinks, carbonated drinks, isotonic/energy drinks, flavoured water, non alcoholic beverages with added sugar
    - Except coffee, all milk products and 100% natural fruit/vegetable juice are exempted
  - Exercise tax of PHP 6 (USD 0.115)/L for beverages using caloric and artificial/non caloric sweeteners or both
  - Exercise tax of PHP 12 (USD 0.23) /L for beverages using HFCS or in combination with any caloric/non caloric sweeteners

ILSI Southeast Asia Region

Sugar reduction tax in Thailand

- Implements progressive tax scheme to be carried out over 6 years since September 2017
  - Adopts a mixed tax rate system with both specific and ad valorem(VAT) duties
  - Beverages with only non-sugar sweeteners are exempted
  - Based on total sugar (added sugar and natural sugar)
  - Sugar≥ 6g/100 ml will be taxed with specific tax
    - ≥ 6 g/100ml ; ≥ 8 g/100ml ; ≥ 10 g/100ml, ≥ 14 g/100ml and ≥ 18 g/100ml

ILSI Southeast Asia Region

Sugar reduction tax in Thailand

- Including
  - Artificial mineral water, soda water, and carbonated soft drinks without sugar or other sweeteners and without flavor
  - Mineral water and carbonated soft drinks with added sugar or other sweeteners or flavors; and other non alcoholic beverages
  - Fruit and vegetable juices
  - Coffee and tea
  - Energy drinks
  - Beverage concentrates to be used with beverage vending machines for distribution at retail areas

ILSI Southeast Asia Region

Thank You!

Any Questions?

ILSI
Southeast
Asia Region

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

the Amendment of the Food Sanitation Act in JAPAN, Promulgated in June 2018 Progress Since

11th BeSeTo Meeting
Sept. 26, 2019

Hidekazu Hosono

Events, Incidents and Revisions of the Food Sanitation Act

Review!

May 1996	Partial revision of the Food Sanitation Act (introduction of HACCP, etc.)
October 2001	Total ban on bone-and-meat feed Start of 100% inspection of beef cattle
June 2002	Enactment of the BSE Special Countermeasures Law
May 2003	Enactment of the Food Safety Basic Law
May 2003	Partial revision of the Food Sanitation Act (introduction of positive list for pesticide- and animal drug- residue)
July 2003	Launch of the Food Safety Commission
September 2009	Launch of the Consumer Agency
June 2018	Partial revision of the Food Sanitation Act (Council for wide area food poisoning, etc.)

May 1996	Outbreak of food poisoning by O-157
June 2000	Snow Brand Milk Products poisoning by *Staphylococcus aureus*
June 2001	1st BSE infected cow confirmed in Japan
February 2002	Standard-exceeding pesticide residue in imported frozen spinach
June 2007	Meat Hope Co. false labelling incident
December 2007	Food poisoning by Chinese frozen “gyoza”
September 2008	Tainted rice distribution incident
September 2017	Wide area outbreak of food poisoning by O157

Outline of the Act Partially Amending the Food Sanitation Act etc.

(Promulgated on June 13, 2018)

Purpose of the amendment

To respond to the change of environment on food in Japan and the globalization, and to ensure food safety, enhance measures for food poisoning on a wider scale, improve operators' hygiene control, gather food-related health hazard information and take the countermeasures appropriately. In addition, organize sanitary regulations for utensils, containers and packaging (UCP) considering international consistency, and take measures such as updating a business approval and application system that reflect the reality of operators' businesses, and establishing a reporting system for food recalls.

Outline of the amendment

1. Enhanc
The gov
Ministe
the cou

2. Require
In princ
hygiene
* HAC
all sta
in dev

3. Gatheri
To prev
that req

4. Improv
Introdu

5. Revisio
Update
belong

6. Establi
Establi

7. Others (for example, a requirement of a hygiene certificate to import dairy products or seafood and establishment of regulations on local governments' works for food export)

To respond to the change of environment on food in Japan and the globalization, and to ensure food safety, enhance measures for food poisoning on a wider scale, improve operators' hygiene control, gather food-related health hazard information and take the countermeasures appropriately. In addition, organize sanitary regulations for utensils, containers and packaging (UCP)considering international consistency, and take measures such as updating a business approval and application system that reflect the reality of operators' businesses, and establishing a reporting system for food recalls.

Effective date of the amended Act

The day specified by the cabinet order, within two years (1 year for above 1. and 3 years for 5. and 6.) from the date of promulgation of the amended Act

https://www.mhlw.go.jp/content/11130500/000537823.pdf

Review!

The main items in the amendment of the Food Sanitation Act:

		Effective date
a)	Strengthening measures taken by national and local governments for interregional food poisoning cases.	1 year
b)	Requirement of food hygiene control based on HACCP principles.	2 years
c)	Establishment of an adverse event reporting system for foods containing the designated substances.	2 years
d)	Improvement of sanitary regulations for utensils, containers and packaging for food and food additives considering international consistency.	2 years
e)	Revision of licensing system and establishment of notification system for food businesses.	3 years
f)	Establishment of a reporting system for food recalls.	3 years
g)	Ensuring safety of imported foods and Legalizing administration related to food export.	2 years
		After promulgation

The main items in the amendment of the Food Sanitation Act (FSA):

* Call for Public comments on the draft of Cabinet/Ministerial Ordinance

Effective within

a) Strengthening measures taken by national and local governments for interregional food poisoning cases.

Enforced!

Seven(7) large area councils are settled on April 1, 2019.

June 2019

b) Requirement of food hygiene control based on HACCP principles.

Public comments*/July 19 to Aug. 17, 2019. Small FBOs are to be exempt.

June 2020

c) Establishment of an adverse event reporting system for foods containing the designated substances.

Four(4) substances are designated in May 20, 2019.

June 2020

d) Improvement of sanitary regulations for utensils, containers and packaging for food and food additives considering international consistency.

Public comments*/Aug. 9 to Sep. 7, 2019. Positive list is to be fulfilled.

June 2020

e) Revision of licensing system and establishment of notification system for food businesses.

June 2021

Public comments*/July 26 to Aug. 24, 2019. 34 licences → 32 (scrap & build)

f) Establishment of a reporting system for food recalls.

Consultation report is issued. Recalls are to be classified Class I, II and III.

June 2021

g) Ensuring safety of imported foods and Legalizing administration related to food export.

June 2020

Public comments*/July 26 to Aug. 24, 2019. Health certificate for milk and MP.

(a) Strengthening measures taken by national and local governments for interregional food poisoning cases

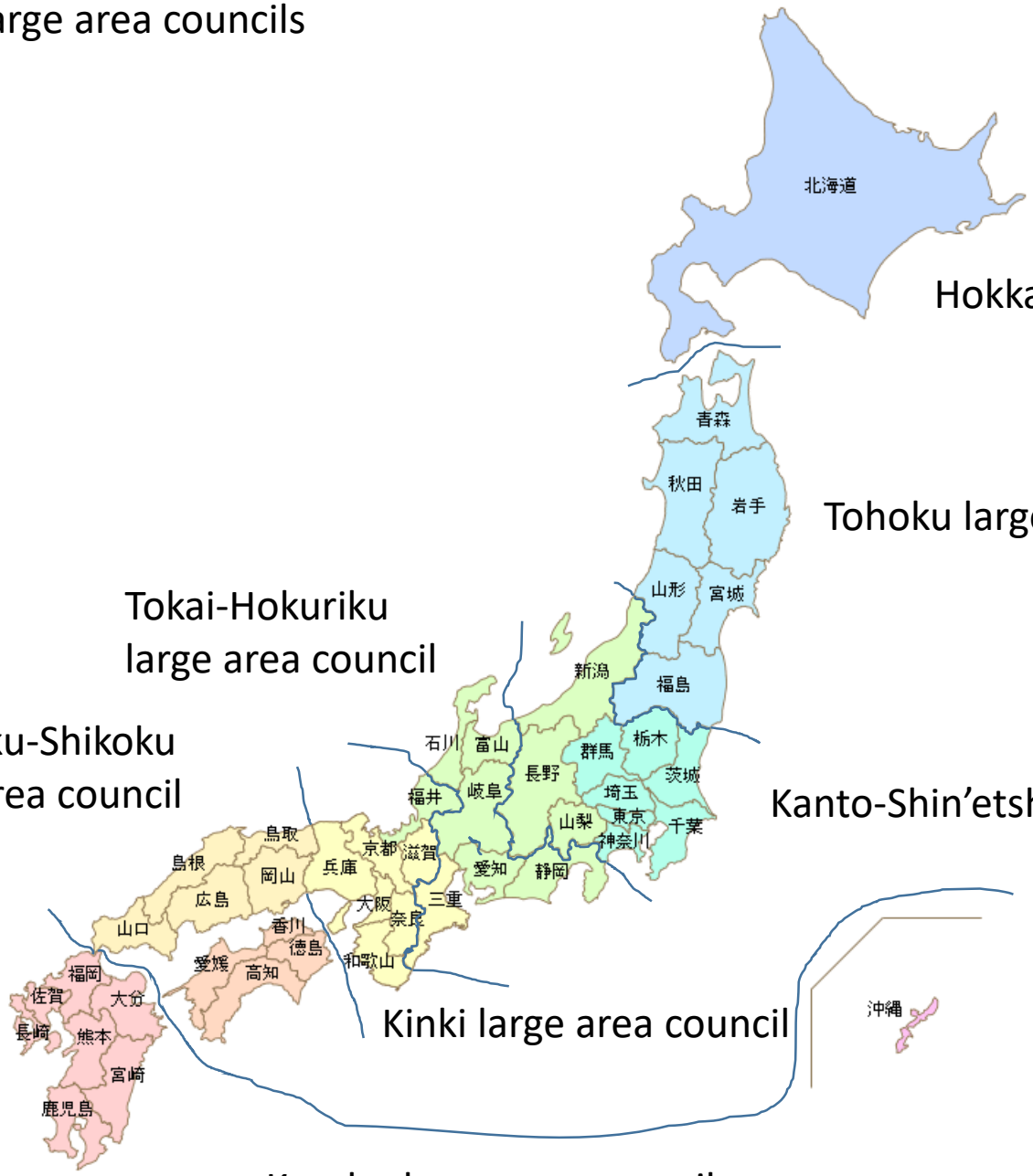
to be enforced within 1 year

Enforced Apr. 1, 2019

In order to prevent occurrence and expansion of interregional food poisoning cases, national and local governments shall mutually cooperate. As a framework of such cooperation, the Minister of Health, Labour and Welfare (MHLW) may establish a council for wide area cooperation which is composed of relevant parties of the national and local governments etc.

When urgent response is required, the MHLW may utilize the council to address interregional food poisoning cases.

Seven(7) large area councils



Hokkaido large area council

Tohoku large area council

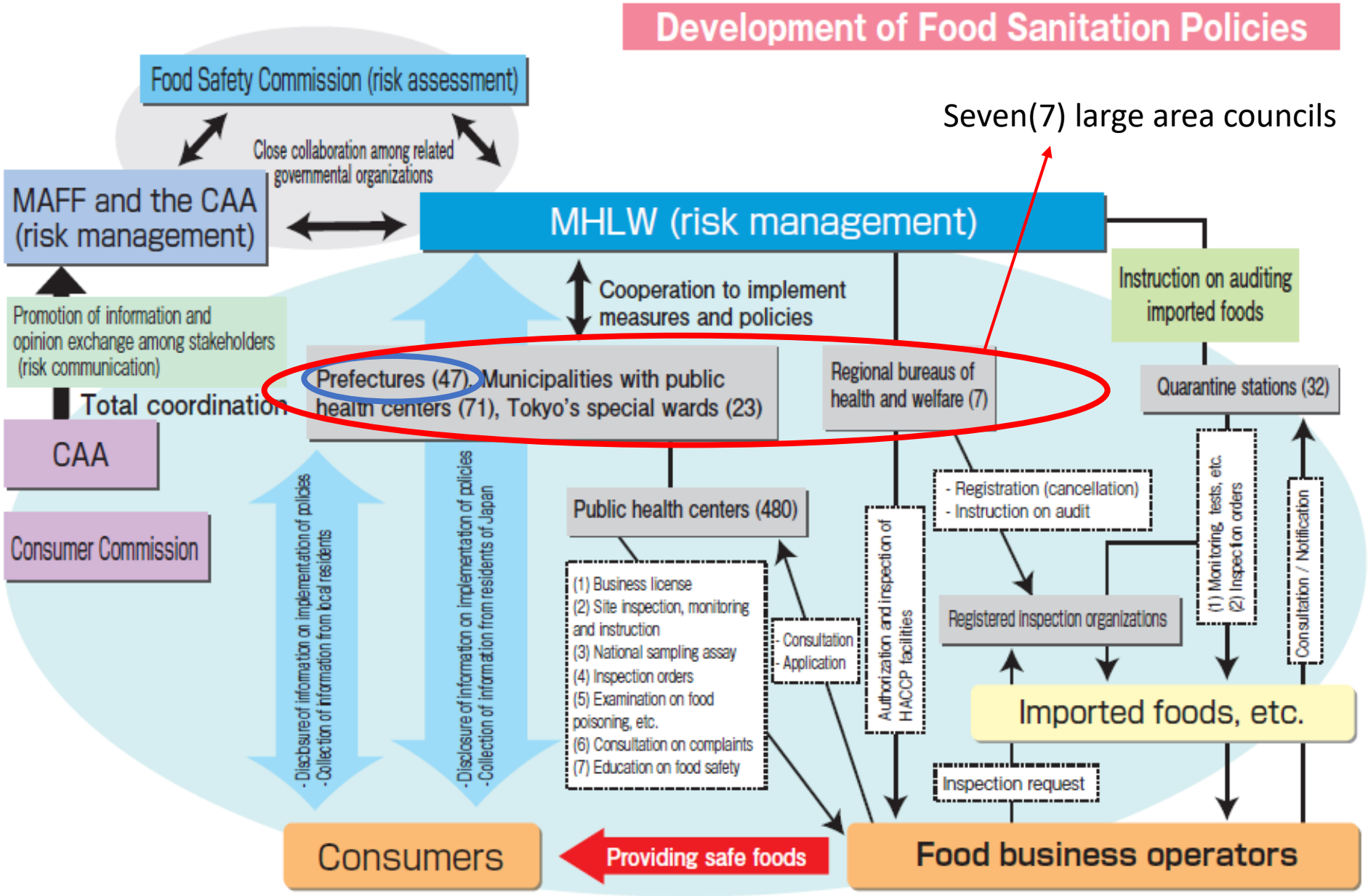
Tokai-Hokuriku
large area council

Chugoku-Shikoku
large area council

Kanto-Shin’etshu large area council

Kinki large area council

Kyushu large area council



https://www.mhlw.go.jp/english/policy/health-medical/food/dl/pamphlet.pdf

(b) Requirement of food hygiene control based on HACCP principles

to be enforced within 2 years (by June, 2020)

In order to increase the level of food hygiene control by food business operators (FBOs) in Japan and to be aligned with the international standards, FBOs* including operators of slaughterhouses and poultry processing plants shall develop and comply with a plan on food hygiene control, adapted to their own situations (e.g. manufacturing methods and raw materials) covering both good hygiene practices such as maintenance and cleaning of the facilities and control measures critically important to prevent or eliminate specific hazards.

For certain category of FBOs, some flexibility will be applied taking into account the nature and size of the operation.

* Industries considered having a low impact on public health will be excluded from the scope (e.g. business that only sells packaged foods that can be stored at room temperature)

(b) Requirement of food hygiene control based on HACCP principles

to be enforced within 2 years (by June, 2020)

Public comments from July 19 to Aug. 17, 2019.

In order to in
business operators (FBOs) in Japan and to be aligned with the international standards, FBOs* including operators of slaughterhouses and poultry
comply with a plan on food h
situations (e.g. manufacturin
both good hygiene practices
the facilities and control mea
eliminate specific hazards.

Flexibility applied to :
- Restaurant, Coffee shop
- Cup-beverage vending with machine
- Subdivide and retail
- Face to Face retail
- Small business with less than 50 person

For certain category of FBOs, some flexibility will be applied taking into account the natu

Exemptions :
- Importer
- Storage, Transfer and/or Retail only packaged foods that can be stored at room temperature

* Industries considered h
be excluded from the scope
foods that can be stored at r

(c) Establishment of an adverse event reporting system for foods containing the designated substances*

to be enforced within 2 years (by June, 2020)

* The substances and/or ingredients with a probability that the uncontrolled use of those may cause serious adverse health consequences will be designated by the MHLW.

To prevent serious adverse events, FBOs that sell foods containing the designated substances shall report health-related adverse events associated with the use of their products to the MHLW through local governments.

In addition, relevant stakeholders shall cooperate with the MHLW for a survey on an adverse event and provide related information.

(c) Establishment of an adverse event reporting system for foods containing the designated substances*

to be enforced within 2 years (by June, 2020)

* The substances and/or ingredients with a probability that the uncontrolle
consequen
To prev
containing
adverse eve
MHLW thro
In addit
MHLW for a
informatior

Cabinet/Ministerial Ordinance is not notified yet, but Four(4) substances are designated in May 20, 2019, by expert committee.

1. White Kwao Krua *Pueraria candollei* var. *mirifica*
2. Black cohosh, Black snakeroot
   Actaea racemose L. *Cimicifuga racemose*
3. Coleus, Forskolin *Plectranthus barbatus* Andr.
   Coleus forskohlii, *C. barbatus*
4. Celandine, Greater celandine, Swallow-wort
   Chelidonium majus L. *var. asiaticm* (H. Hara) *Ohwi*

(d) Improvement of sanitary regulations for utensils, containers and packaging for food and food additives considering international consistency

to be enforced within 2 years (by June, 2020)

In order to ensure the safety of utensils, containers and packaging, and to ensure international consistency of regulations, FBOs associated with these products shall not sell those made of raw materials, such as synthetic resins, for which specifications are not established, except cases that the MHLW specifies as having no risk to human health. In addition, the manufacturers shall comply with the codes of good manufacturing practices.

Elution Test for Synthetic Resin
- Cd, Pb
- Total Organic Carbon
- Evaporation Residue

:

→

List of Specified Raw Materials for SR
- Base Polymers : Plastics
- Base Polymers : Coatings, etc.
- Minor Monomers for polymerization of Base Polymers
- Additives, coating agents, etc.

Positive List Format

(1) Base polymers

More than 98 wt% of the components of a base polymer shall be polymers listed below.

● AA resin

No	Polymers		CAS No	Food types					Maximum temperature I. ≤70°C II. ≤100°C III. ≥101°C	Group	Remarks
	Japanese name	English name		Acidic	Oily and fatty	Milk and milk product	Alcoholic beverage	Others			
1	Homopolymer of AA	AA polymer	0000-00-0	○	○	○	○	○	III	1	
2	Copolymer of AA and BB	AA polymer with BB	1111-11-1	○	—	—	○	○	III	2	

● BB resin

No	Polymers		CAS No	Food typ					I. ≤70°C II. ≤100°C III. ≥101°C	Group	Remarks
	Japanese name	English name		Acidic	Oily and fatty	Milk and milk product	beverage	Others			
1	Homopolymer of BB	BB polymer	2222-22-2	○	○	○	○	○	III	3	
2	Copolymer of BB and ZZ	BB polymer with ZZ	3333-33-3	—	○	○	○	○	II	3	

Set "group" for each polymer

● Minor monomers can be used for polymerization of base polymers

No	Minor monomers		CAS No	Remarks
	Japanese name	English name		
1	XX	XX	5555-55-5	
2	YY	YY	6666-66-6	

※ Minor monomers are restricted to be used in some polymers and managed by the current risk management method (negative list system) as needed.

(2) Additives, coating agents, etc.

No	Substance name		CAS No	Maximum use level by group (wt%)						
	Japanese name	English name		1	2	3	4	5	6	7
1	aaa	aaa	9999-99-9	1.0	1.0	-	-	1.5	1.0	-
2	bbb	bbb	8888-88-8	-	5.0	2.0	2.0	2.0	2.0	2.0

Restrictions on use level of additives and other agents will be set by polymer group.

The use level of the additives etc. is described in percentage for the whole synthetic resin including the additives etc.

Appended Table 1　Draft of the Table1 (1)(Base polymers (Plastics))　別表第１　第１表（１）案（基ポリマー（プラス

✓The mark in “Food types” means as follows.
〇: May be used in UCP for the type of food.
－: Not allowed to be used in UCP for the type of food.
✓The Roman numeral in “Maximum temperature” means as follows.
I: May be used at 70°C or lower.
II: May be used at 100°C or lower.
III: May be used at a temperature exceeding 100°C or lower.

"# " Is not described in "Remarks".
（#: Falls under Article 11, paragraph (1), item (iii) of the Food Safety Basic Act.）

a　表中使用可能食品の欄は、次に定めるとおりとする。
①「〇」は、使用可能であることを示す。
②「－」は、使用不可であることを示す。
b　表中使用可能最高温度の欄は、次に定めるとおりとする。
①「Ⅰ」は、70℃以下で使用可能であることを示す。
②「Ⅱ」は、100℃以下で使用可能であることを示す。
③「Ⅲ」は、100℃超で使用可能であることを示す。

特記事項欄における「#」の記号等は記載されていない。
（「#」は食品安全委員会第１１条第１項第３項に該当するものである

(1) Base polymers (Plastics) 基ポリマー（プラスチック）

１．Polyehylene（PE）ポリエチレン（PE）

No	Polymerポリマー Japanese name和名	English name英名	CAS No CAS登録番号	Food types使用可能食品 Acidic 酸性	Oily and fatty 油性及び脂肪性	Milk and milk product 乳・乳製品	Alcoholic beverage 酒類	Others その他	Maximum temperature 使用可能温度 I. ≤70°C II. ≤100°C III. ≥101°C	Group 区分
1	エチレン単独重合体	Ethylene, homopolymer	9002-88-4	〇	〇	〇	〇	〇	III	5
2	エチレン・１－アルケン共重合体	Copolymers of ethylene and 1-alken	9010-79-1 25087-34-7 25213-02-9 25213-96-1 25895-47-0 26221-73-8 25895-46-9 60785-11-7 28829-58-5	〇	〇	〇	〇	〇	III	5

Schedule for Establishment of the PL for the Existing Materials

- List substances using the information from business operators and associations
- Preparation of the draft PL

May-June 2019 The draft PL / Committee for UCP established under the Pharmaceutical Affairs and Food Sanitation Council

Summer 2019 Update of the draft PL / Public comment / WTO notification

August 2019 Ask the Food Safety Commission for risk assessment

- List substances to be added in the PL List
- Final work of the drat PL

As necessary The draft PL / Committee for UCP established under the Pharmaceutical Affairs and Food Sanitation Council

December 2019 Public notice of the PL

June 2020* Start of the PL system / enforcement of the amended Food Sanitation Act

*within two years from the date of promulgation of the amended Act

(e) Revision of licensing system and establishment of notification system for food businesses

to be enforced within 3 years (by June, 2021)

Prefectural governments shall take into consideration the criteria to be specified by the Ordinance of the MHLW when establishing their own food business licensing requirements in the prefectural ordinance, which now greatly differ from prefecture to prefecture.

(Note) The category of food businesses requiring license which are specified by the Cabinet Order will also be reviewed in light of the current situation.

Those who intend to operate food business shall notify their local government prior to doing so. Food related businesses with little impact on public health will be exempt.

(e) Revision of licensing system and establishment of notification system for food businesses

to be enforced within 3 years (by June, 2021)

Public comments from July 26 to Aug. 24, 2019.
34 licences → 32 (scrap & build)

Prefectural gove
criteria to be specifi
establishing their own food business licensing requirements in the prefectural ordinance, which now greatly differ from prefecture to prefecture.

(Note) The category of food businesses requiring license which are specified by the Cabinet Order will also be reviewed in light of the current situation.

Those who intend to operate food business shall notify their local government prior to doing so. Food related businesses with little impact on public health will be exempt.

The category of food businesses requiring license which are specified by the Cabinet Order will also be reviewed

Article 35 Businesses for which prefectures shall establish the criteria for their facilities pursuant to the provisions of Article 51 of the Act shall be as follows:

(i) Restaurant businesses (meaning businesses of general eating places, cooking stores, sushi restaurants, soba noodle shops, Japanese inns, caterers, lunch box stores, restaurants, cafes, bars, and cabarets, and other businesses for cooking food or setting up facilities to serve customers, and excluding businesses falling under the following item);
(ii) Coffee shop businesses (meaning businesses of coffee shops and salons, and other businesses for setting up facilities to serve drinks other than alcoholic beverages or refreshments to customers);
(iii) Confectionery businesses (including bakery businesses);
(iv) Bean jam manufacturing industry;
(v) Ice cream manufacturing industry(meaning businesses for producing ice cream, ice sherbet, ice candy, and other fluid food, or food made by freezing a mixture of fluid food and other food);
(vi) Milk processing businesses (meaning businesses for processing or producing cow's milk (including skim milk and other milk beverages appearing similar to cow's milk) or goat's milk);
(vii) Special milking and processing businesses (meaning businesses for collecting cow's milk and processing it into milk that meets ingredient standards specified by an Ordinance of the Ministry of Health, Labour and Welfare without a sterilization process or through treating it by pasteurization);

The category of food businesses requiring license which are specified by the Cabinet Order will also be reviewed

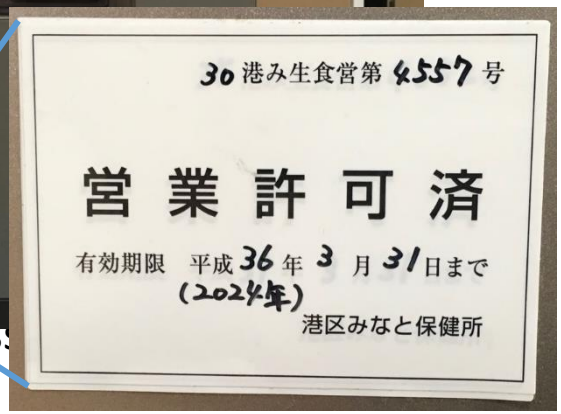
Article 35 Businesses for which prefectures shall esta
pursuant to the provisions of Article 51 of the Act sha

(i) Restaurant businesses (meaning businesses of gen ushi restaurants, soba noodle shops, Japanese inns, catere es, bars, and cabarets, and other businesses for cooking f customers, and excluding businesses falling under the

(ii) Coffee shop businesses (meaning businesses of c businesses for setting up facilities to serve drinks othe refreshments to customers);

(iii) Confectionery businesses (including bakery busin

(iv) Bean jam manufacturing industry; erbet,



A cup- beverage vending machine needed to be licensed as 'a coffee shop business', machine by machine.
Vending machine inside building will not need to be licensed in new system. It should be only 'notified' as 'a restaurant business'.
Outdoor machine needs to be licensed as 'a restaurant business' under new system.

(f) Establishment of a reporting system for food recalls

to be enforced within 3 years
(by June, 2021)

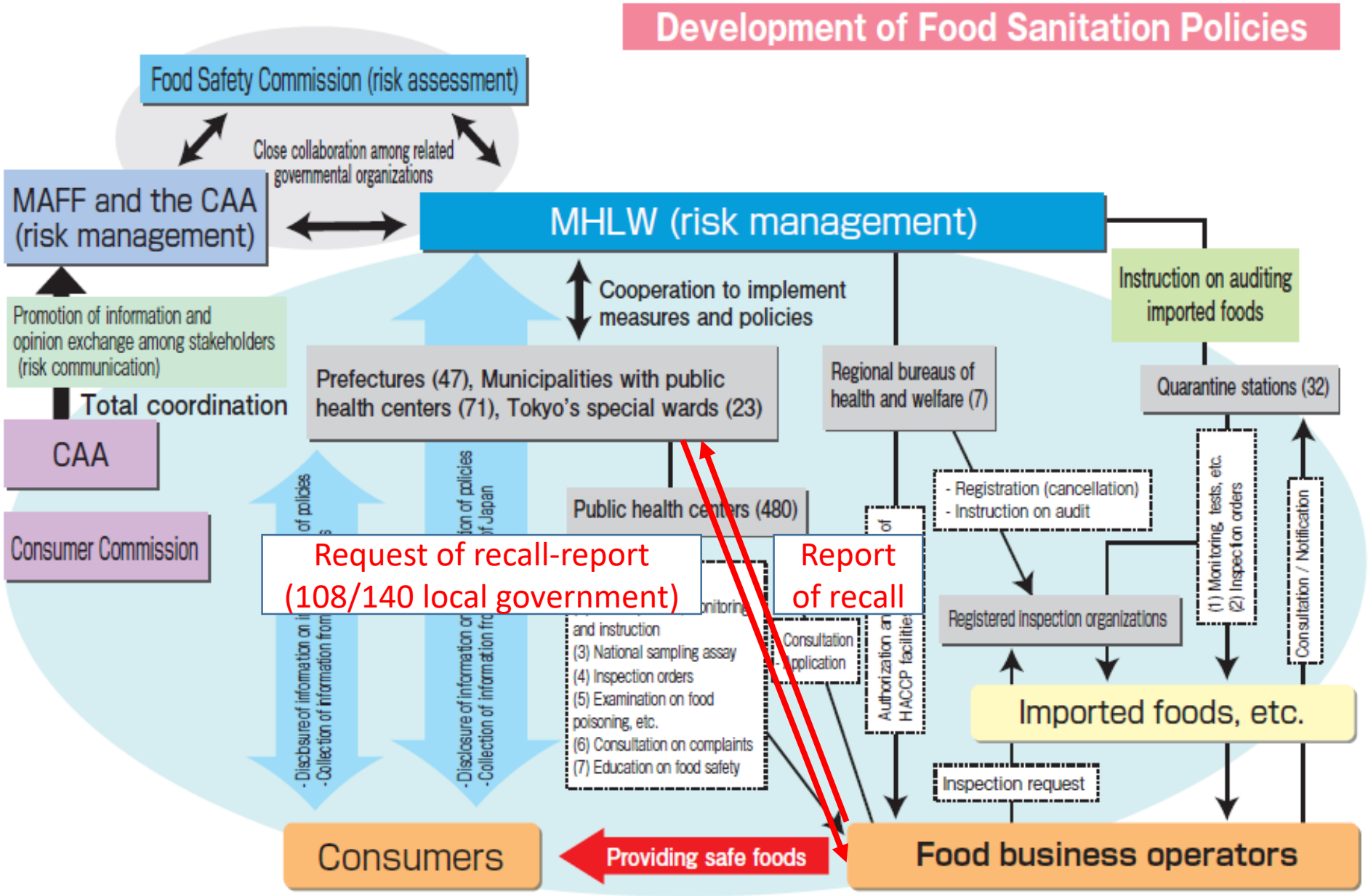
When a food is in violation of the FSA and is recalled, the manufacturers or sellers shall notify the prefectural governor of initiation progress of the recall, unless any food safety hazard etc. is not expected to occur. The governor who received the information shall report it to the MHLW.

(f) Establishment of a reporting system for food recalls

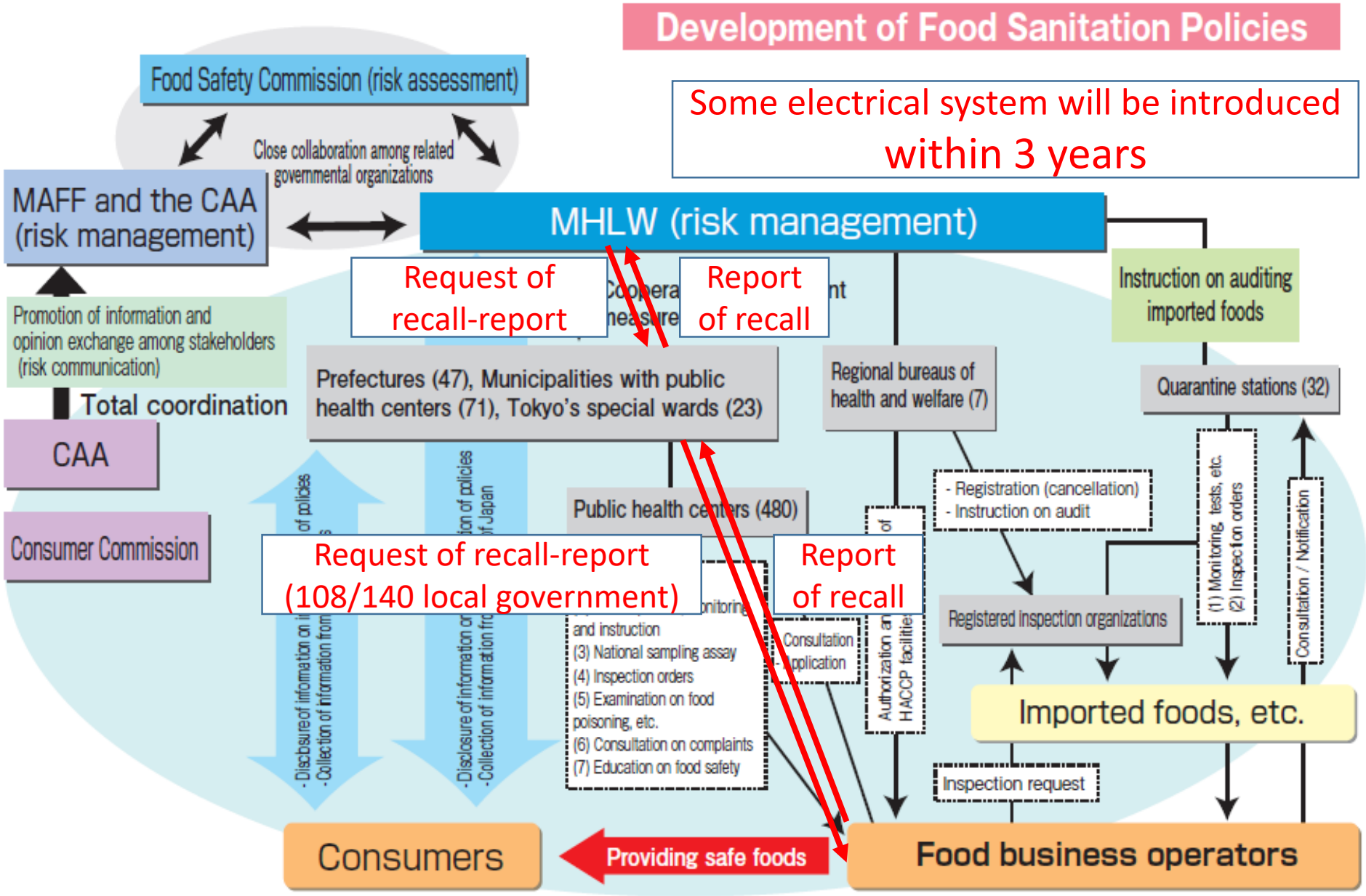
to be enforced within 3 years
(by June, 2021)

Consultation report is issued.
Recalls are to be classified Class I, II and III.

When a food is in violation of the FSA and is recalled, the manufacturers or sellers shall notify the prefectural governor of initiation progress of the recall, unless any food safety hazard etc. is not expected to occur. The governor who received the information shall report it to the MHLW.



https://www.mhlw.go.jp/english/policy/health-medical/food/dl/pamphlet.pdf



https://www.mhlw.go.jp/english/policy/health-medical/food/dl/pamphlet.pdf

(g) Ensuring safety of imported foods and Legalizing administration related to food export

to be enforced within 2 years (by June, 2020)

Foods requiring measures to control processes particularly important to prevent occurrence of adverse health effects*, food hygiene control based on HACCP principles, in exporting countries shall not be imported, unless they are manufactured at a facility where the competent authorities of the exporting country confirm that such measures are taken.

*Foods such as meat and poultry meat, etc. are assumed.

No HACCP requirement → HACCP requirement (meat, poultry meat)

In addition, when importing food of which risk may increase depending on hygiene practices*, health certificate issued by the exporting country which describes the status of hygiene control shall be attached.

* Milk, milk products, oysters to be eaten raw and puffer fish are assumed.

Export food-related measures such as issuance of health certificates and other necessary measures by local governments are stipulated.

Health Certificate requirement for meat, bowels, meat products → Additional requirement for milk, milk products, oysters to be eaten raw and puffer fish

(g) Ensuring safety of imported foods and Legalizing administration related to food export

to be enforced within 2 years (by June, 2020)

Public comments/July 26 to Aug. 24, 2019.
HACCP requirement for meat, poultry meat.
Health certificate requirement for milk and MP.

Foods requiring meas
prevent occurrence of ad
HACCP principles, in expo
manufactured at a facility
country confirm that such measures are taken.

*Foods such as meat and poultry meat, etc. are assumed.

No HACCP requirement → HACCP requirement (meat, poultry meat)

In addition, when importing food of which risk may increase depending on hygiene practices*, health certificate issued by the exporting country which describes the status of hygiene control shall be attached.

* Milk, milk products, oysters to be eaten raw and puffer fish are assumed.

Export food-related measures such as issuance of health certificates and other necessary measures by local governments are stipulated.

Health Certificate requirement for meat, bowels, meat products → Additional requirement for milk, milk products, oysters to be eaten raw and puffer fish

The main items in the amendment of the Food Sanitation Act (FSA):

* Call for Public comments on the draft of Cabinet/Ministerial Ordinance

Effective within

a) Strengthening measures taken by national and local governments for interregional food poisoning cases.

Enforced!

Seven(7) large area councils are settled on April 1, 2019.

June 2019

b) Requirement of food hygiene control based on HACCP principles.

Public comments*/July 19 to Aug. 17, 2019. Small FBOs are to be exempt.

June 2020

c) Establishment of an adverse event reporting system for foods containing the designated substances.

Four(4) substances are designated in May 20, 2019.

June 2020

d) Improvement of sanitary regulations for utensils, containers and packaging for food and food additives considering international consistency.

Public comments*/Aug. 9 to Sep. 7, 2019. Positive list is to be fulfilled.

June 2020

e) Revision of licensing system and establishment of notification system for food businesses.

June 2021

Public comments*/July 26 to Aug. 24, 2019. 34 licences → 32 (scrap & build)

f) Establishment of a reporting system for food recalls.

Consultation report is issued. Recalls are to be classified Class I, II and III.

June 2021

g) Ensuring safety of imported foods and Legalizing administration related to food export.

June 2020

Public comments*/July 26 to Aug. 24, 2019. Health certificate for milk and MP.

Thank you
for
your attention!

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

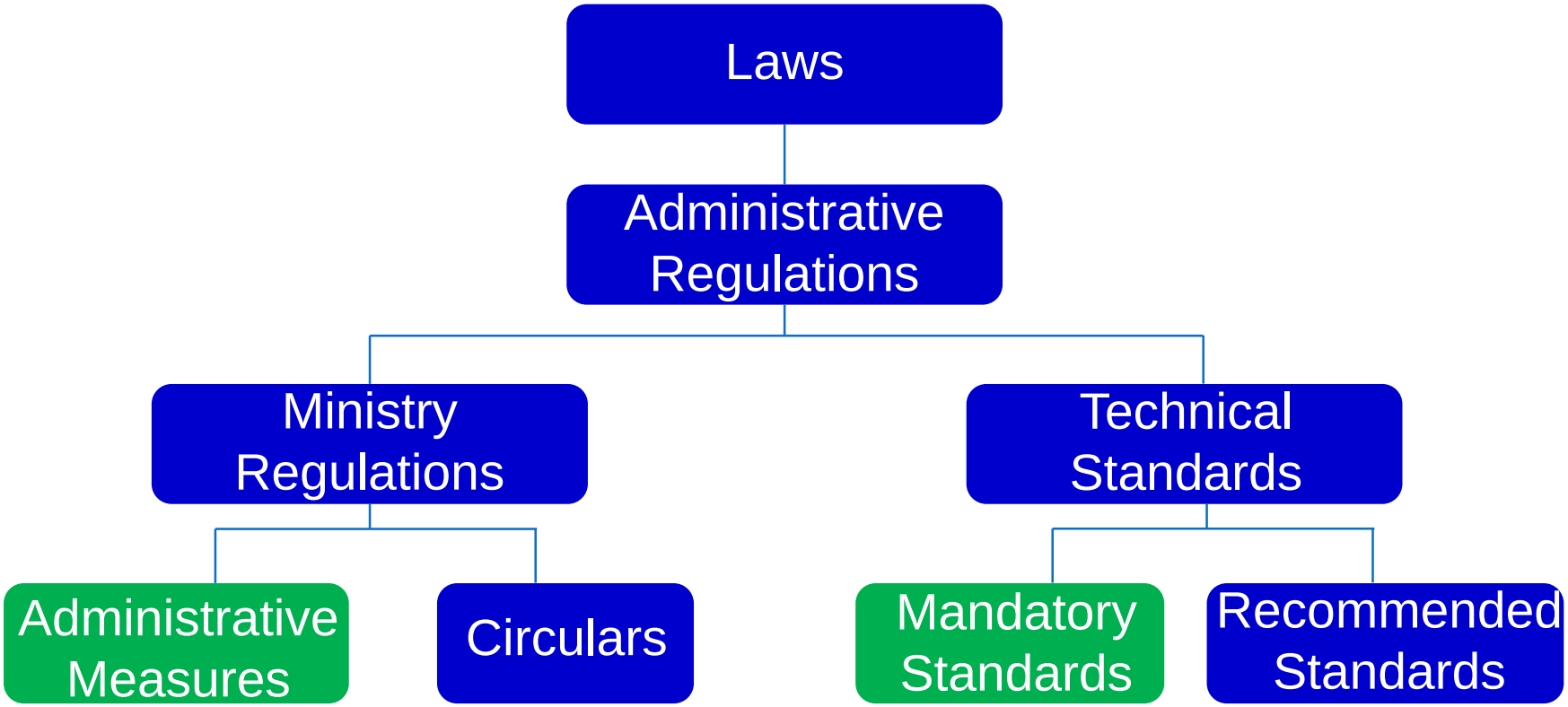
11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

China Labeling Regulations Update

Wendy Gao
Cargill Hong Kong Ltd.
September 26th, 2019

Food Related Regulations System



Mandatory Standard – GB7718 Labeling of Prepackaged Foods (1)

- ✓ It is being revised. The draft will be notified to WTO for public comments next year. The key changes that may happen are listed as below.

	Current	To be revised
Allergen	Voluntary	Mandatory – intentionally used allergen Voluntary – unintended allergen presence No threshold
	Big Eight	Big Eight (Cereals containing gluten, Crustacea, eggs, fish, peanuts, soybeans, milk, tree nuts) + Sulphite ≥10mg/kg
	—	Exemptions: ingredient free of protein, e.g. highly refined oils, wheat based maltodextrins.

Mandatory Standard – GB7718 Labeling of Prepackaged Foods (2)

	Current	To be revised
"Free of", "No added" Claim	Can use "no added" claim, e.g. no added sucrose.	Can't use "no added" claim. Should use "free of" instead.
	Can claim a certain food additive is not added if it can be used in relevant food category.	Can't use "free of" or "no added" claim for food additives.
Quantitative Ingredient Declaration	Not required to declare the content of an ingredient if it is shown in the food name, e.g. red date milk.	Required to declare the content of the ingredient shown in the food name unless: a) the ingredient is used in a small quantity for the flavor purpose; or b) the food name is regulated by other standard.

Mandatory Standard – GB7718 Labeling of Prepackaged Foods (3)

	Current	To be revised
"For a Specified Group of People" Claim	No restriction.	Can be used only if: a) it is an infant formula, FSMP, or health food product; or b) there is sufficient scientific evidence to prove the product can meet the nutrition need of a specified group of people.
Ingredient List for Oil Products	Declare "vegetable oil" or "refined vegetable oil".	Declare the specific name of each vegetable oil, e.g. soybean oil, palm oil.

Mandatory Standard – GB28050 Nutrition Labeling of Prepackaged Foods (1)

- ✓ It is being revised. The draft will be notified to WTO for public comments next year. The key changes that may happen are listed as below.

	Current	To be revised
Mandatorily Claimed Nutrients	1+4: Energy, Protein, Fat, Carbohydrate, Sodium	1+6: Energy, Protein, Fat, Saturated Fat, Carbohydrate, Sugar, Sodium
Voluntarily Claimed Nutrients	—	Add n-3 PUFAs, EPA, DHA
Nutrient Content Claim	—	Add "contain" and "high" claim for n-3 PUFAs.

Mandatory Standard – GB28050 Nutrition Labeling of Prepackaged Foods (2)

	Current	To be revised
Comparative Claim	—	Add "saturated fat reduced".
Nutrient Function Claim	—	Add nutrient function claims for n-3 PUFAs.
	The cholesterol daily intake for adults is no more than 300mg.	Delete it.
FOP	—	Encourage to use informative FOP (i.e. GDA).
Serving Size	—	Add "reference amounts of serving size".

SAMR Administrative Measures on Food Labeling

SAMR will solicit public comments on the draft, and plan to have it officially published around End 2019. The regulation would include the following new requirements:

- ✓ Set the requirement on color different between words and background.
- ✓ Imported prepackaged food: require original Chinese labeling.
- ✓ Only top 3 ingredients can be shown in the food name.
- ✓ For the product produced by different manufacturers, it is required to have the separate label for each manufacturer.
- ✓ GMO labeling is not in the scope.

Thank you
for your attention!

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

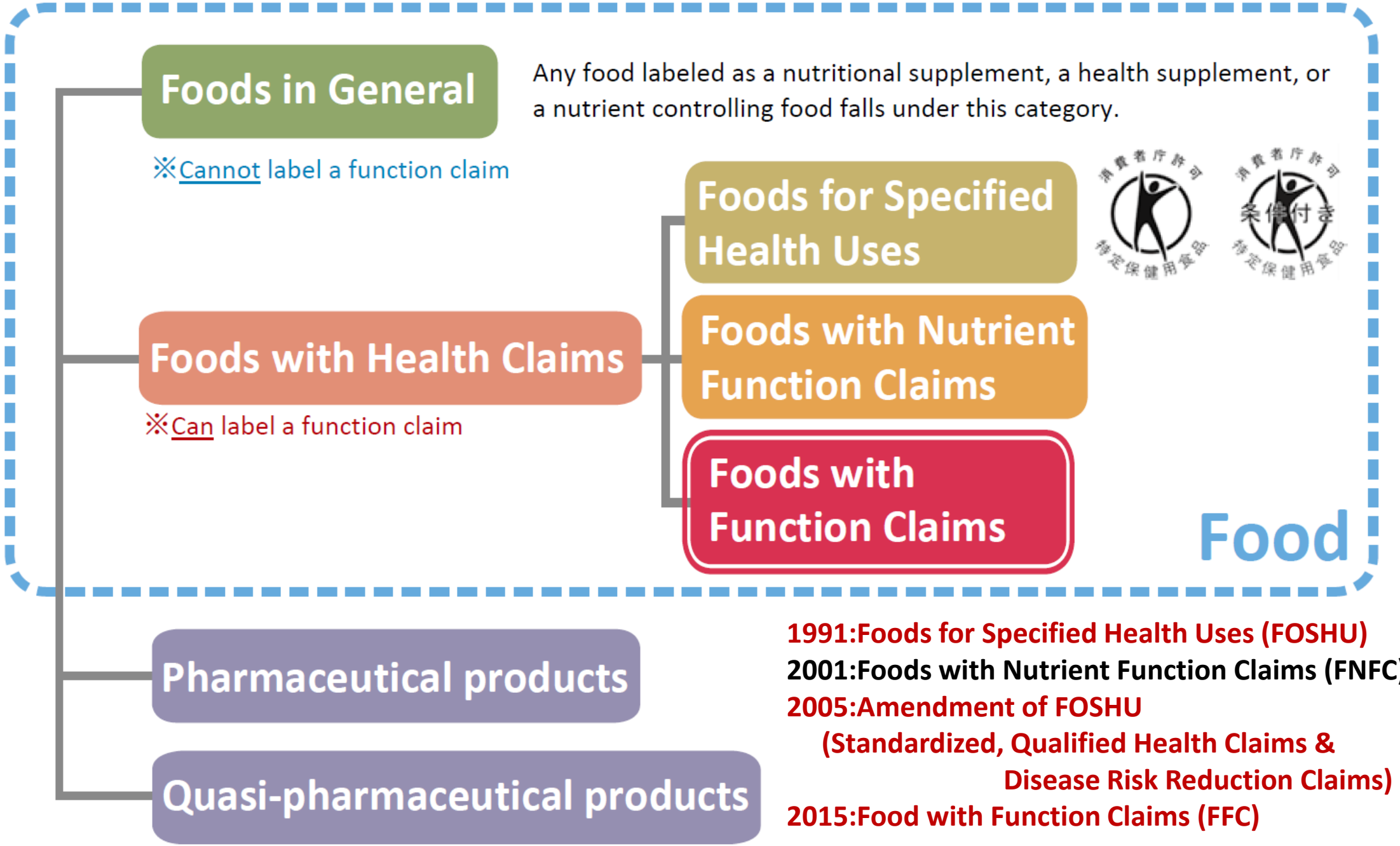
September 26-27, 2019, Penang, Malaysia

Foods with Function Claims in Japan
Update 2019

The 11th BeSeTo Meeting
Penang Malaysia

26-27th Sept, 2019

Satofumi Hashimoto Ph. D.
Regulatory Science Group, Quality Assurance Dept.,
Ajinomoto Co., Inc.



1991:Foods for Specified Health Uses (FOSHU)
2001:Foods with Nutrient Function Claims (FNFC)
2005:Amendment of FOSHU
(Standardized, Qualified Health Claims & Disease Risk Reduction Claims)
2015:Food with Function Claims (FFC)

https://www.caa.go.jp/policies/policy/food_labeling/information/pamphlets/pdf/151224_1.pdf

History and categories of Food for Specified Health Uses (FOSHU)

1991~

Requirements for FOSHU Approval

- Effectiveness on the human body is clearly proven
- Absence of any safety issues (animal toxicity tests, confirmation of effects in the cases of excess intake, etc.)
- Use of nutritionally appropriate ingredients (e.g. no excessive use of salt, etc.)
- Guarantee of compatibility with product specifications by the time of consumption
- Established quality control methods, such as specifications of products and ingredients, processes, and methods of analysis

2005 : Amendment

(1) Qualified Health Claims FOSHU (条件付き特定保健用食品):

Food with health function which is not substantiated on scientific evidence that meets the level of FOSHU, or the food with certain effectiveness but without established mechanism of the effective element for the function will be approved as qualified FOSHU.

(2) Standardized FOSHU (規格基準型特定保健用食品):

Standards and specifications are established for foods with sufficient FOSHU approvals and accumulation of scientific evidence. Standardized FOSHU are approved when it meets the standards and specifications.

No clinical efficacy study, but safety study on excessive consumption is still required on a product basis

Dietary fibers and oligosaccharides etc.

(3) Reduction of disease risk FOSHU (疾病リスク低減表示特定保健用食品):

Reduction of disease risk claim is permitted when reduction of disease risk is clinically and nutritionally established in an ingredient.

No clinical efficacy study, but safety study on excessive consumption is still required on a product basis

Calcium and Osteoporosis, Folic Acid and Neural Tube Defect

Clinical study using final products is needed!

Foods with Function Claims (FFC)

2015~

We can apply(notify) FFC without Clinical study.

	FFC	FOSHU
application procedures	・Notification	・Permission
Evaluation method for the Function	・Clinical Study or ・Systematic Review (SR)	・Clinical Study
Responsibility	・Company	・Government

So not only big enterprises but also small-to-medium-sized enterprises can make health foods as FCC

Subjects for Clinical Study

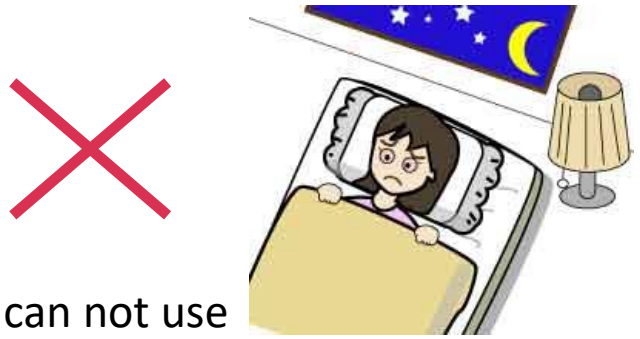
Basically…

For the setting of the clinical study participants, participants must be selected from those without disorders (excluding minors, pregnant women and women giving birth, and women giving milk) with consideration for the definition of foods with function claims and the ideas regarding the target of the applicable food products.

※The guideline is adapted to the articles for SR.

For example, we can use participants like this…

The lifestyle questionnaire indicated that each subject had dissatisfaction with their sleep. The mean Pittsburgh Sleep Quality Index score was 8.07±1.34 (range 7-11), indicating that the subjects had been continuously experiencing unsatisfactory sleep.



We can not use data of insomnia patients

BUT there are exception…

The data collected through some study methods for FOSHU shown in Attachment 2 “Considerations for the Preparation of Application for Foods for Specified Health Uses” in “Permission for Labeling of Foods for Specified Health Uses” (excluding study methods for Standardized, Qualified Health Claims, and Reduction of disease risk FOSHU) **can be use, even if that includes those with mild conditions may be used as exceptional measures.**

7 categories are shorn in the Attachment 2
I will show it at the Next page

7 Categories of FOSHU whose Study methods are shown in Attachment 2

Foods related to blood cholesterol level	Boundary area：LDL cholesterol 120 ～ 139 mg/dL Mild area：LDL cholesterol 140 ～ 159 mg/dL
Foods related to blood triacylglycerol levels (long term)	High-normal：blood triacylglycerol 120 ～ 149 mg/dL Borderline high：blood triacylglycerol 150 ～ 199 mg/dL
Foods related to blood triacylglycerol levels (after meal)	
Foods related to blood pressure	Prehypertension：Systolic 130 ～ 139 mmHg or Diastolic 85 ～ 89 mmHg Hypertension Stage 1：Systolic 140 ～ 159 mmHg or Diastolic 90 ～ 99 mmHg
Foods related to blood sugar levels	Boundary area：Prediabetes Fasting Plasma 110 ～ 125 mg/dL or 75gOGTT (2hr later) 140 ～ 199mg/dL or casual blood (plasma) glucose 140 ～ 199mg/dL
Foods related to body fat	High-normal：BMI 23 ～ 25 Over weight：BMI 25 ～ 30
Foods to modify gastrointestinal conditions	Tendency toward constipation or diarrhea

Differences between FOSHU and FFC in the 7 Categories

		Healthy subject (include Boundary area)	Mild symptom	Remarks
FOSHU		Significant difference Significant difference is not required	Significant difference is not required	Significant difference with whole subjects' data is required. Stratified analysis is recommended (Significant difference is not required).
FFC	Principle (other than 7 categories)	Significant difference	We CAN NOT use the data.	Significant difference with healthy subjects' data is required.
	7 categories	Significant difference Significant difference	Significant difference	Significant difference with whole subjects' data is required Significant difference with each subjects' data is required

We CAN NOT use the data of Mild symptom for notification of FFC except the 7categories.

Latest topic about Mild symptom for notification of FFC

Differences of FOSHU and FCC in the 7 Categories

2018. 4 ~

Consumer Affairs Agency (CAA) announced general competitive bidding for "Investigation research project for the data collected from Mild symptom patients".

Fields of investigation research are **"Allergy", "Uric acid" and "Cognition function".**

And Japan Health and Nutrition Food Association (JHNFA) got it.

※JHNFA was established in April 1985 and authorized by the Cabinet Office as a public interest incorporated foundation in July 2011.

2019. 3

The report was published on the CAA's web page.

https://www.caa.go.jp/policies/policy/food_labeling/information/research/2018/pdf/information_research_2018_190326_0001.pdf

Commission Member

Takao Saruta : Keio University
Masahiro Akishita : Tokyo University
Keiichi Abe : National Institute of Health and Nutrition
Mariko Uehara : Tokyo University Of Agriculture
Kimihiro Okubo : Nippon Medical School
Toyama Kenji : Kanagawa University of Human Services
Fujimori Shin : Teikyo University Hospital
Shigeru Miyazaki : Japan Anti-Tuberculosis Association
Takeshi Yamazaki : Jissen Women's University

New 3 categories “Allergy”, “Uric acid” and “Cognition function”

	Allergy (itchy eyes and rhinorrhea)	Uric acid		Cognitive
		Long term	After meal	
Healthy subject	Participants have itchy eyes and rhinorrhea, but do not use allergy medicine before and during clinical study.	< 7.0 mg / dL		include MCI as Boundary area
Mild symptom	Participants have itchy eyes and rhinorrhea, and use allergy medicine sometimes before and during clinical study.	7.1~7.9 mg / dL		undefined
Subjectss	Over half of participants should be healthy subjects			-
Clinical study	Randomized Controlled Trial (RCT)	・RCT ・over 12weeks observation period and 4weeks post-treatment observation period	・RCT	・RCT ・over 12weeks observation period
Evaluation index	Japanese Guidelines for Allergic Rhinitis or JRQLQ	serum uric acid	serum uric acid and AUC	Japanese Guidelines for The Treatment of Dementia 2017

※AUC（Area Under the blood concentration-time Curve）, MCI(Mild Cognitive Impairment)

“Allergy”(eye and nose): Japanese guidelines for allergic rhinitis

Japanese guidelines for allergic rhinitis

severity		Severity Paroxysmal sneezing or rhinorrhea				
		4+	3+	2+	1+	–
Nasal blockage	4+	most	most	most	most	most
	3+	most	severe	severe	severe	severe
	2+	most	severe	moderate	moderate	moderate
	1+	most	severe	moderate	mild	mild
	–	most	severe	moderate	mild	silent

Sneezing and rhinorrhea type
Nasal blockage type
Combined type

https://www.researchgate.net/publication/313777358_Japanese_guidelines_for_allergic_rhinitis_2017

	4+	3+	2+	1+	-
Paroxysmal sneezing (Average number of episodes of paroxysmal sneezing in a day)	≧21 times	20-11 times	10~6 times	5~1 times	Below +
Rhinorrhea (Average number of episodes of nose blowing a day)	≧21 times	20-11 times	10~6 times	5~1 times	Below +
Nasal blockage Completely	obstructed all day	Severe nasal blockage causing prolonged oral breathing in a day	Severe nasal blockage causing occasional oral breathing in a day	Nasal blockage without oral breathing	Below +

“Allergy”(eye and nose): Japanese Rhino-conjunctivitis Quality of Life Questionnaire (JRQLQ)

Japanese Rhino-conjunctivitis Quality of Life Questionnaire (JRQLQ No1)

To patients with allergic rhinitis (including pollinosis)

These days, the aim of medical treatment is not just to cure disease but also to give patients a better quality of life. The purpose of this survey is to determine to what extent your rhinitis interferes with your life and whether it would be improved by treatment. As with all medical treatment, the information you provide in this survey will remain strictly confidential.

You may find some of the following questions difficult to answer, but just answer to the best of your ability.

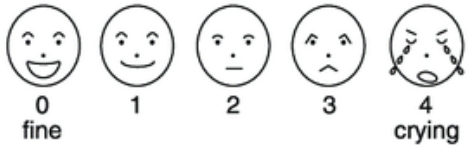
I Tick the box that best describes the severity of the worst nasal and eye symptoms you have experienced in the past 1-2 weeks.

Nasal and eye symptoms	0, No symptoms	1, Mild	2, Moderate	3, Severe	4, Very severe
Runny nose	☐	☐	☐	☐	☐
Sneezing	☐	☐	☐	☐	☐
Blocked nose (nasal congestion)	☐	☐	☐	☐	☐
Itchy nose	☐	☐	☐	☐	☐
Itchy eyes	☐	☐	☐	☐	☐
Watery eyes	☐	☐	☐	☐	☐

II Tick the box that best describes the worst extent to which the symptoms in I above have interfered with your quality of life in the past 1-2 weeks. If any of the items listed under Quality of life below definitely do not relate to the symptoms in I (nose, eye). then there is no need to tick a box for that particular item.

Quality of life	0, No	1, Yes, slightly	2, Yes, moder-ately	3, Yes, greatly	4, Yes, very greatly
1. Reduced productivity at work/home	☐	☐	☐	☐	☐
2. Poor mental concertration	☐	☐	☐	☐	☐
3. Reduced thinking power	☐	☐	☐	☐	☐
4. Impaired reading book/newspaper	☐	☐	☐	☐	☐
5. Reduced memory loss	☐	☐	☐	☐	☐
6. Limitation of outdoor life (e.g. sport, picnics)	☐	☐	☐	☐	☐
7. Limitation of going out	☐	☐	☐	☐	☐
8. Hesitation visiting friend or relatives	☐	☐	☐	☐	☐
9. Reduced contact with friends or others by telephone or conversation	☐	☐	☐	☐	☐
10. Not an easy person to be around	☐	☐	☐	☐	☐
11. Impaired sleeping	☐	☐	☐	☐	☐
12. Tiredness	☐	☐	☐	☐	☐
13. Fatigue	☐	☐	☐	☐	☐
14. Frustration	☐	☐	☐	☐	☐
15. Imitability	☐	☐	☐	☐	☐
16. Depression	☐	☐	☐	☐	☐
17. Unhappiness	☐	☐	☐	☐	☐

III Please circle the number of the face that best describes your general state (including your symptoms, life and emotion) in the past 1-2 weeks.



- Do not fill out the following.

To be completed by physician

Patient's name: Medical record no: Age: yr Sex: M F

Name of medical Institution: Physician's name: Date:

Diagnosis:
SAR: (Antigen:) Treatment (prevention, drug, immunology therapy, operation)
PAR: (Antigen:) Treatment (prevention, drug, immunology therapy, operation)
Non-Allergy: (Disease:) Treatment ( )

QOL score: None 0, Mild 1, Moderate 2, Severe 3, Very severe 4.
Total QOL score
Score by QOL category: ❑ 1-5 points daily life ❑ 6-7 points out-door
❑ 8-10 points social ❑ 11 points sleep
❑ 12, 13 points body ❑ 14-17 points psycho-life
*Please write the names of drugs used if possible

Score: None: 0 points Mild: 1 point Moderate: 2 points Severe: 3 points
Very severe: 4 points

https://www.sciencedirect.com/science/article/pii/S1323893016301654?via%3Dihub

“Cognitive”: Japanese Guidelines for The Treatment of Dementia 2017

Function		Abbreviation	Name
Multiple		MMSE	Mini-Mental State Examination
		HDS-R	Hasegawa’s dementia scale
		MoCA-J	Japanese Version of the Montreal Cognitive Assessment
		ACE-Ⅲ	Addenbrooke’s Cognitive Examination III
		N-D test	Nishimura Dementia test
		COGNISTAT	Neurobehavioral Cognitive Status Examination
		ADAS-Jcog	Alzheimer’s Disease Assessment Scale-cognitive component-Japanese version
		SIB	Severe Impairment Battery
Intelligence		WAIS-Ⅲ	Wechsler adult intelligence scalethird edition
		RCPM	Raven’s Colored Progressive Matericces
Estimate of intelligence befor the disease		JART	Japanese Adult Reading Test
Memory	General	WMS-R	Wechsler memory scale-revised
		RBMT	Rivermead behavioural memory test
	Visual	ROCFT	Rey-Osterrieth complex figure test:
		BVRT	Benton Visual Retention Test
	Verbal	S-PA	Standard verbal paired-associate learning test
Language		WAB	western aphasia battery:
		SLTA	Standard Language Test of Aphasia
Visuospatial ability		ROCFT	Rey-Osterrieth complex figure test
		kohs	Kohs Block Design Test
		VPTA	Visual Perception Test for Agnosia
Attention		CAT	clinical assessment for attention:
Directional attention		BIT	Behavioural inattention test
Frontal lobe function		TMT	Trail Making Test
		FAB	Frontal Assessment Battery
		WCST	Wisconsin Card Sorting Test
		BADS	behavioural assessment of the dysexecutive syndrome

summary

		Healthy subject (include Boundary area)	Mild symptom	Remarks
FOSHU		Significant difference Significant difference is not required	Significant difference is not required	Significant difference with whole subjects' data is required. Stratified analysis is recommended (Significant difference is not required).
FFC	Principle (other than 7 categories) +Cognitive	Significant difference	We CAN NOT use the data.	Significant difference with healthy subjects' data is required.
	7 categories +Allergy(eye and nose) +Uric acid	Significant difference Significant difference	Significant difference	Significant difference with whole subjects' data is required Significant difference with each subjects' data is required

Thank you for your attention!

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

Updates on Nutrition Labeling and Claims Regulations in Indonesia and Thailand

Pauline Chan
Director
Scientific Programs
ILSI SEA Region

ILSI
Southeast Asia Region

New Update: Thailand

- Expansion of positive list of nutrient function claims
  - Notice of the Food and Drug Administration (2019). RE: The Statement of Claims of Nutrients released in June 2019
    - Covering 29 nutrients (no additional nutrients)
    - A total of 135 claim statements
      - Expanded from the original 46 statements

ILSI Southeast Asia Region

New Update: Thailand

- Expansion of positive list of nutrient function claims
  - Describes the general growth, development and the functions of the body, in relation to nutrients
  - For example, for Vitamin C, previous statements were:
    - Vitamin C aids in strengthening blood vessels
    - Vitamin C aids in the helping of anti-free radical process
    - Vitamin C aids in helping of collagen and ligament of cartilage tissue formation

ILSI Southeast Asia Region

New Update: Thailand

- Expansion of positive list of nutrient function claims
  - For example, for Vitamin C, new expanded statements (3 to 13) were:
    - Vitamin C contributes to strengthen blood vessel.
    - Vitamin C aids in helping of anti-free radical process.
    - Vitamin C contributes to the protection of cells from oxidative stress.
    - Vitamin C contributes to normal collagen formation for the normal function of cartilage.
    - Vitamin C contributes to normal collagen formation for the normal function of bones.
    - Vitamin C contributes to normal collagen formation for the normal function of gums.

ILSI Southeast Asia Region

New Update: Thailand

- Expansion of positive list of nutrient function claims
  - For example, for Vitamin C, new expanded statements were:
    - Vitamin C contributes to normal collagen formation for the normal function of skin.
    - Vitamin C contributes to normal collagen formation for the normal function of teeth.
    - Vitamin C contributes to normal energy yielding metabolism.
    - Vitamin C contributes to the normal function of the nervous system.
    - Vitamin C contributes to the normal function of the immune system.
    - Vitamin C contributes to the regeneration of the reduced form of vitamin E.
    - Vitamin C increases iron absorption.

ILSI Southeast Asia Region

New Update: Indonesia

- A new nutrition labelling regulation was published on Aug 22, 2019 on Nutritional Value Information on Processed Food Labels (No 22 of 2019)
  - Nutrition labelling is now **mandatory** for a wide variety of processed foods
  - The NIP now includes:
    - Total energy (total amount derived from fat, protein and carbohydrate)
    - Total Fat
    - Saturated Fat
    - Protein
    - Total carbohydrate
    - Sugar and
    - Salt (Sodium)

ILSI Southeast Asia Region

New Update: Indonesia

- A new nutrition labelling regulation was published on Aug 22, 2019 on Nutritional Value Information on Processed Food Labels (No 22 of 2019)
  - New NIP formats
    - Other vitamins and minerals can be declared only if they are present in amounts not less than **2% AKG** per serving (from 5% in previous regulations)
    - Serving sizes have also be defined for foods from a total of 12 categories and 31 sub-categories

ILSI Southeast Asia Region

New Update: Indonesia

- A new nutrition labelling regulation was published on Aug 22, 2019 on Nutritional Value Information on Processed Food Labels (No 22 of 2019)
  - Voluntary Front-of-Pack Labeling schemes
    - A. Healthier Choice Logo

    - Currently, only two categories of food are allowed to carry the Healthier Choice Logo:
      1. Ready-to-drink beverages
      - Maximum limit of sugar: 6 g per 100 ml, sugar excludes lactose
      - Ready-to-drink beverages shall not contain food additive sweeteners
      2. Instant pasta and instant noodles
      - Maximum limit of total fat: 20 g/100g
      - Maximum limit of Sodium: 900 mg/100g

ILSI Southeast Asia Region

New Update: Indonesia

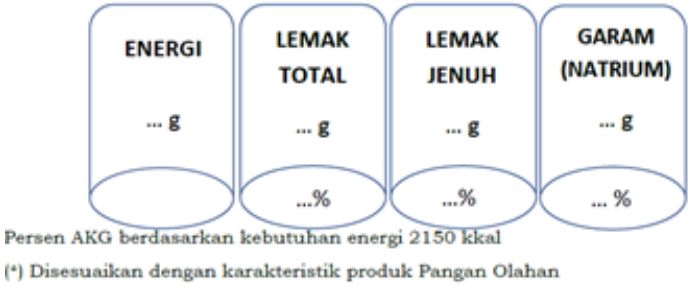
- A new nutrition labelling regulation was published on Aug 22, 2019 on Nutritional Value Information on Processed Food Labels (No 22 of 2019)
  - Voluntary Front-of-Pack Labeling schemes
    - B. GDA Type
      - The following types of nutrients, the amount of nutrients, and the percentage of AKG per serving or per package are to be included:
        - Total energy
        - Total fat
        - Saturated fat
        - Sugar (excluding lactose) and
        - Salt (sodium)

Persen AKG berdasarkan kebutuhan energi 2150 kkal

ILSI Southeast Asia Region

New Update: Indonesia

- A new nutrition labelling regulation was published on Aug 22, 2019 on Nutritional Value Information on Processed Food Labels (No 22 of 2019)
  - Voluntary Front-of-Pack Labeling schemes
    - B. GDA Type
      - GDA label must be in the same form with the same colour
      - For food products that do not contain one or more of the nutrients, those nutrients can be removed from the label
      - For example, if the food does not contain sugar, then the following format without sugar can be used



ILSI Southeast Asia Region

Status Update: Asian Report on Review of NL and Claims in Asia

- Updated Indonesia and Thailand reports and Conclusion chapter
- Received input from Hong Kong
- Other countries: completed
- Cutoff date: September 2019
- Publication October 2019

ILSI Southeast Asia Region

Thank You!

Any Questions?

ILSI
Southeast
Asia Region

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia


Taiwan Dietary Supplement Regulations

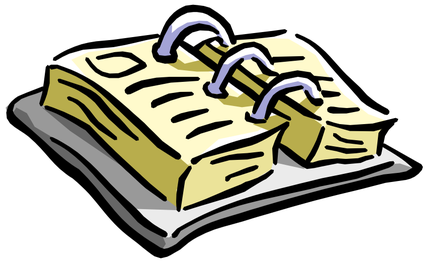
September 26, 2019

HERBALIFE NUTRITION

Making the World Healthier and Happier

Outline

- **Pre-market regulations**
  - ✓ **Foods in tablet or capsule form registration**
  - ✓ **Health food registration**
- **Post-market surveillance**



Definition

Based on the elements above, the essential elements of a food supplement definition are generally:

- foods (referring to the general legal framework applicable) that are concentrated sources of nutrients or other compounds, alone or in combination. These may include nutrients (vitamins/minerals), fish oils (essential fatty acids), botanicals (dried or extracts), microorganisms (probiotics), other substances or bioactives (e.g. polyphenols, glucosamine, CoEnzyme Q10, lutein), for example.
- marketed in dose form (e.g. tablets, capsules, pills, sachets of powder, ampoules of liquids, drop dispensing bottles, etc) and not in conventional food form
- to be taken in unit doses
- intended to supplement the diet for a nutritional or physiological purpose

IADSA (Int'l Alliance of Dietary/Food Supplement Associations)国际膳食补充剂联盟

2. DEFINITIONS

2.1 Vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral food supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., that are designed to be taken in measured small-unit quantities[1] but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet.

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)'s the *Guidelines for Vitamin and Mineral Food Supplements*

Definition

功能性食品（具有特定营养保健功能的食品）

编辑

本词条由"科普中国"科学百科词条编写与应用工作项目 审核 。

功能性食品（Functional food）是指具有特定营养保健功能的食品，即适宜于特定人群食用，具有调节肌体功能，不以治疗为目的的食品。功能性食品有时也称为保健品食品。在学术与科研上，叫"功能性食品"更科学些。它的范围包括：增强人体体质（增强免疫能力，激活淋巴系统等）的食品；防止疾病（高血压、糖尿病、冠心病、便秘和肿瘤等）的食品；恢复健康（控制胆固醇、防止血小板凝集、调节造血功能等）的食品；调节身体节律（神经中枢、神经末稍、摄取与吸收功能等）的食品和延缓衰老的食品。

Article 2 For the purposes of this Act, the term "health food" shall denote food with health care effects, having been labeled or advertised with such effects.
The term “health care effects” shall mean an effect that has been scientifically proven to be capable of improving people’s health, and decreasing the harms and risks of diseases. However, it is not a medical treatment aimed at treating or remedying human diseases; such “health care effects” shall be announced by the central competent authority.

FDA 衛生福利部食品藥物管理署
Taiwan Food and Drug Administration

Definition

衛生福利部
Ministry of Health and Welfare
促進全民健康與福祉

請輸入關鍵字 進階

熱門關鍵字： 醫事人員 長期照顧 十大死因 食品

本部簡介 最新消息 便民服務 法令規章 衛教視窗 本部各單位及所屬機關

103年衛生福利部新聞

- 12月新聞
- 11月新聞
- 10月新聞
- 9月新聞
- 8月新聞
- 7月新聞
- 6月新聞
- 5月新聞
- 4月新聞
- 3月新聞
- 2月新聞

首頁 / 最新消息 / 焦點新聞 / 103年衛生福利部新聞 / 7月新聞

什麼是「健康食品」？讓食品藥物管理署來告訴您!

- 資料來源：食品藥物管理署
- 建檔日期：103-07-24
- 更新時間：103-07-24

一般民眾於日常飲食之外，可能為了保養或補充營養等需求，去購買相關食品，而這些產品，常常被誤冠上「健康食品」的名號，食品藥物管理署提醒消費大眾，自88年「健康食品管理法」上路以來，「健康食品」已成為法律名詞，需向衛生福利部申請查驗登記許可，才可以稱為「健康食品」。依健康食品管理法之定義，「健康食品」係為具有實質科學證據之「保健功效」，並標示或廣告具該功效，非屬治療、矯正人類疾病之醫療效能為目的之食品。

一般坊間所謂的「營養保健食品」、「機能性食品」等產品，可能採用類似於健康食品之產品成分，但這兩者有何不同呢？以食品本質而言，兩者成分或許相同，不同之處在於，健康食品係經過產品安全性、功效性評估試驗，即產品本身經過科學驗證其「保健功效」，依建議攝取量，係安全又有效，並對產品的品質予以嚴格把關，以確保核准的保存期限內之產品有效性。坊間其他類似產品，產品未經科學實證，僅能當一般食品販售，依一般食品管理，廣告及標示不得有不實、誇張、易生誤解及醫療效能之情形，若產品涉及健康食品保健功效宣稱，還會依違反健康食品管理法論處。

對於核准通過之「健康食品」須於產品包裝標示「健康食品」字樣及(小綠人)標準圖像、許可證字號、保健功效敘述等相關規定項目，核可產品資訊並公布於食品藥物消費者知識服務網 http://consumer.fda.gov.tw/(首頁 > 整合查詢中心 > 食品 > 核可資料查詢 > 衛生福利部審核通過之健康食品資料查詢)。食藥署再次強調，健康食品本質仍屬食品，並非藥品，亦無治療疾病或瘦身減肥的作用，若身體有任何不良狀況仍應循正常醫療管道診治，亦切勿自行食用誇大功效或療效產品，以免花錢又傷身。

Ministry of Health and Welfare: “Health Food” is legal term and “dietary supplement” is part of ordinary foods

Foods? Or Health Food? Or Drug?

Drug	Foods	
	Health Food	Ordinary Food
Medical Claim	Health Care effect	Nutritional effect

Pre-market regulations

Act Governing Food Safety and Sanitation

- ✓食品安全衛生管理法施行細則
- ✓食品良好衛生規範準則
- ✓食品安全管制系統準則
- ✓食品業者登錄辦法
- ✓輸入食品查驗辦法
- ✓市售包裝食品營養標示規範
- ✓食品廣告標示詞句涉及虛偽、誇張或醫藥效之認定表
- ✓食品衛生標準
- ✓食品工廠建築及設備設廠標準
- ✓.....

Health Food Control Act

- ✓健康食品管理法施行細則
- ✓健康食品申請許可辦法
- ✓健康食品器具容器包裝衛生標準
- ✓健康食品原子塵放射能污染之安全容許量標準
- ✓健康食品殘留農藥安全容許量標準
- ✓健康食品衛生標準
- ✓健康食品工廠良好作業規範
- ✓健康食品管理法未規定者，則適用食品安全衛生管理法相關規定

http://www.fda.gov.tw/ 首頁 > 法規資訊 >

Act Governing Food Safety and Sanitation

Article 3 For purposes of this Act, the following terms shall have the meaning set forth below:

1. The term "foods" shall mean goods provided to people for eating, drinking, or chewing, and the raw materials of such goods.

Article 21 None of the foods, food additives, food cleansers, food utensils, food containers or packaging and food cleansers which are designated by the central competent authority in a public announcement shall be manufactured, processed, prepared, repacked, imported or exported without filing product registration with and procuring a permit document from the central competent authority. Any change in the registered matters shall be subject to the prior approval of the central competent authority.

Health Food Control Act

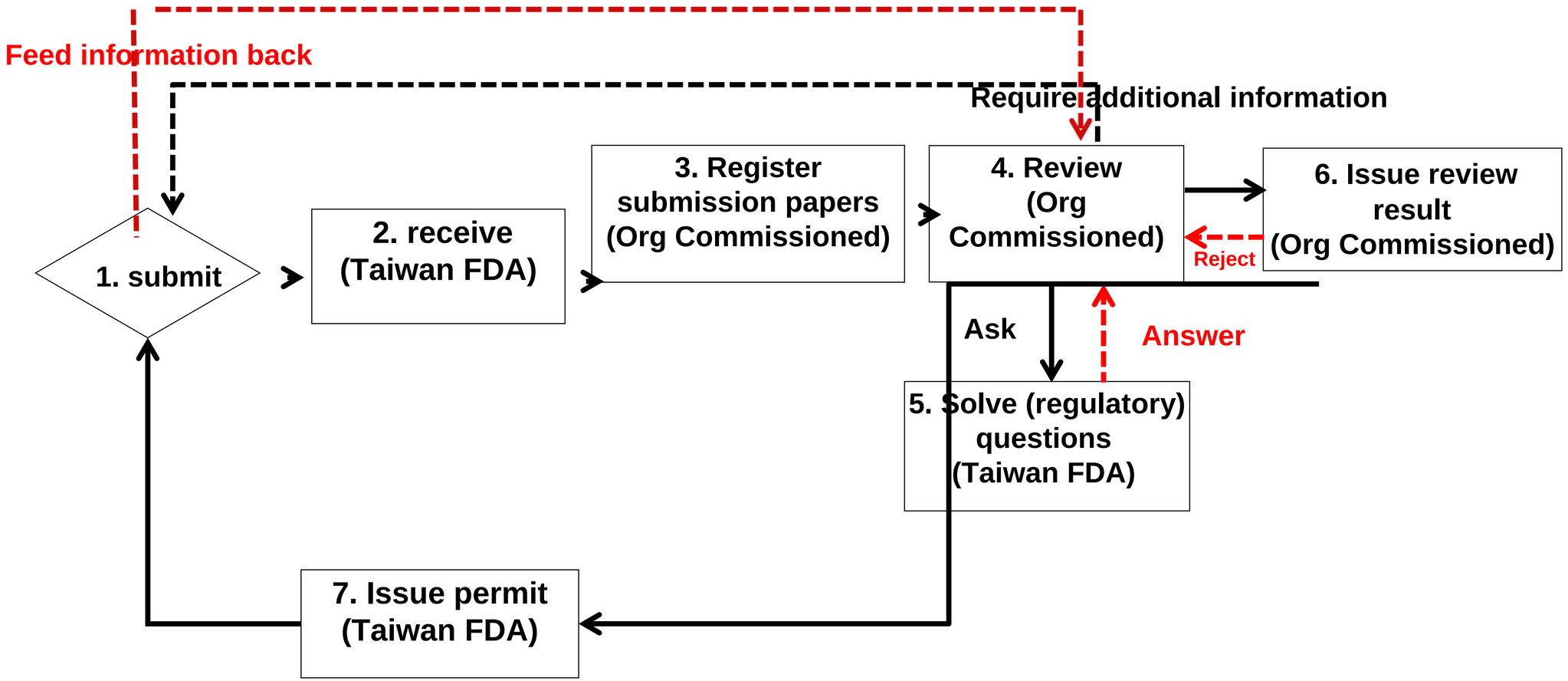
Article 7 No health food shall be manufactured or imported unless and until an application for review and testing registration supported by information on its ingredients, specifications, functions and effects, a summary of the manufacturing process, specifications and methods of analysis, other relevant data and documentation, as well as label and sample are submitted along with permit fee, review and testing fees to, and a product registration permit is issued by, the central competent authority or the organization commissioned thereby.

Foods in tablet or capsule form registration

Foods in Tablet or Capsule Form registration

- Registration Purpose of Imported Prepackaged Food in Tablet or Capsule Form:
  - ✓**Help customs clearance**
- Registration Purpose of Domestic Prepackaged Vitamin and Mineral Tablets and Capsules:
  - ✓**Help consumer Protection**
  - ✓**Help conversion of drug into food product**

Foods in Tablet or Capsule Form registration flow chart



2019 new Organization Commissioned：

* Imported Prepackaged Food in Tablet or Capsule Form -財團法人優良農產品發展協會(CAS Association)

* Domestic Prepackaged Vitamin and Mineral Tablets and Capsules -台灣優良食品發展協會(TQF: Taiwan Quality Food Association)

Health Food Registration

Health Food Registration

	Review time	Trial	Cost	Reference # and standard logo	Health Care Effect category	Claim
Track 1 Case-by-case	**long 180 days**	**v**	**High**	 **衛部健食字**	***Protection of the liver; Relieving physical fatigue; Regulation of blood lipid; Regulation of blood sugar level; Regulation of immune system; Alleviation of osteoporosis; Maintenance of dental health; Anti-aging; Promotion of iron absorption; Promotion of gastrointestinal functions; Aiding blood pressure regulation; Attenuation of body fat accumulation; Reducing allergic reactions***	**Evidence-based**
Track 2 Spec. standard	**short 120 days**	**-**	**Low**	 **衛部健食規字**	**1. Red Yeast Rice** **2. Fish Oil**	**Standardized**

✓GRAS
✓Health care effect mechanism is clear
✓Functional ingredient is clear
✓Ingredient assessment method is clear

The health care effect is from theory instead of trial result

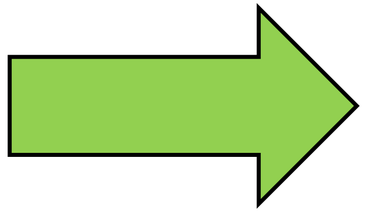
Health Food Review Organization Commissioned

- All processes are based on regulations
- Keep transparent

Taiwan FDA

Partially Commission

The Center for Drug Evaluation (CDE)

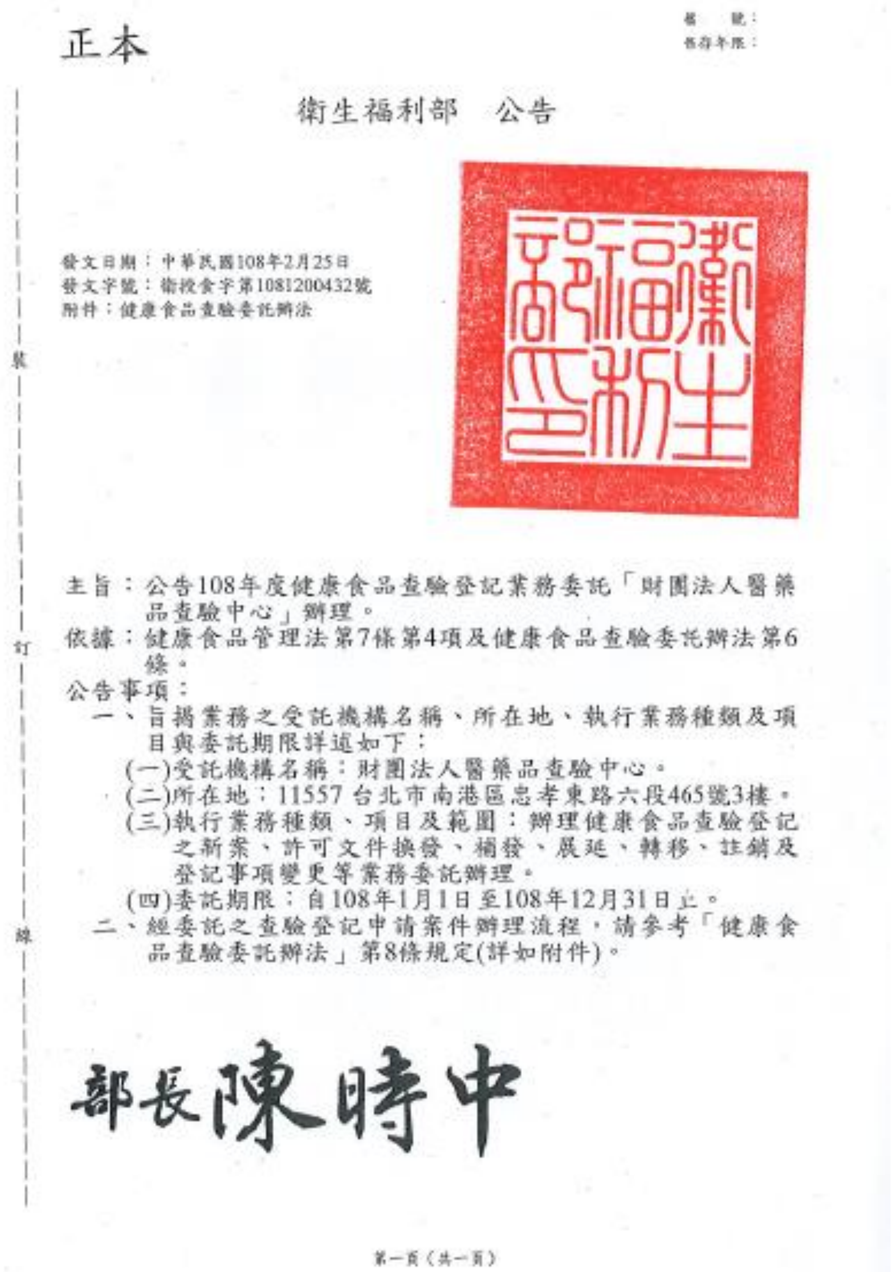


Recording the application upon receipt/ Accept the case?/// At last, decide whether issue the permit

Complete the draft assessment report// Complete the revision of the assessment report

Ministry of Health and Welfare Announcement 2019-02-25

The Center for Drug Evaluation (CDE) is commissioned by the MoHW.



正本

衛生福利部　公告

發文日期：中華民國108年2月25日
發文字號：衛授食字第1081200432號
附件：健康食品查驗委託辦法

主旨：公告108年度健康食品查驗登記業務委託「財團法人醫藥品查驗中心」辦理。

依據：健康食品管理法第7條第4項及健康食品查驗委託辦法第6條。

公告事項：

一、旨揭業務之受託機構名稱、所在地、執行業務種類及項目與委託期限詳述如下：

(一)受託機構名稱：財團法人醫藥品查驗中心。

(二)所在地：11557 台北市南港區忠孝東路六段465號3樓。

(三)執行業務種類、項目及範圍：辦理健康食品查驗登記之新案、許可文件換發、補發、展延、轉移、註銷及登記事項變更等業務委託辦理。

(四)委託期限：自108年1月1日至108年12月31日止。

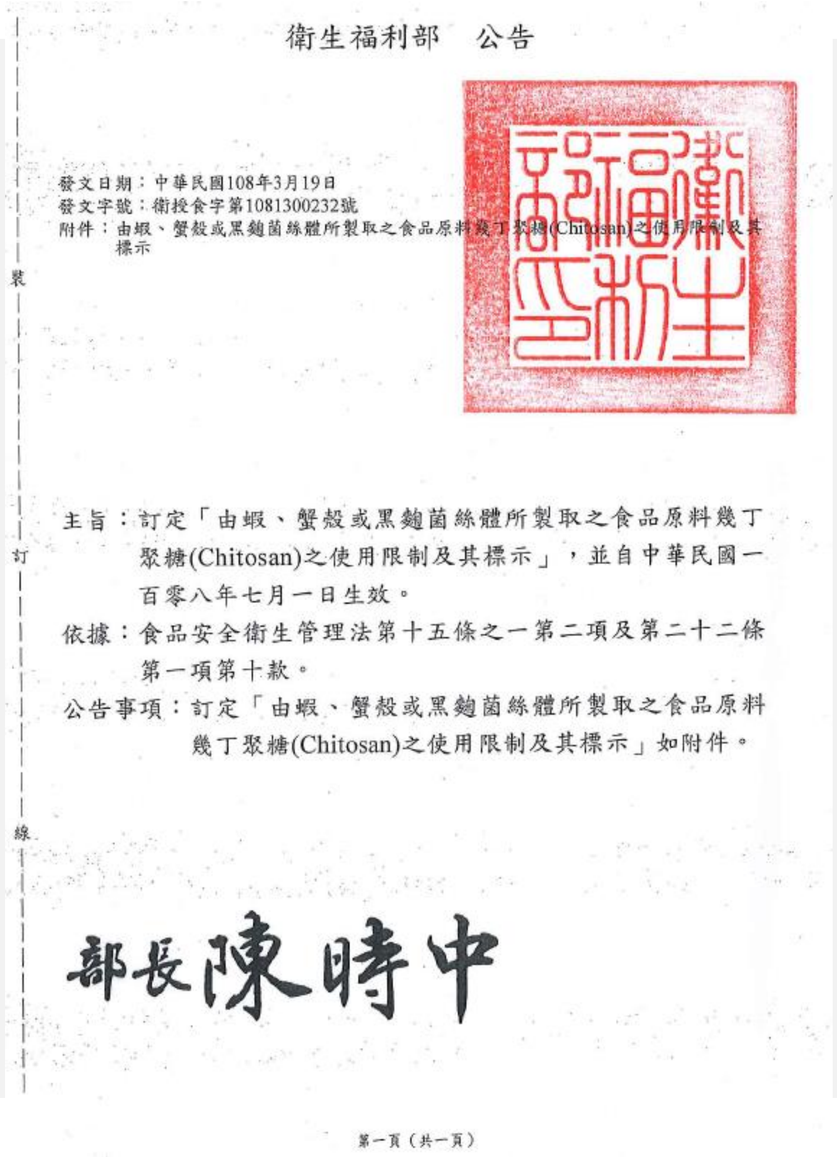
二、經委託之查驗登記申請案件辦理流程，請參考「健康食品查驗委託辦法」第8條規定(詳如附件)。

部長 陳時中

第一頁（共一頁）

Update in 2019

MoHW's Chitosan precautions required (2019 new)



衛生福利部　公告

發文日期：中華民國108年3月19日
發文字號：衛授食字第1081300232號
附件：由蝦、蟹殼或黑麴菌絲體所製取之食品原料幾丁聚糖(Chitosan)之使用限制及其標示

裝

主旨：訂定「由蝦、蟹殼或黑麴菌絲體所製取之食品原料幾丁聚糖(Chitosan)之使用限制及其標示」，並自中華民國一百零八年七月一日生效。

訂

依據：食品安全衛生管理法第十五條之一第二項及第二十二條第一項第十款。

公告事項：訂定「由蝦、蟹殼或黑麴菌絲體所製取之食品原料幾丁聚糖(Chitosan)之使用限制及其標示」如附件。

線

部長陳時中

第一頁（共一頁）

由蝦、蟹殼或黑麴菌絲體所製取之食品原料幾丁聚糖(Chitosan)之使用限制及其標示

一、 本規定依食品安全衛生管理法第十五條之一第二項及第二十二條第一項第十款規定訂定之。

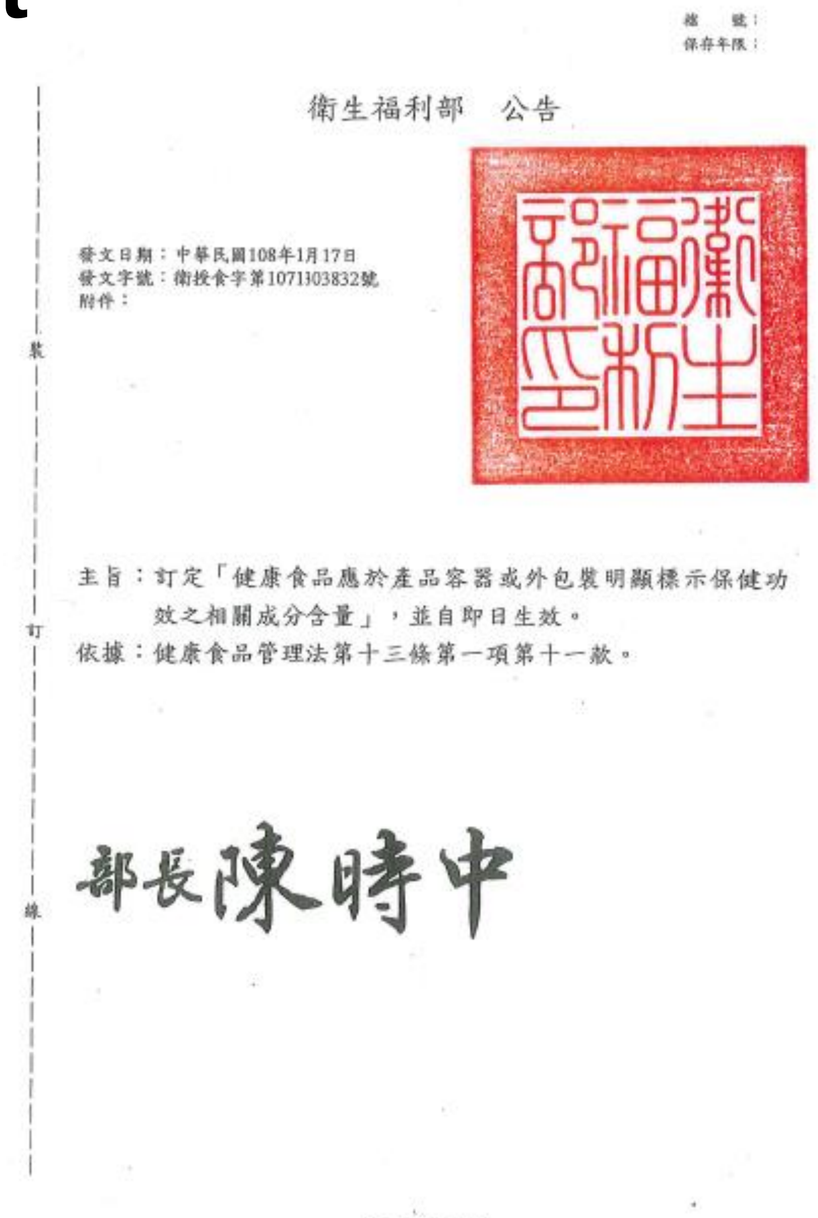
二、 由黑麴菌絲體(*Aspergillus niger* mycelium)所製取者，其赭麴毒素A(Ochratoxin A)含量應小於一ppb。

三、 使用由蝦、蟹殼或黑麴菌絲體製取之幾丁聚糖作為原料之食品，其容器或外包裝應以中文顯著標示「有服用慢性病藥物者，應諮詢醫師後，方可使用」及「不建議孕婦、授乳者及嬰幼兒食用」之警語字樣。

- ✓ Ochratoxin A in chitosan from *Aspergillus niger mycelium*, should be less than 1ppb
- ✓ Warning must be in traditional Chinese: "A patient with chronic disease taking medicine should consult physicians first" and "Pregnant women, breastfeeding women and infants are not recommended for consumption"

MoHW’s labeling requirement for Health Food (2019 new: 2019-01-17)

Health food products should significantly label the amount of related health care effect ingredients on the label of container or package



字　號：
保存年限：

衛生福利部　公告

發文日期：中華民國108年1月17日
發文字號：衛授食字第1071303832號
附件：

裝

主旨：訂定「健康食品應於產品容器或外包裝明顯標示保健功效之相關成分含量」，並自即日生效。

訂

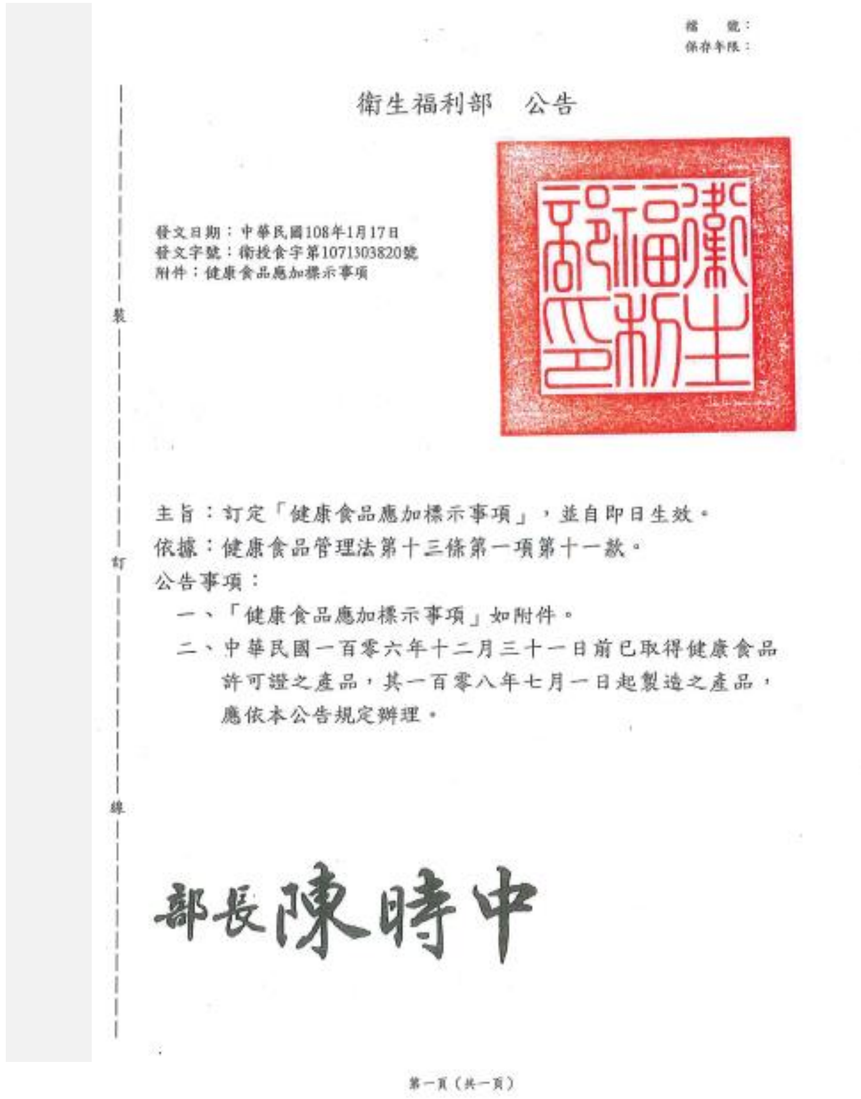
依據：健康食品管理法第十三條第一項第十一款。

線

部長陳時中

第一頁（共一頁）

MoHW's warning requirement for Health Food (2019 new)



檔　號：
保存年限：

衛生福利部　公告

發文日期：中華民國108年1月17日
發文字號：衛授食字第1071303820號
附件：健康食品應加標示事項

主旨：訂定「健康食品應加標示事項」，並自即日生效。
依據：健康食品管理法第十三條第一項第十一款。
公告事項：
一、「健康食品應加標示事項」如附件。
二、中華民國一百零六年十二月三十一日前已取得健康食品許可證之產品，其一百零八年七月一日起製造之產品，應依本公告規定辦理。

部長陳時中

第一頁（共一頁）

健康食品應加標示事項

一、 膠囊及錠狀健康食品，應於其容器或包裝上之「注意事項」中加註下列事項：
(一) 「本產品非藥品，供保健用，罹病者仍需就醫。」字樣。
(二) 「請依建議攝取量食用，勿過量。」字樣。
二、 膠囊及錠狀以外健康食品，應於其容器或包裝上之「注意事項」中加註下列事項：「本產品供保健用，請依建議攝取量食用。」字樣。
三、 前二點加註事項字體應與底色加以區別。

- ✓ Warning must be in traditional Chinese
- ✓ Health Food in Tablet or Capsule Form: "The product isn't medicine but for health care, and patients still need to see a doctor" and "The consumption should follow recommended dosage. Don't overdose!"
- ✓ Health Food except Tablet or Capsule Form: "The product is for health care and please follow recommended dosage!"

Health food labeling limitation

Article 14 No health food labeling or advertisement shall misrepresent or exaggerate, and the health claims shall not extend beyond the approved scope and shall be limited to the content registered at the central competent authority.

No labeling or advertisement of health food shall claim or refer to medical efficacy.

Food labeling and advertising (2019 new)

- “Guideline of identifying foods and related products labeling and advertising involved with misleading, exaggerative or medical claims” (The guideline is based on Article 28 of the Act Governing Food Safety and Sanitation)- (2019-06-12)
- “Guideline of identifying foods and related products labeling and advertising involved with misleading, exaggerative or medical claims” Q&A- (2019-08-15) (https://www.fda.gov.tw/TC/newsContent.aspx?cid=3&id=25519)

Food labeling and advertising (2019 new)

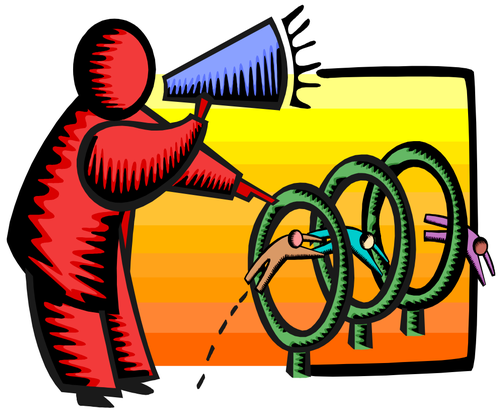
Taiwan Legislative Yuan promulgates penalty for misleading food safety rumors or fake news to damage the public or personal interest.

(2019-05-24)

食品安全衛生管理法增訂第四十六條之一條文

108.5.24 立法院三讀通過條文	說　　明
第四十六條之一　散播有關食品安全之謠言或不實訊息，足生損害於公眾或他人者，處三年以下有期徒刑、拘役或新臺幣一百萬元以下罰金。	一、本條新增。 二、散播係指散布、傳播於眾之意，而所謂「謠言」或「不實訊息」，係指該「捏造之語」或「虛構之事」，其內容出於故意虛捏者而言，倘有合理之懷疑，致誤認有此事實而為傳播或散布時，即欠缺違法之故意（參照最高法院九十七年度台上字第六七二七號刑事判決）。因此，關於「散播謠言或不實訊息」，係以散布、傳播「捏造或虛構事實」為其構成要件（參照最高法院一〇六年度台上字第九六號刑事判決），行為人將自己或他人捏造、扭曲、篡改或虛構全部或部分可證明為不實的訊息（包括資訊、消息、資料、數據、廣告、報導、民調、事件等各種媒介形式或內容），故意甚至是惡意地藉由媒體、網路或以其他使公眾得知之方法，以口語、文字或影音之形式傳播或散布於眾，引人陷入錯誤，甚至因而造成公眾或損害個人，即具有法律問責之必要性。 三、食品安全與否乃涉及民生議題之重要資訊，其正確性與民眾生活息息相關，若有謠言或不實訊息之散播，除將影響交易價格及業者營業信譽外，亦將引起民眾恐慌，進而危害公眾安全，爰增訂本條刑事處罰規定。

Post-market surveillance



2019 Adverse Reactions Reporting System

正本

衛生福利部食品藥物管理署　公告

發文日期：中華民國108年3月19日
發文字號：FDA食字第1081300831號
附件：

主旨：公告108年度健康食品、特殊營養食品及膠囊錠狀食品非預期反應通報案件業務委託「財團法人藥害救濟基金會」辦理。

公告事項：

一、為保障全民食用食品之安全性，並建立本土之食品安全相關資料，本署設置「全國健康食品、特殊營養食品及膠囊錠狀食品非預期反應通報系統（網址：http://qms.fda.gov.tw/）」線上通報系統，以利各界發現食品非預期反應，即時通報。

二、旨揭業務之受託機構名稱、所在地、電話及傳真詳述如下：

(一)受託機構名稱：財團法人藥害救濟基金會。

(二)所在地：100台北市中正區愛國東路22號10樓。

(三)電話：02-23587343。

(四)傳真：02-23584098。

三、如發現食品非預期反應時，請立即通報「全國健康食品、特殊營養食品及膠囊錠狀食品非預期反應通報系統」，或撥打通報電話。

署長 吳秀梅

2019 Taiwan Drug Relief Foundation is commissioned by Taiwan FDA to set up “the adverse reactions reporting system” of Health Food, Foods in Tablet or Capsule Form and Special Dietary Food

健康食品及膠囊錠狀食品非預期反應通報系統

健康食品助健康　　即時通報更安康

何種情況可以通報

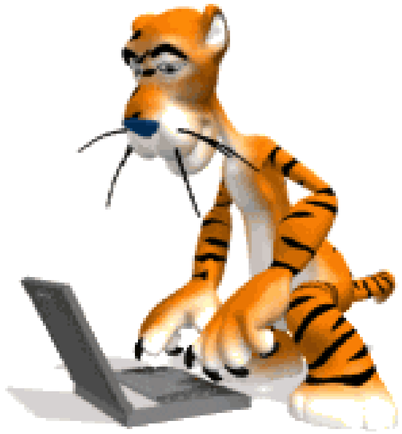
1.食用健康食品後發生身體不適而就醫或沒有達到宣稱的保健功效。
2.食用膠囊錠狀食品發生身體不適而就醫。

通報作業流程:

財團法人藥害救濟基金會
通報網站:http://hf.doh.gov.tw
電子郵件信箱：hf@tdrf.org.tw
地址:100台北市中正區羅斯福路一段32號2樓
傳真:(02)2358-4098
電話:(02)2358-7343

FDA 行政院衛生署食品藥物管理局　保障你我健康

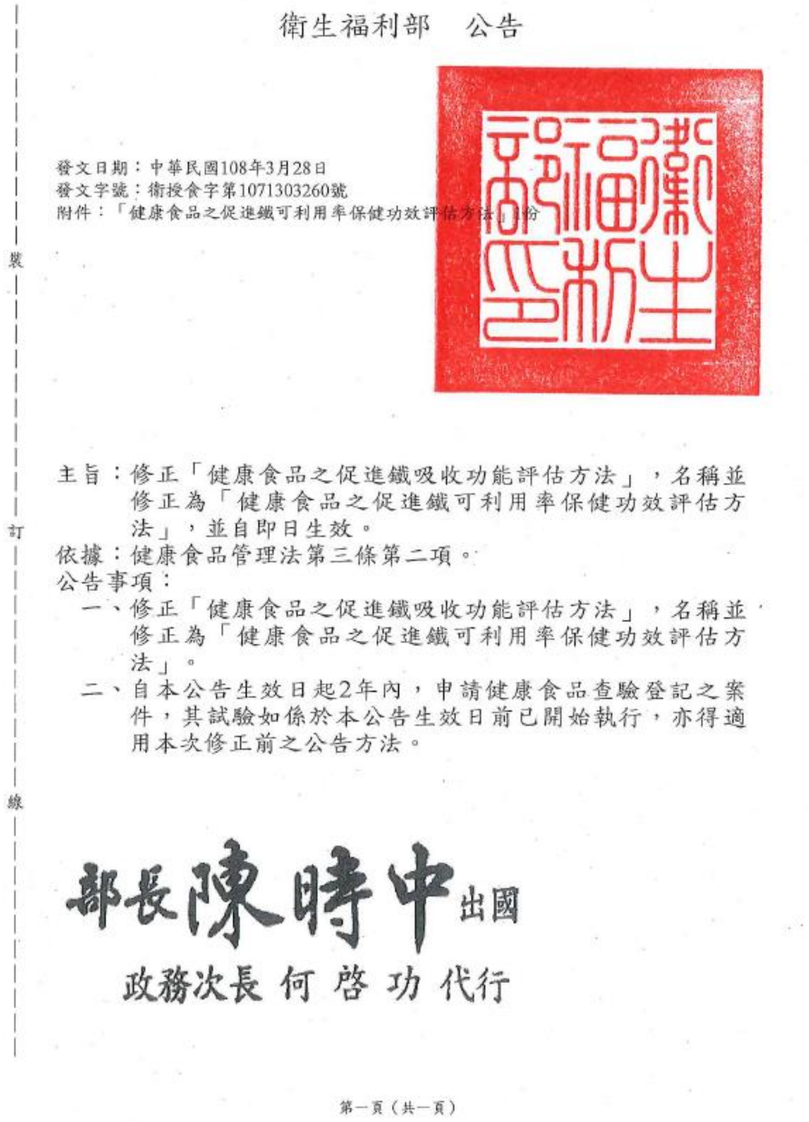
THANK YOU



HERBALIFE NUTRITION

Making the World Healthier and Happier

健康食品之促進鐵可利用率保健功效評估方法 (2019-03-28)



衛生福利部　公告

發文日期：中華民國108年3月28日
發文字號：衛授食字第1071303260號
附件：「健康食品之促進鐵可利用率保健功效評估方法」1份

裝

主旨：修正「健康食品之促進鐵吸收功能評估方法」，名稱並修正為「健康食品之促進鐵可利用率保健功效評估方法」，並自即日生效。

訂

依據：健康食品管理法第三條第二項。

公告事項：

一、修正「健康食品之促進鐵吸收功能評估方法」，名稱並修正為「健康食品之促進鐵可利用率保健功效評估方法」。

二、自本公告生效日起2年內，申請健康食品查驗登記之案件，其試驗如係於本公告生效日前已開始執行，亦得適用本次修正前之公告方法。

線

部長陳時中出國

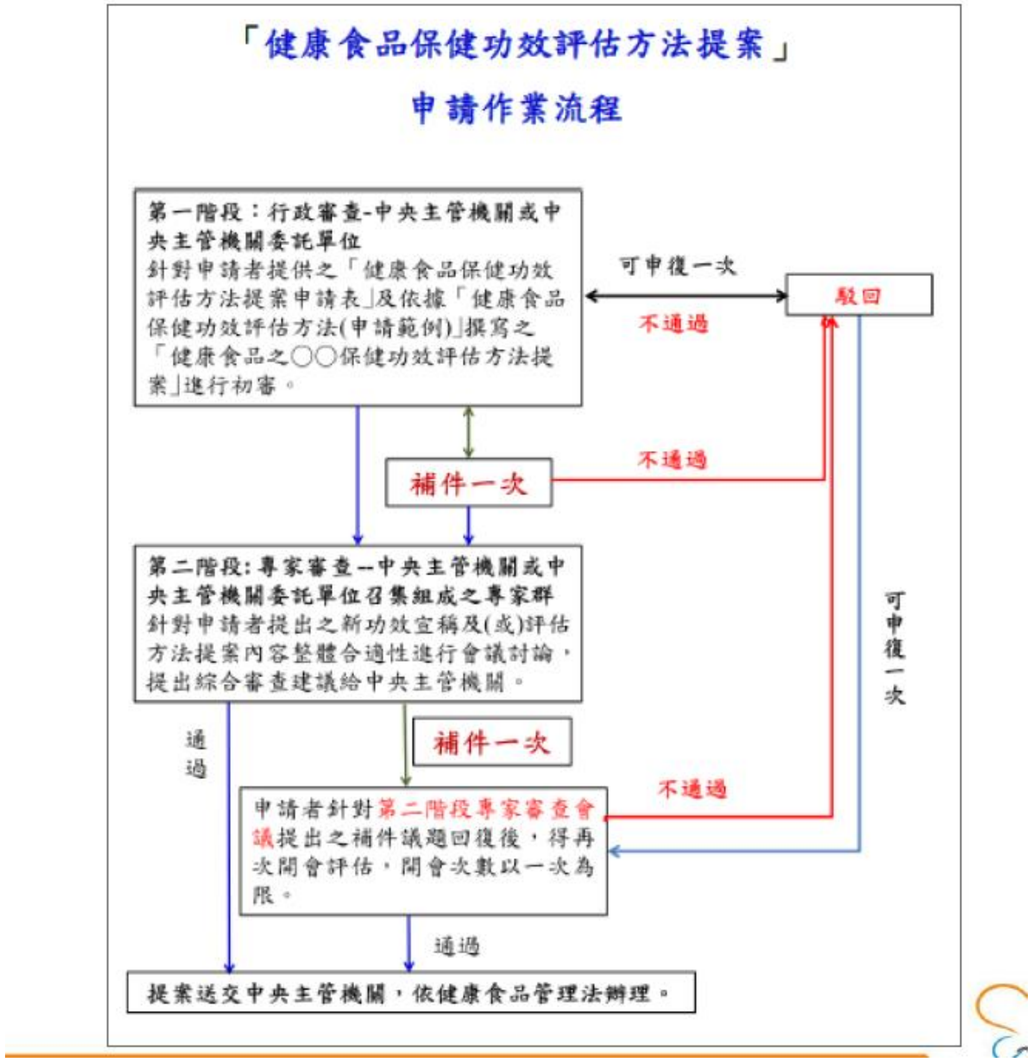
政務次長何啓功代行

第一頁（共一頁）

https://www.fda.gov.tw/TC/newsContent.aspx?cid=3&id=25047

健康食品審查流程 (保健功效評估流程)

106年4月17日 衛授食字第1061300298號公告



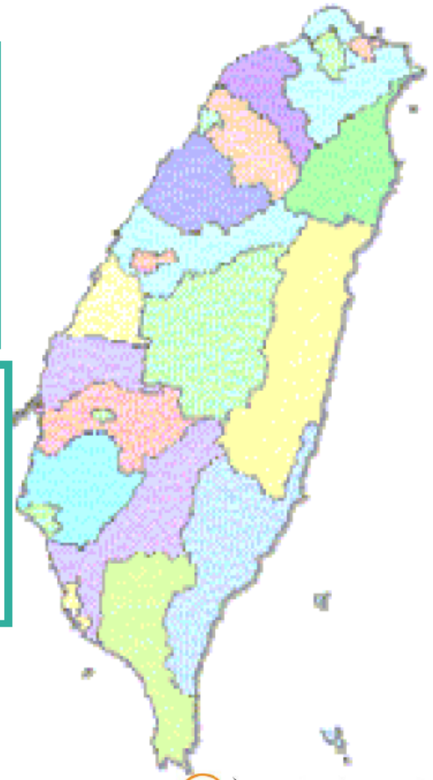
食品安全衛生管理法

- 「食品添加物」、「基因改造食品」、「特殊營養食品」、「輸入錠狀、膠囊狀食品」、「國產維生素類錠狀、膠囊狀食品」須先向衛福部辦理查驗登記取得許可證後，才可以上市。
- 一般食品(包含坊間所稱「功能性食品」、「營養保健食品」...)
  - ✓由合法業者使用合法之食品原料及添加物，經良好製程及品管產製即可自行上市販售。
  - ✓業者應自主管理，產品之成分、衛生安全、標示及廣告等均應符合食品衛生相關法規。
  - ✓衛生機關於抽驗、監測食品發現有與規定不符之情事，必將依相關處辦，以維護民眾權益。

Cooperation between FDA and local DoHs

Taiwan FDA:
Make and interpret regulations and monitor the customs import food products

Local Depts of Health:
Inspect local manufacturers and sellers and related product labeling and advertising



衛生福利部
食品藥物管理署
FDA Food and Drug Administration

〔Yahoo 新聞〕食藥署籲落實健康食品自主管理 / 2019-08-21

隨著養生風潮興起，各種調節生理機能保健功效之健康食品應運而生，為保障此類食品之衛生安全，食品藥物管理署於106-107年完成具抗疲勞、免疫調節、護肝功能及調節血脂保健功效健康食品製造業者之稽查，所見業者登錄資料不完整、產品標示不符合規定或健康食品工廠良好作業規範未臻完善等缺失，均已改善完竣。

今（一○八）年度食藥署將會同地方政府衛生局針對調節血糖、骨質保健、牙齒保健、延緩衰老、促進鐵吸收、胃腸功能改善、輔助調節血壓、不易形成體脂肪、輔助調整過敏體質保健功效之健康食品工廠啟動稽查，查核重點包含食品業者登錄、原料之來源及驗收、業者自主管理、食品追溯追蹤系統、查驗登記許可內容符合性、產品標示及廣告、健康食品工廠良好作業規範等。

食藥署呼籲食品業者應落實自主管理，並符合健康食品管理法相關規定。未經核准擅自製造或輸入健康食品或非依健康食品管理法之規定而標示或廣告為健康食品者，依健康食品管理法處三年以下有期徒刑，得併科新臺幣一百萬元以下罰金；不符健康食品工廠良好作業規範及本法標示規定者，分別違反第10條及第13條規定，依同法第23條處新臺幣3萬元以上15萬元以下罰鍰。

產品標示或廣告虛偽不實、誇張或其宣稱之保健效能超過許可範圍者，係違反第14條第1項規定，依同法第24條第1項第1款處新臺幣10萬元以上50萬元以下罰鍰。標示或廣告涉及醫療效能者，則涉違反第14條第2項規定，可依同法第24條第1項第2款處新臺幣40萬元以上200萬元以下罰鍰。

Health Food Registration-key points (Track 1)

一. 申請書表。
二. 產品原料成分規格含量表。
三. 產品之安全評估報告。
四. 產品之保健功效評估報告。
五. 產品之保健功效成分鑑定報告及其檢驗方法。
六. 產品及其保健功效安定性試驗報告。
七. 產品製程概要。
八. 良好作業規範之證明資料。
九. 產品衛生檢驗規格及其檢驗報告。
十. 一般營養成分分析報告。
十一. 相關研究報告文獻資料。
十二. 產品包裝標籤及說明書。
十三. 申請者公司登記或商業登記之證明文件。
十四. 完整樣品及審查費。

Safety assessment:			
(1)第一類 傳統食用且為通常加工食品形式 完整安全性文獻資料 免進行毒性測試 提供文獻資料證明	(2)第二類 非通常加工食品形式 28日連續口服餵食試驗 基因毒性試驗	(3)第三類 非傳統食用 90日餵食試驗 基因毒性試驗 致畸試驗	(4)第四類 (riskiest) 含致癌類似物 90日餵食試驗 基因毒性試驗 致畸/繁殖試驗 致癌性試驗

Health Care Effect Category:

◎調節血脂 ◎腸胃功能改善 ◎免疫調節 ◎護肝
◎輔助調整過敏體質 ◎不易形成體脂肪 ◎調節血糖 ◎抗疲勞
◎骨質保健 ◎牙齒保健 ◎延緩衰老 ◎促進鐵吸收
◎輔助調節血壓

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

Health Supplement & Nutraceutical Regulations - India

Isha Singh, Worldwide Scientific Affairs

HERBALIFE NUTRITION
Making the World Healthier and Happier

Market Overview

Market Overview

Global Nutraceuticals market is predicted to record a revenue of **$671.30 billion by 2024**

APAC Nutraceuticals Market

CAGR of 7.5% during the forecast period (2018-2023)

Functional food, functional beverage, dietary supplements

Segmented into 3 categories:

type, application, geography

Key markets: Japan, China, India, Korea

References: Mordor Intelligence Report, 2018

Global Terminologies

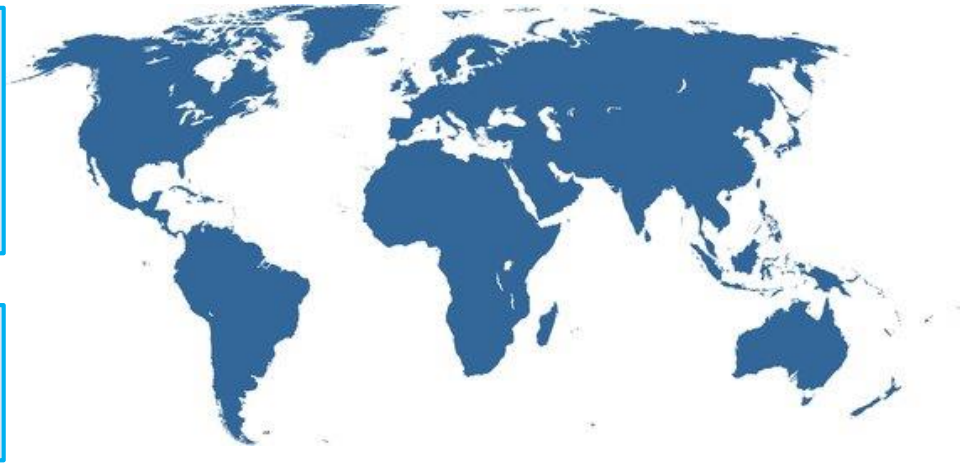
Terminologies used for Health Supplements/Nutraceuticals

The term "Health Supplements and Nutraceuticals" is evolving and the nomenclature varies across countries

European Union: Food Supplements
concentrated sources of nutrients; or other substances with a nutritional or physiological effect

Russia: Biologically Active Supplements
products containing: minerals, amino acids, fibers, microorganisms, vitamins, etc.

Canada: Natural and Non-prescription Health Products
vitamins, minerals, herbal remedies, homeopathic medicines, traditional medicines, probiotics, amino acids, etc.



Japan: Foods for Special Health Use
Products divided into 2 categories:
1) Food with nutrient function claims;
2) Food for specified health uses

USA: Dietary Supplements
products containing vitamins, minerals, herbs, amino acids & enzymes

Australia: Complementary Medicines
herbal, vitamin, mineral, and nutritional supplements

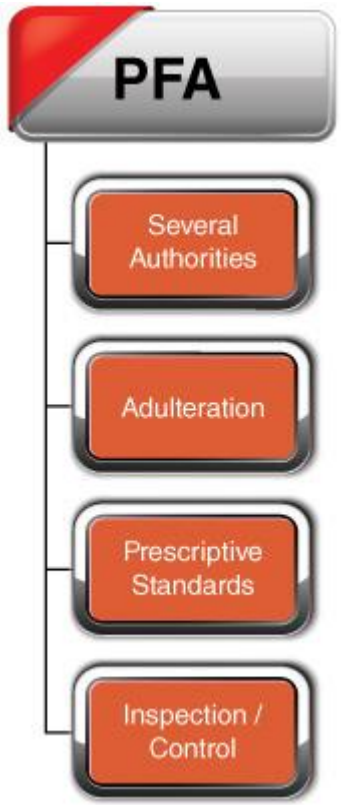
India: Health Supplements; Nutraceuticals
sources of nutrients; or substances with a nutritional or physiological benefits

References: Links provided in references slide

Evolution of Indian Food Laws & Regulations

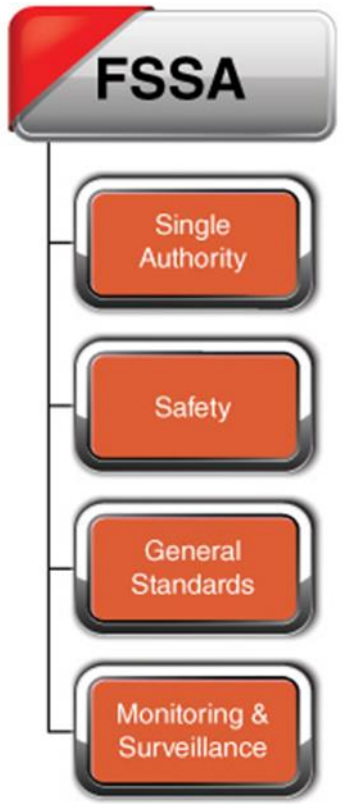
Evolution of Indian Food Laws & Regulations

PFA
Prevention of Food Adulteration Act, 1954



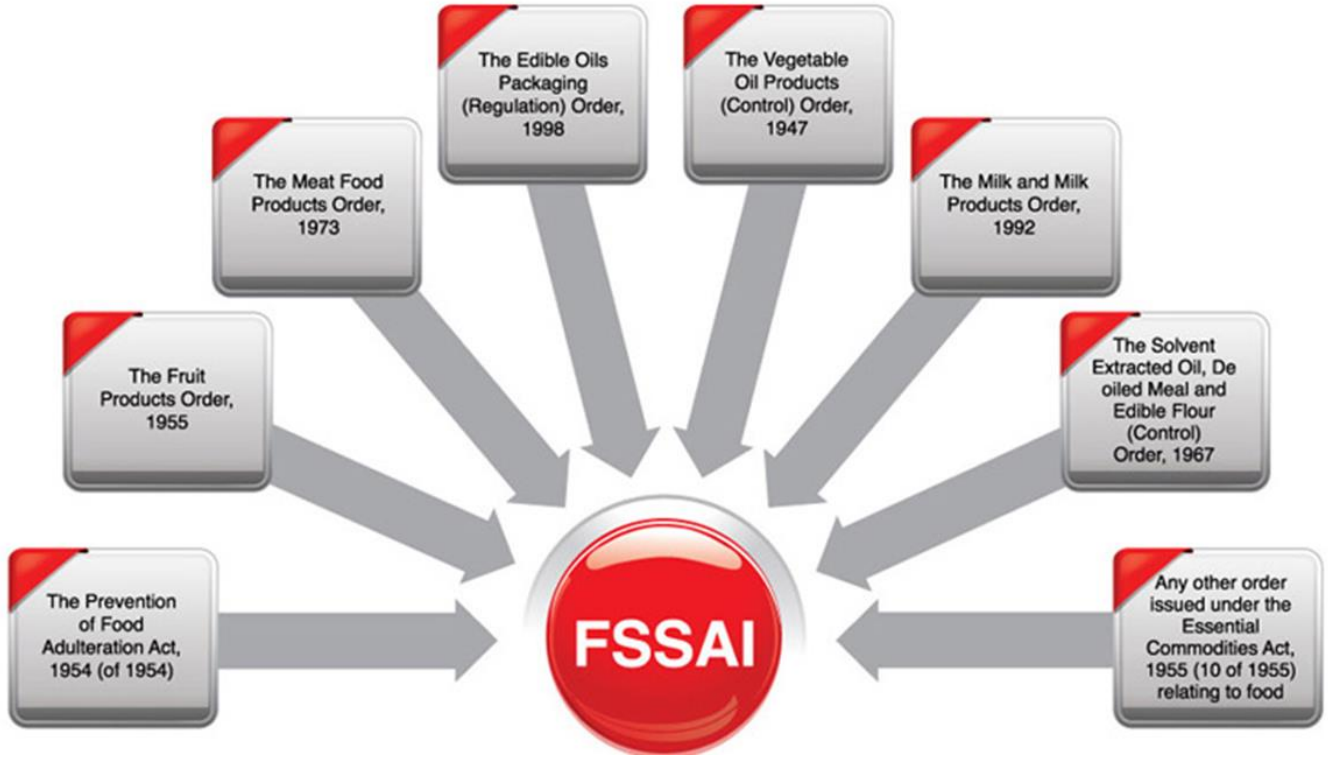
To prevent the adulteration of any article of food/ drinks for human consumption excluding drugs and water

FSSA
Food Safety & Standards Act, 2006



Consolidate all the laws related to food

FSSAI
Food Safety & Standards Authority of India, 2011 (MoH)



Science based standards & regulations for manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption

References: PFA, 1954; FSSA, 2006; FSSAI website; reference images (google search)

Health Supplement & Nutraceutical Regulations

Health Supplement & Nutraceutical Regulations - India

FSSAI, India notified the **Food Safety and Standards** (health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food) **Regulations, 2016 (*aka* Nutra Regulations)**

- **cover 8 categories of food**
- **definition includes the use of each categories and the content of the food**

FSSAI regulates the articles of food covered under "Nutra" regulations through **Food Safety and Standards Act, 2006**

- Regulations were notified **on 23rd December, 2016;** Food Business Operators (FBOs) were required to **comply by 1st January, 2018**.
- Industry was provided **12 month's window to comply** with these regulations

References: FSSAI Regulations, 2016

8 Product Categories in Nutra Regulation

Category	1) Health Supplements 2) Nutraceuticals 3) Foods for Special Dietary Uses (FSDU)	4) Foods for Special Medical Purpose (FSMP)	5) Foods with added Probiotic ingredients	6) Food with added Prebiotic ingredients	7) Novel Food	8) Specialty food containing Plant or Botanical ingredients
Content	1. HS: Used as **supplement to the diet** 2. NS: Must provide a **"physiological health benefit"** 3. FSDU: Formulated for special dietary uses, e.g., weight loss/weight management – **MR products**; specific guidelines for calories & nutrient levels/serve	**Dietary management under medical advice** Exclusive or partial feeding for medical conditions	Food added with **live microorganisms** beneficial to human health	Food added with **prebiotic ingredients** which are nonviable food components	**Novel ingredients/foods** Food for which standards are not specified but is not unsafe	Food containing **Plant or botanical Ingredients** not specified in regulations
Notes	Label: **Not to cure or mitigate any specific disease**, disorder or condition as may be permitted by the regulations	Label: "recommended to be used under medical advise only"	Label: Probiotic food; Strain, shelf-life, efficacy levels must be stated	Label: Prebiotic food	Does not contain any of the foods/ ingredients prohibited ***submit application for approval***	**Having history of safe usage in India/ elsewhere** ***submit application for approval***

References: FSSAI Regulations, 2016

Schedules for Allowable Ingredients in Nutra Regulation

Schedule	Schedule IV List of Plant or Botanical Ingredients	Schedule VI List of Nutraceutical Ingredients	Schedule VII List of Probiotic Strains	Schedule VIII List of Prebiotic ingredients
Content	List of Plant or Botanical Ingredients = **400 ingredients** **botanical name & part used, common name; permitted range of usage for adults per day (raw herb/ material)**	List of Nutraceutical Ingredients = **200+ ingredients**	**List of Probiotic strains**	**List of Prebiotic ingredients**
Notes	• **Permissible usage range children between 5-16 years is ½ of adults range** • **Not recommended for children below age of 5yrs**	The enzymes listed in this schedule are primarily used as processing aids, but also may be used in nutraceutical products	**May be used either singly or in combination; has to be Non-GMO** Open for additions after proper scientific evaluation	Open for additions after proper scientific evaluation

References: FSSAI Regulations, 2016: Schedule – IV: List of plant or botanical ingredients; Schedule –VI: List of Ingredients as Nutraceuticals; Schedule –VII: List of strains as probiotics (live micro-organisms); Schedule VIII: List of Prebiotic Compounds.

Advertising & Claims Regulations

Advertising & Claims Regulations					
Claims	**Health Claims**	**Nutrition Claims**	**Non-addition Claims**	**Claims related to Dietary Guidelines**	**Conditional Claims**
Content	**Physiological role of the nutrient** or substance or an accepted **diet- health relationship**	**(a) Nutrient Content Claim; (b) Nutrient Comparative Claim**	Claims on **non-addition** of sugars, salt (sodium chloride), additives	Claims made **related to a "healthy diet"** referring to the pattern of eating as per current ICMR's Dietary Guidelines for Indians	Claim made where a food is by its **nature high or low or free** of a specific nutrient; preceded by the words **'natural or naturally'** in the claim statement

**Health and nutritional claims are mentioned under Nutra regulations.*

References: Food Safety and Standards (Advertising & Claims) Regulations, 2018; Food Safety and Standards (Advertising & Claims) Amendment Regulations, 2019.

Ayurveda vs FSSAI

Ayurveda vs FSSAI Regulations

AYURVEDA	FSSAI
Ayurveda – under Ministry of AYUSH	**FSSAI – under Ministry of Health & Family Welfare**
➢ **Product Categories under AYUSH:** 1. ASU Prescription Medicines (Classical formulations) 2. Patent or Proprietary Medicines 3. Balya Poshak/Positive health promoter (Herbal supplements, Food supplements, Nutraceuticals, Dietary supplements) 4. Saundarya Prasadak (cosmetics for oral, skin, hair & body care) 5. Aushadha ghana (Medicinal Plants extracts dry/wet, aqueous or hydro-alcoholic) **ASU: Ayurveda, Siddha, Unani Traditional Medicines* **Mention "Ayurvedic Medicine" on label** **Product classification shall be made basis on the formulation, usage and its benefits*	➢ **Product Categories under FSSAI regulations:** 1. Health Supplements 2. Nutraceuticals 3. Foods for Special Dietary Use (FSDU) 4. Food for Special Medical Purpose (FSMP) 5. Foods with added Probiotics ingredients 6. Foods with added Prebiotics ingredients 7. Novel Foods 8. Specialty food containing Plant or Botanical ingredients **Product Category to be mentioned on label** **Product classification shall be made basis on the formulation and presence of ingredients available in the schedules*

References: Drugs and Cosmetics Act, 1940; Drugs and Cosmetics (6th Amendment) Rules, 2010; FSSAI Regulations, 2016.

Claims & Substantiation

AYURVEDA	FSSAI
➢ Evidence regarding efficacy can be **supported by text reference, published literature & monograph with reference of classical texts**.	➢ Claims can be made based on: **1. Nutrient or nutritional ingredients** **2. Health related benefits**
➢ **Detailed clinical research to establish new formulation**	➢ All **health claims must be validated through adequate scientific data** and on the basis of human studies.
➢ Every product needs to be called out as **"Ayurvedic Medicine"**- this is a mandatory labelling requirement	➢ **No claims to be made to treat or cure diseases**
➢ Manufacturing, process, specification and draft label – licensing approval.	➢ Label requires self compliance

**ASU: Ayurveda, Siddha, Unani Traditional Medicines*

References: Patvardhan et al, 2017; FSSAI Regulations, 2016

Focus of FSSAI for Future

"One Nation One Food Law"

FSSAI's Focus – 3 Way Partnership:

- **Robust Regulatory Framework** – to have globally benchmarked food standards & practices, expansion of Food Laboratories Network capacities
- **Self-Regulation -** responsible food business operators to ensure compliance to regulations
- **Increasing Awareness -** the last mile connectivity through consumer awareness & education, National food campaign #EatRightIndia; Public Private Partnerships (PPPs), etc.


THANK YOU
for listening!

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

GMO Labeling in Korea

2019. 9. 27

DAESANG CORP.

Agenda

1. Opinions on GMO Labeling
2. International GMO Labeling Status
3. GMO Labeling in Korea
4. Conclusion /Suggestions

GMO Labeling …

○ **Proponents:**

- Provide the Rights to choose because GM Foods are different from regular foods and there are no hard evidence or information to approve of its safety.

○ **Opponents:**

- Science and related industries report that GM foods are safe and not different from regular foods, and the implementation of the labeling system is costly, while the effects are minimal.

Various GM labeling standards among countries depending on their opinions.

International GMO Labeling Status

[GM Labeling Standards by Different Countries]

Types	Country	Items	Unintentional Contamination Allowance Rate (%)
'Not Concerning' Residual GM DNA * Raw-material based	EU	5 Agricultural Produce Types and Processed Goods	0.9 %
	Russia	5 Agricultural Produce Types and Processed Goods	0.9 %
	China	Specified Agricultural Produce Types and Processed Goods (Total 17)	-
	Taiwan	Specified Agricultural Produce Types and Processed Goods (Total 20)	3 %
'Concerning' Residual GM DNA	U.S	Specified Agricultural Produce Types and Processed Goods (Total 13)	5 % (various rules for exemption avail.)
	Australia/ N.Zealand	9 Agricultural Produce Types and Processed Goods	1 %
	Japan	8 Agricultural Produce Types and 33 Processed Goods	5 %
	Korea	6 Agricultural Produce Types and Processed Goods - soybean, maize, cotton, canola, potato, alfalfa, sugar beet	3 %

※ Grain Self-Sufficiency Rate: World Avg. 102.5 %, FR 193 %, US 125 %, CN 98 %, JPN 28 %, S.KOR 24% (Soybean 5.4 %, Corn 0.8%)

※**World-wide GMO Plantation Area:** Continual growth since '96

※ **Price Trends :** Non-GMO products are more expensive (Recent 5 year average: Soybeans x1.47, Corns x1.12)

GMO Labeling in Korea

❍ **Definition: Genetically Modified Foods**

FOOD SANITATION ACT

Article 12-2 (Labeling of Genetically Modified Foods, etc.)

(1) **Foods or food additives that are manufactured or processed with agricultural products, livestock products, fishery products, etc. cultivated or bred by utilizing biological engineering technologies** falling under any of the following as their raw materials (hereinafter referred to as "genetically modified foods, etc.) shall be labeled as genetically modified foods: Provided, That the foregoing shall be limited to genetically modified foods, etc. in which genetically engineered DNA (Deoxyribonucleic acid) or genetically engineered protein remains after the manufacturing or processing thereof:

① Technologies that artificially recombine genes or directly inject nucleic acids forming genes into cells or organelles within cells;

② Cell fusion technology beyond a family on the basis of taxonomy.

(2) Genetically modified foods, etc. that are required to be labeled pursuant to paragraph (1) shall not be sold, or imported, displayed, transported or used for business for sale unless they have been labeled.

(3) Matters necessary for persons that are obliged to label, objects and methods for labeling, etc. pursuant to paragraph (1) shall be determined by the Minister of Food and Drug Safety.

GMO Labeling in Korea

❍ **Implement of GMO Labeling (2001)**

「FOOD SANITATION ACT」 Article 10 (Standards for Labeling)
(Established '00.1.12, Enforced '00.7.13)

「Labeling of Genetically Modified Foods, etc.」
(Established '00.8.30, Enforced '01.7.13)

√(Labeling Target) the food or food additive to be labeled as GMOs pursuant to Article 16 of the Agricultural and Fishery Products Quality Control Act shall be used as the **main raw material (five ingredients used in large quantities) to indicate that it is a genetically modified agricultural and fisheries product, and shall be classified as the next item that contains DNA or foreign protein of the genetic material** after manufacturing and processing.

GMO Labeling Implement in Korea

❍ **Major Progress of GMO Labeling (2017)**

1. Labeling Target Range: From the 5 major raw materials to all raw materials;
2. Enlargement of labeling font size from 10 pt to 12 pt
3. 'Non-GMO', 'GMO-Free'
   - In case the GMO approved ingredients are not used (0 % unintentional contamination); first raw materials with the highest contents over 50 %

① According to Article 18 of the 「Food Sanitation Act」, genetically modified resources that are approved for food uses; and any products using those as raw materials of which a trace of protein is remaining after manufacturing processes must label GMO.

② **Exceptions:**

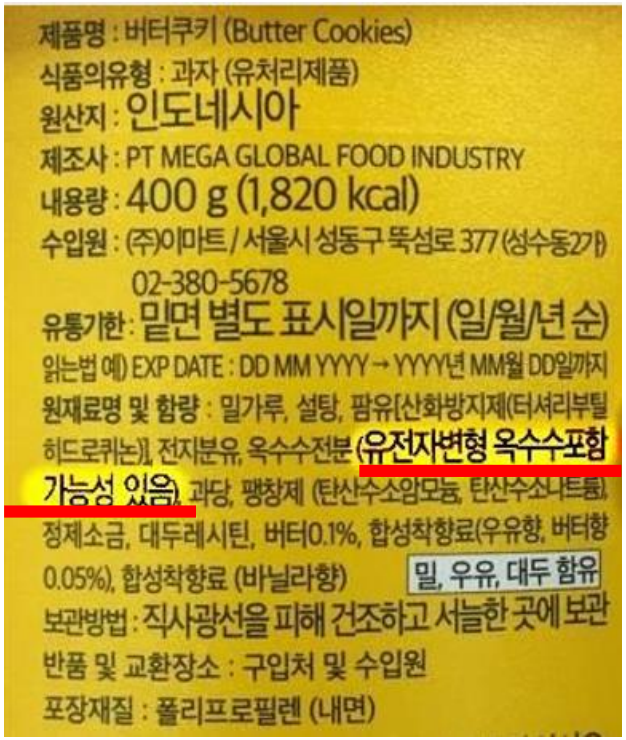
1. Agricultural products whose genetic modification is unintentionally less than 3% and foods prepared and processed using this as raw material or food additives. However, in this case, **a separate distribution certificate or a government certificate must be prepared.**
2. **certain food types (i.e. sugars, oils etc.) which are highly refined and do not contain a trace of genetically modified DNA or proteins**

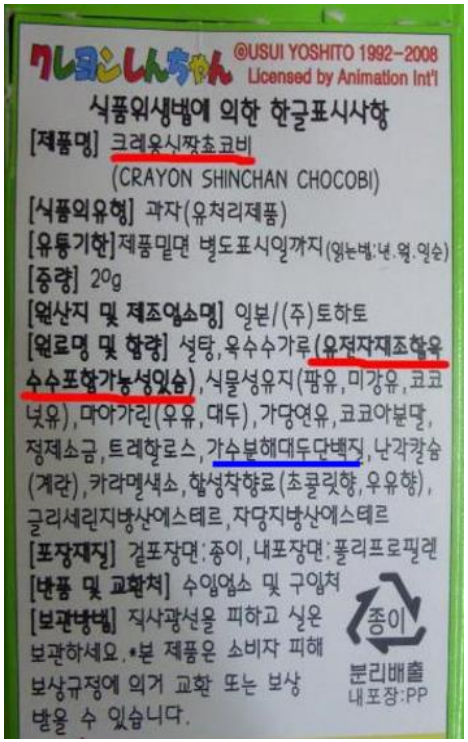
GMO Labeling Implement in Korea

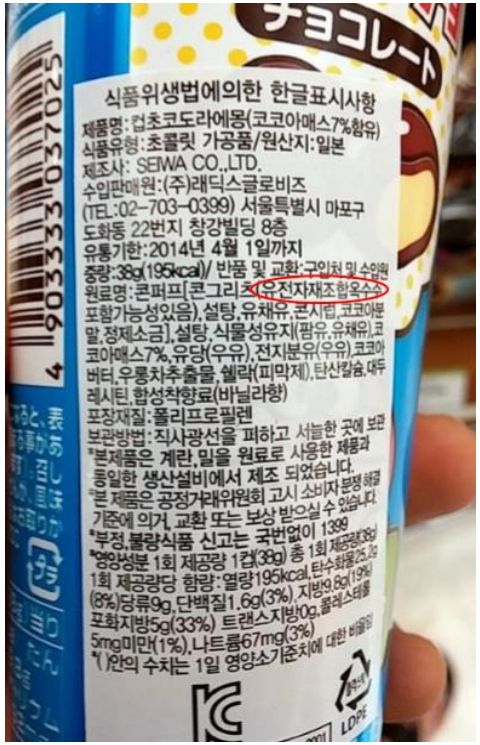
❍ **GMO Labeling Example:**

"May contain genetically modified [name of agricultural product]"

- to mention possible composition of genetically modified materials if it is difficult to identify the status



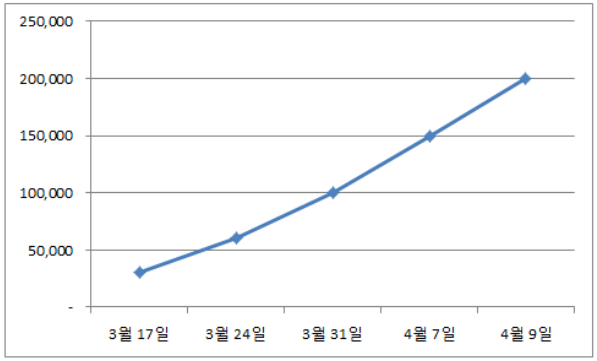




GMO Labeling Implement in Korea

❍ NGOs demands full GMO labeling based on raw material

- To indicate GMO status of soy sauce, oil, and sugar which undergo high-refining processes and do not have protein remaining



[National Petition System]

Issues on GMO

DAESANG

No Consensus on Safety

Scientifically Unmanageable to Detect

NON-GMO Labeling

Unintentional Contamination

Price Increase
(production equipment, storage, new package, testing…)

Trade Friction

……..

Conclusion / Suggestions

❍ **Need an Advancement of GMO Inspection Methods**

- A standardized method for detecting GMO in soy sauce, oil, sugar that have undergone a high-refining process.

❍ **Establishment of International Standard for GMO Labeling**

- As with the Codex and OECD Guidelines on GM Analysis, an internationally harmonized standard for GMO Labeling could be effective.

❍ **Public Educations**

- By the different age groups (i.e. children, housewives, etc.)
- The government approval processes to confirm the safety of GMO
- Risk of non-government approved GMO

Thank you

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

Updates on the Amendment of Infant Formula and FSMP Regulations in China

Yili Group

Julia Wang

11th BeSeTo Meeting, Penang, Malaysia

Updates on Amendment of Infant Formula Regulations

- Management Measures for Formulation Registration of Infant Formula Milk Powder Products (Draft for comments) (WTO Notification Aug.05th.2019)
- Working Rules for On-site Inspection Of Special Food Registration(Interim) (Draft for comments)（July.17th.2019）
- GB 10765 Infant formula,GB10766 Older Infant，GB10767 Young Children Formula (Draft for comments) (Aug.31.2018)
- Technical Guidelines for the Alteration of Formulation Registration of Infant Formula Milk Powder Products (Draft for comments) （July.24th.2018）
- GB 23790 Good Manufacturing Practice for Powdered Formula for Infants and Young Children (Draft for comments) (not public)

Management Measures for Formulation Registration of Infant Formula Milk Powder Products (Draft for comments)

Key Changes

1. The whole production process capability
2. Seven cases that registration is not granted
3. Working days of procedures are shortened
4. Clarify that for practical manufacturing reasons, the formula can be adjusted in a specific range, no need to apply for alteration registration

Technical Guidelines for the Alteration of Formulation Registration of Infant Formula Milk Powder Products (Draft for comments)

If the science and safety of the formula is not being affected

The name of the enterprise, the production address and the legal representative.

The content claims on the label and instruction allowed by the GB standard.

Registered trademarks , graphics, product standard codes, certification items on the label and instruction etc.

If the science and safety of the formula is being affected

Relocation of the manufacturer.

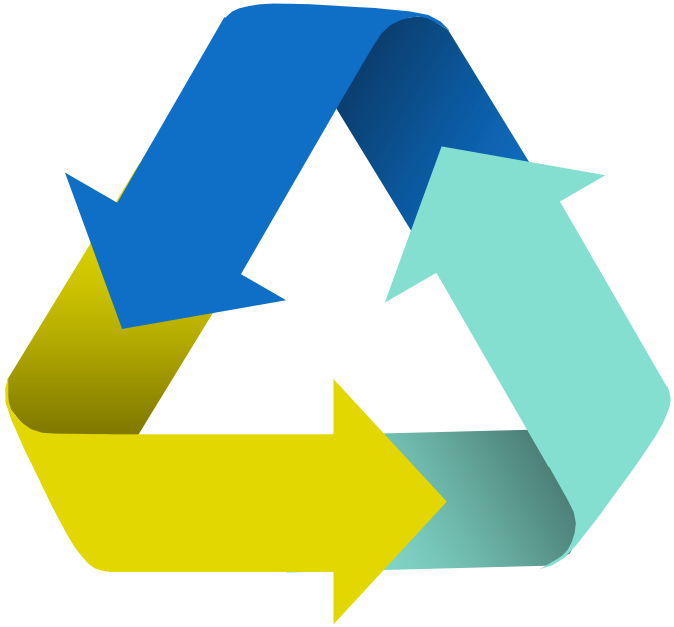
Variety, status and quality specifications of food additives and raw materials.

The amount of raw materials and food additives is altered and caused the sequence change of the ingredient list on the label etc.

Technical Guidelines for the Alteration of Formulation Registration of Infant Formula Milk Powder Products (Draft for comments)

Should re-apply for new registration

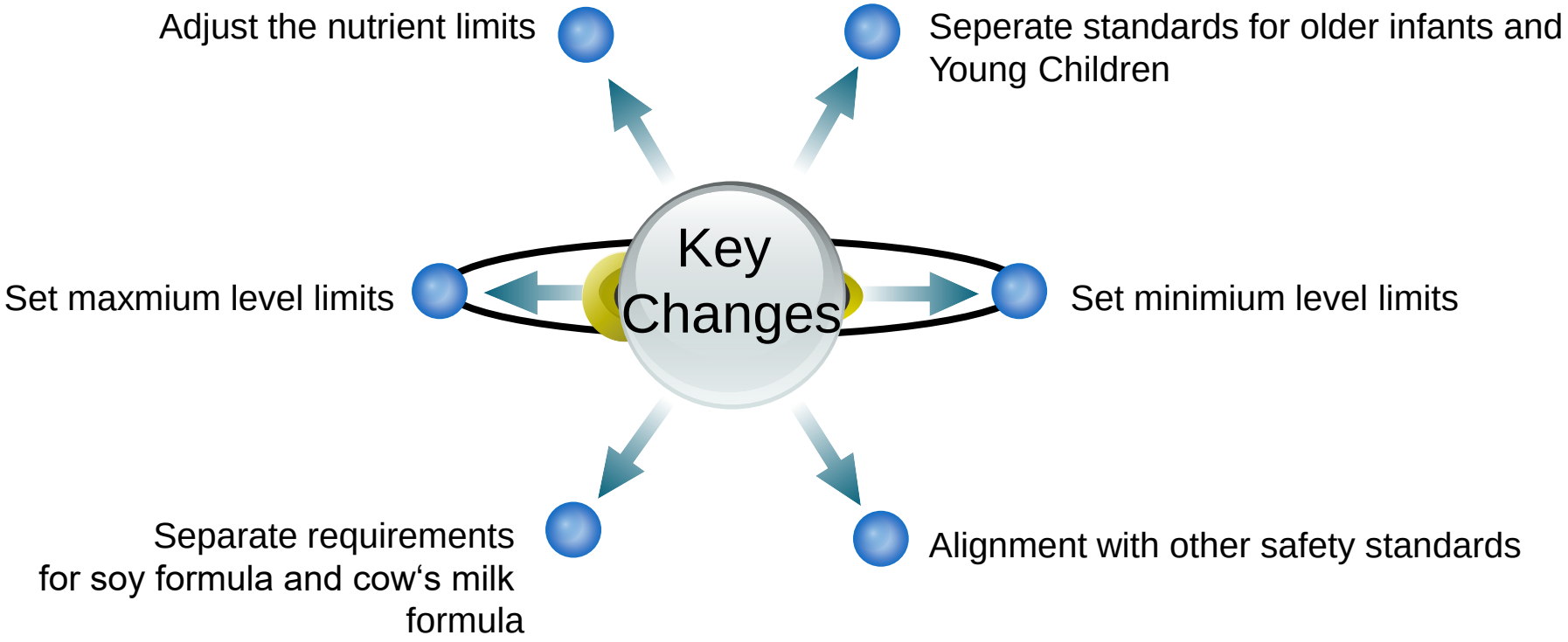
Obvious alteration of product formula;



The production process type(wet process, dry and wet process) being altered;

The nutrition composition table being altered

Key Changes on Infant Formula Standards



Key Changes on Infant Formula Standards

Nutrients	Infant GB10765		Older Infants GB10766		Young Children GB10767	
	Current	Revised	Current	Revised	Current	Revised
Se((μg/100kcal)	2.01~7.95(essential)	3.0~8.6(essential)	2.01~7.95 (optional)	2.0~8.0(essential)	2.01~7.95(optional)	2.0~8.0(optional)
Choline(mg/100kcal)	7.1~50.2(optional)	20~100(essential)	7.1~50.2(optional)	20~100(essential)	7.1~50.2(optional)	20~100(optional)
Mn(μg/100kcal)	5.0~100.4(essential)	3.0~100.0(essential)	1.05~100.4(optional)	1.0~100.0(essential)	1.05~100.4(optional)	1.0~100.0(optional)

Under discussion

Key Changes on Infant Formula Standards

Optional Nutrients	Infant GB10765		Older Infants GB10766		Young Children GB10767	
	Current	Revised	Current	Revised	Current	Revised
Taurine（mg/100kcal)	N.S.~13	3.5~16.7	N.S.~13	3.5~16.7	N.S.~13	3.5~16.7
DHA（mg/100kcal)	N.S.~0.5(%total fatty acid)	15~40	N.S.~0.5(%total fatty acid)	15~40	N.S.~0.5(%total fatty acid)	N.S.~40
AA/ARA(mg/100kcal)	N.S.~1(%total fatty acid)	N.S.~80	N.S.~1(%total fatty acid)	N.S.~80	N.S.~1(%total fatty acid)	N.S.~80

Under discussion

Working Rules for On-site Inspection Of Special Food Registration(Interim)

1.This regulation applies to infant formula, FSMP and health food on-site inspection. When necessary, it applies to the inspection of the raw materials, excipients, packaging materials and other production process.

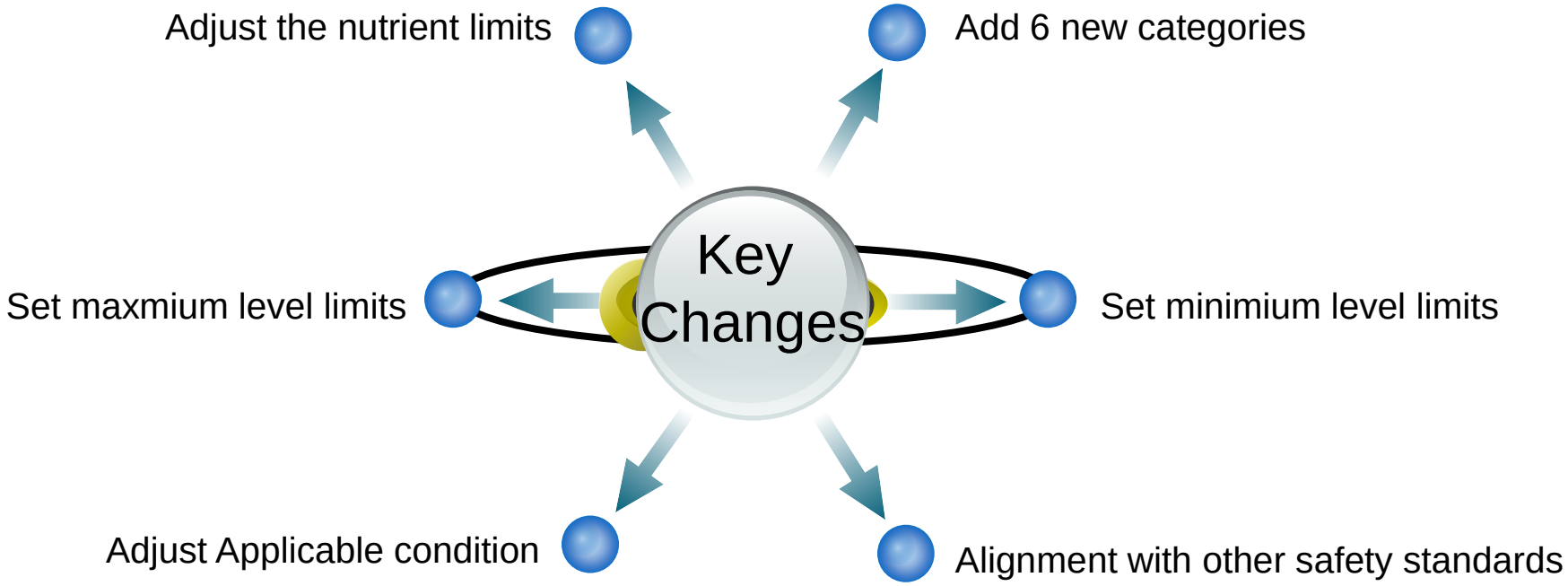
2.SAMR could authorize a qualified third-parties to conduct on-site registration inspection.

3.The applicant shall be prepared to accept the on-site inspection of registration before submitting the application for registration; the applicant shall, within 30 working days from the date of being informed, correspond and confirm.

Amendment on the Regulations of FSMP

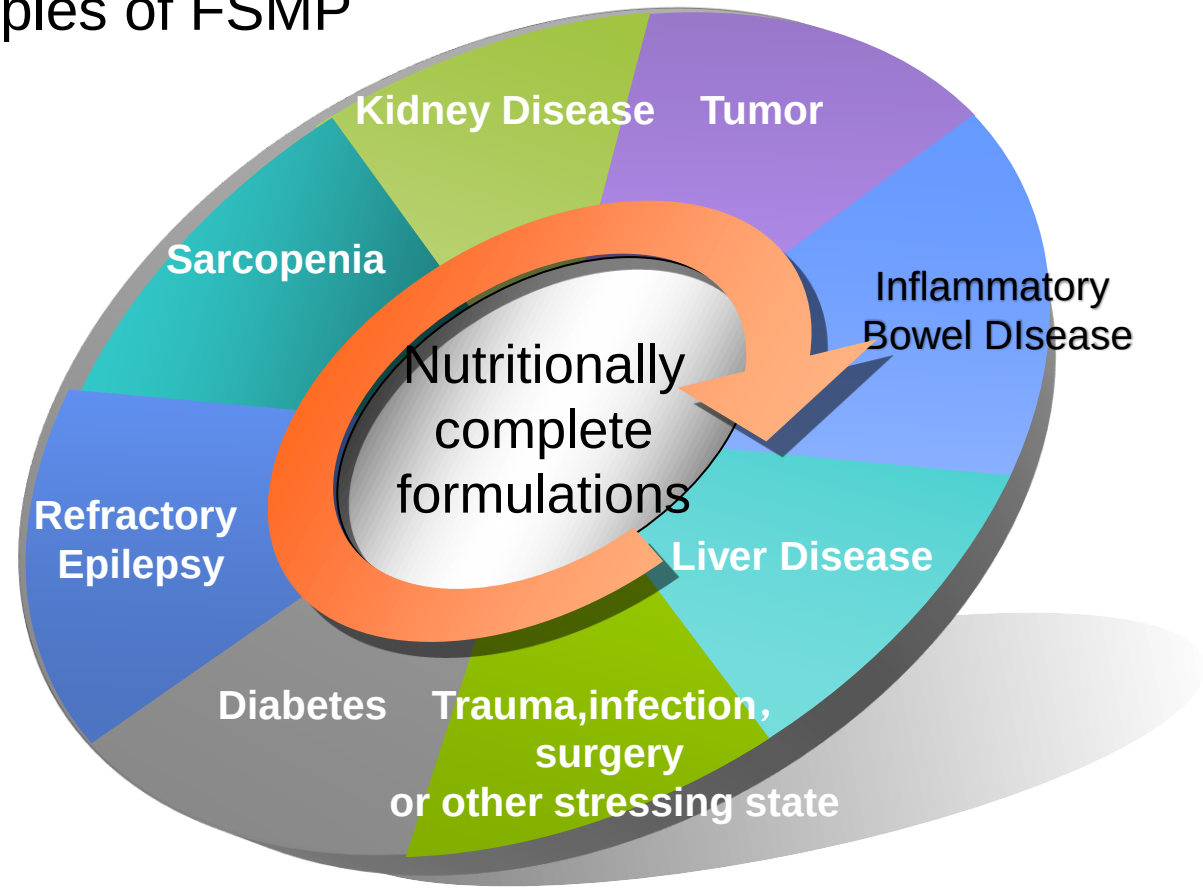
- GB 29923 GMP of FSMP(draft for comments) July.22th.2019
- Working Rules for On-site Inspection of Special Food Registration(Interim) (draft for comments) July.17th.2019.
- Administrative measures for the examination of Advertising of Drugs, Medical Devices, Health Food, FSMP (draft for comments) June.6th.2019
- Detailed rules for examination of production license of FSMP Feb.1th.2019.
- GB25596 Standard of FSMP Intended for Infants(draft for comments)（not public)
- GB29922 General Principles of FSMP,other nutritional complete formulation standards for specific diseases
- Guidelines for Clinical Trial of FSMP

Key Changes on GB25596 Standard of FSMP Intended for Infants(draft for comments)

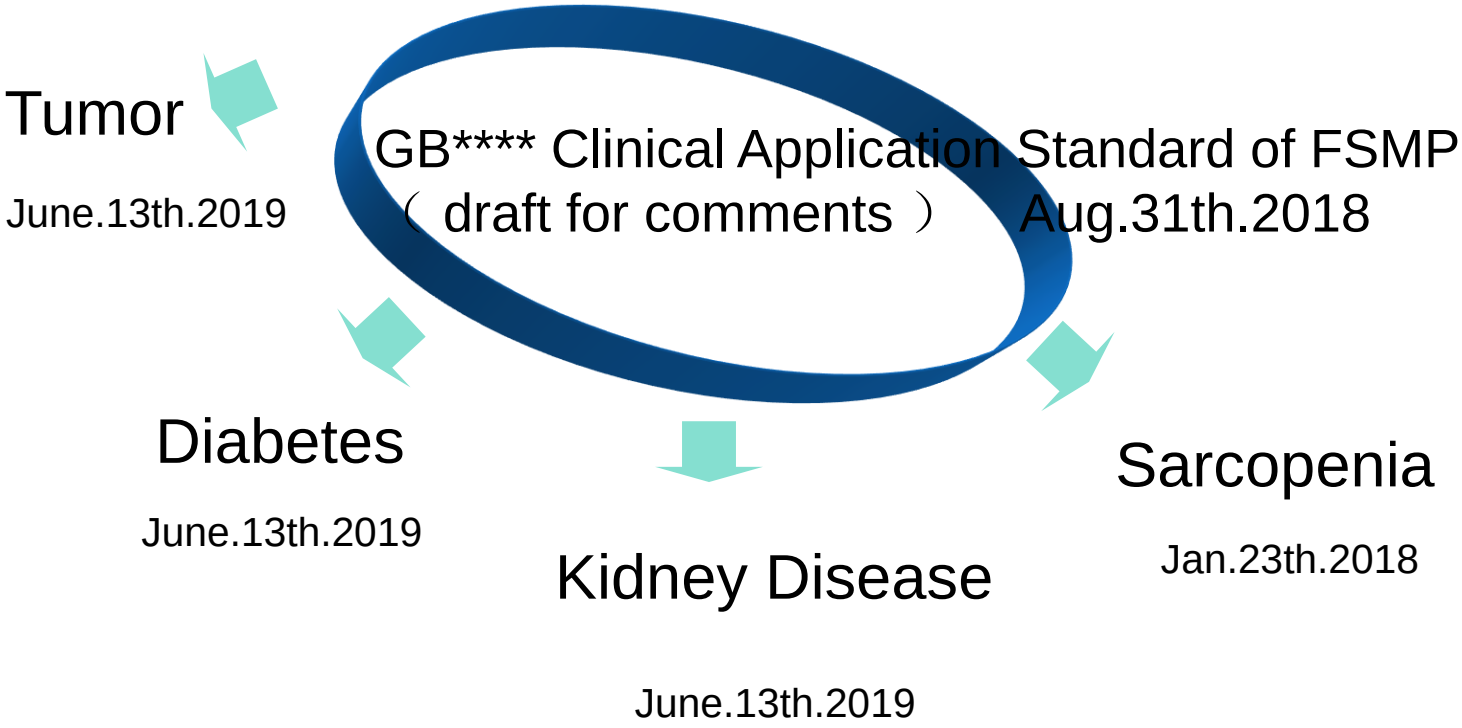


Other Standards of FSMP

GB29922
General Principles of FSMP



Guidelines for Clinical Trial of FSMP



THANK YOU

谢 谢

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

The Update of Regulations for Food Cultures and Probiotics in China

11th BeSeTo Meeting

Penang, Malaysia

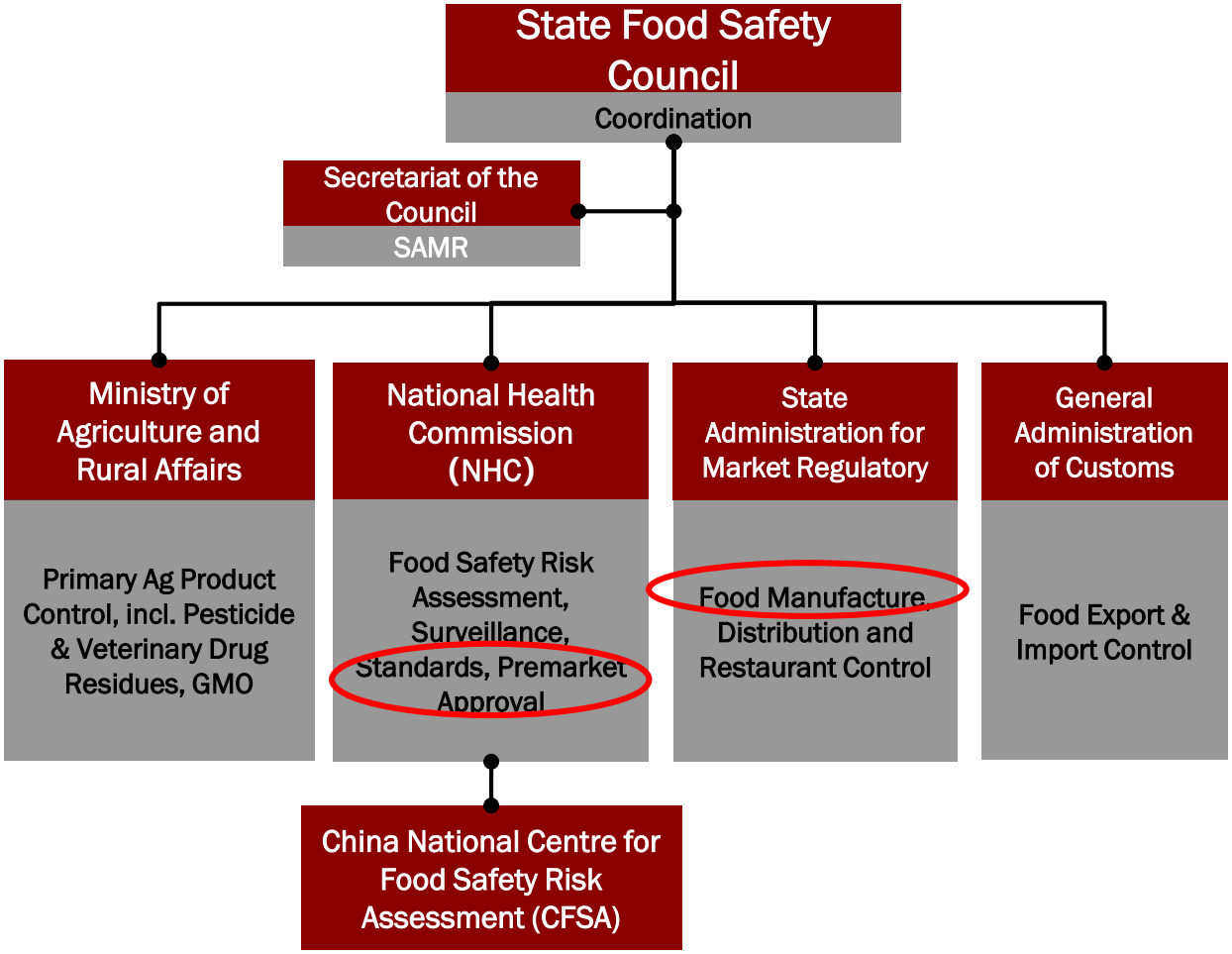
September 26-27, 2019

Yan Wen
Head of Regulatory Affairs & Product Stewardship, Greater China
DuPont Nutrition & Biosciences

Contents

- Food Safety Control Framework in China
- NHC Regulations for Food Cultures and Probiotics
- SAMR Probiotics Health Food Regulation
- Scientific Consensus on Probiotics
- Summary

Food Safety Control Framework in China



CFSA serve as secretariat for

- National Food Safety Standards Committee
- National Food Safety Risk Assessment Committee

Live Microorganisms

Distinguished by function

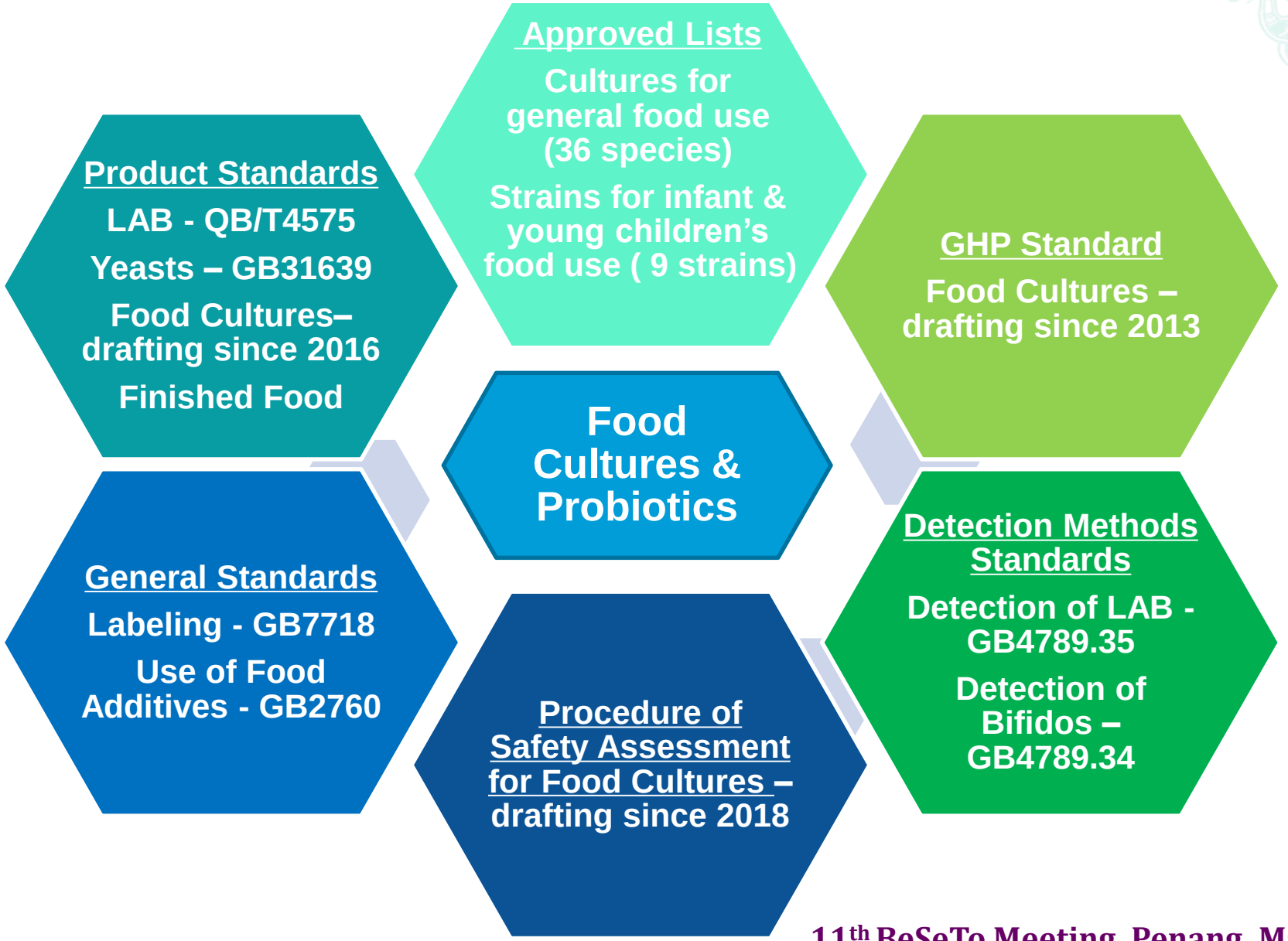
Used for food fermentations – starter culture

Substantial and characterizing component

Used as a probiotic

Beneficial physiological effect on the host

NHC Regulations for Food Cultures and Probiotics



NHC Regulations for Food Cultures and Probiotics

The list of culture species permitted for use in general food (excluding fungi)

Year of approval	Sum of species	Latin Name
<2005	10	*Bifidobacterium bifidum*
		B. adolescentis
		B. infantis
		B. longum
		B. breve
		L. acidophilus
		L. Casei subsp. Casei
		Lactobacillus. bulgaricus
		Streptococcus thermophilus
		Lactobacillus reuteri
2010	21	*Bifidobacterium animalis* (*B. lactis*)
		Lactobacillus delbrueckii subsp. Lactis
		L. fermentium
		L. gasseri
		L. helveticus
		L. johnsonii
		L. paracasei
		L. plantarum
		L. rhamnosus
		L. salivarius
		L. crispatus
2010	22	*Propionibacterium.freudenreichii ssp.shermanii*
2011	25	*Lactococcus lactis subsp.lactis*
		Lactococcus lactis subsp.cremoris
		Lactococcu lactis subsp. Diacetylactis
2012	26	*Leuconostoc.mesenteroides subsp.mesenteroides*
2014	28	*Pediococcus acidilactici*
		Pediococcus pentosaceus
		Kluyveromyces marxianus
2015	30	*Lactobacillus sakei*
		Propionibacterium acidipropionici
2016	35	*Staphylococcus vitulinus*
		Staphylococcus carnosus
		Staphylococcus xylosus
		Bacillus coagulans
2019	36	*Lactobacillus curvatus*

"List of probiotics for Health Food" -2005 CFDA

Approved Lists

Cultures for general food use (36 species)

Strains for infant & young children's food use (9 strains)

The list of strains permitted for use in infant and young children's food

Year of approval	Sum of strains	Latin Name	No. Strains
2011	6	*Bifidobacterium animalis*	Bb-12
		Lactobacillus acidophilus	NCFM
		Bifidobacterium lactis	HN019
			Bi-07
		Lactobacillus rhamnosus	HN001
			LGG
2014	7	*Lactobacillus reuteri*	DSM17938
2016	9	*Lactobacillus fermentum*	CECT5716
		Bifidobacterium breve	M-16V

NHC Regulations for Food Cultures and Probiotics

Approved Lists

Cultures for general food use (36 species)

Strains for infant & young children's food use (9 strains)

Procedure of Safety Assessment for Food Cultures – drafting since 2018

- **Traditional food cultures** not in the list – grey area (mold cheeses ban crisis)
- Follow the procedure of **Novel Food Ingredients** for adding **new** species
- **Specie** level for use in general food, **strain** level for use in Infant and young children's food
- No regulatory term for "**probiotics**" within NHC

- **Scope** may include microorganisms as food starter cultures, probiotics, strains for food enzyme productions, but GMMs are not included.
- Procedure applied to **new** microorganisms to be added in the **positive list**.
- **WGS taxonomy, virulence, AMR, pathogenicity assessment** will be required.

NHC Regulations for Food Cultures and Probiotics

Product Standards

LAB - QB/T4575, Yeasts – GB31639

Food Cultures– drafting since 2016

Finished Food

GHP Standard

Food Cultures – drafting since 2013

Food Cultures

- **Scope** (bacteria, molds and yeasts)
- **Application** (ready to eat, food processing)
- **Pathogens** (free of salmonella, listeria, etc.)
- **Viable cell count** (>=1x10^8 CFU/g(ml))
- **Labeling**

Finished Food

- **Exemption of TPC** requirement when live food cultures are added in finished foods, e.g. infant formulas, beverages, confectionary.

Plants

- **General Principles**
- **Design and Facilities**
- **Maintain and Sanitation**
- **Control of Operation**
- **Environment and Personal Hygiene**
- **Handling, Storage and Transportation**

NHC Regulations for Food Cultures and Probiotics

General Standards

Labeling - GB7718

Use of Food Additives - GB2760

Detection Methods Standards

Detection of LAB - GB4789.35

Detection of Bifidos – GB4789.34

In revision

Labeling – GB7718

- In finished food, possibility to label "**starter culture**" as a generic name, instead of every culture specie's name in the list of ingredients

Use of Food Additives – GB2760

- Cultures are food, added "**food cultures**" into the list of **food categories** in GB2760.

Detection Methods

- Plan to develop the enumeration methods for **all species** approved in the positive list, while in the current version only Bifidobacterium, Lactobacillus and Streptococcus can be detected

SAMR Probiotics Health Food Regulation

Where probiotics are used and regulated?

Application of Probiotics

- General Food (SAMR)
- **Special Food (SAMR)**
  - ***Health Food**
    - With approved Health Claims
  - Infant and young children's Formula
  - FSMP
- Pharma (NMPA)
- Cosmetic (NMPA)
- Feed (MARA)

保健食品

SAMR-State Administration for Market Regulation
NMPA-National Medical Products Administration
MARA-Ministry of Agriculture and Rural Affairs

SAMR Probiotics Health Food Regulation

Food Safety Law
Implemented on Oct 1st 2015

Regulation for Health Food

The Administrative Measure of Registration and Notification for Health Food

Implemented on July 1st 2016

Section 4: Special Food

Article 76 Health food made of raw materials not included in the catalog of raw materials for health care and imported health food shall be subject to **registration** with the food and drug administration under the State Council.

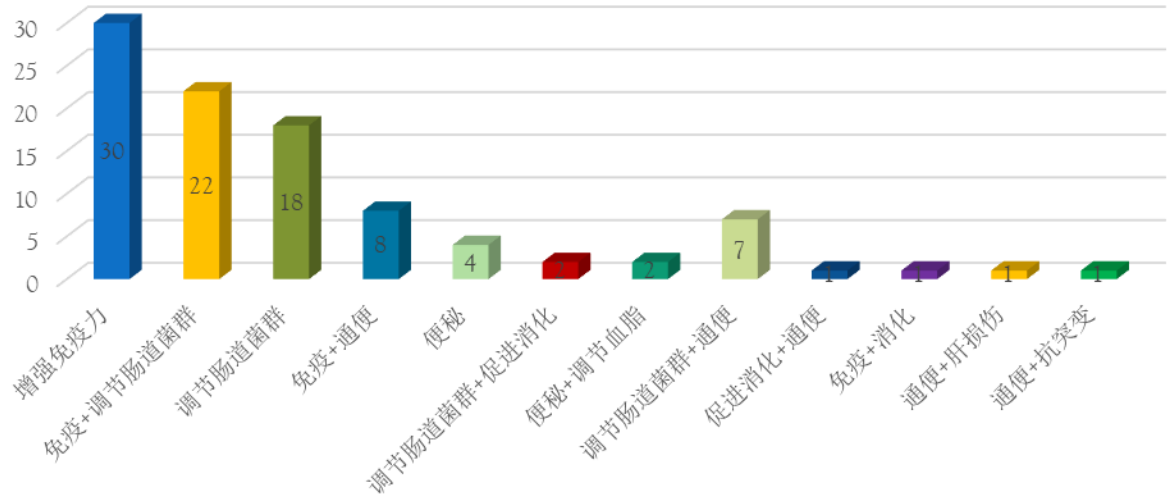
In the event that the imported health food is made of nutrient ingredients such as **supplementary vitamins and minerals**, it shall be filed with the food and drug administration under the State Council for **notification.**

Highlights:

- **Dual-track approach**
  - ✓ Registration - slow, complicate, minority
  - ✓ **Notification - fast, simple, majority**
- **Functional ingredients list for Notification**
  - ✓ Current: vitamins, minerals
  - ✓ Developing: melatonin, lutein, DHA, etc.
  - ✓ Ongoing project: **probiotics** and prebiotics, etc.

SAMR Probiotics Health Food Regulation

Approved probiotics health food before new regulation (No. 100+)



Approved Probiotics Health Claims

- **Immune**: 61
- **Balance gut flora**: 49
- **Constipation**: 22
- **Digestion**: 4

Only 2 new approvals recently after new regulation (submitted in 2013)

国食健申G20131108	海王牌益生菌粉	杭州海王生物工程有限公司
国食健申G20131136	百合牌益生菌颗粒	郑州金百合生物工程有限公司

6 years!

SAMR Probiotics Health Food Regulation

In revision

Regulation for Probiotics Health Food Registration

Circulated for public comments by SAMR

- March 21th, 2019

Summary of comments received

- July 15th, 2019 published by SAMR
- Total 101 comments received, only 4 accepted

Main Changes	2005	2019+
Scope	Live, dead, metabolisms	**Live probiotic only**
Definition	No definition for Probiotic	**Definition of Probiotic**, follow FAO/WHO
Function	Specie level.	**Strain level**
Taxonomy & Safety	Pheno, virulence	WGS, AMR, **virulence, pathogenicity evaluation**
Label	Specie or strain	**Strain designation is mandatory**
Probiotic list	10 species, NHC list acceptable.	**Refer to NHC list**
Total viable count	10^6 CFU/g	**10^7 CFU/g**

SAMR Project on Probiotics and Prebiotics Functional Ingredients for Health Food

Called for bidding on Sep 25th 2018

第一章 招标公告

根据《食品安全法》《保健食品注册与备案管理办法》等关于保健食品原料目录的有关规定，为落实原国家食品药品监督管理总局保健食品原料目录年度制修定计划，受国家中药品种保护审评委员会委托，国信招标集团股份有限公司对保健食品原料目录研究专项课题（以下简称专项）（招标编号：GXTC-18700106）进行国内公开招标，欢迎国内合格的投标人参加投标。现将有关事项公告如下：

06	1.益生菌：两岐双岐杆菌、长双岐杆菌、短双岐杆菌、青春双岐杆菌、动物双岐杆菌、嗜酸乳杆菌、植物乳杆菌、罗伊氏乳杆菌、鼠李糖乳杆菌。 2.益生元：异麦芽低聚糖（IMO）、低聚果糖（FOS）、低聚半乳糖（GOS）、低聚木糖（XOS）、低聚乳果糖（LACT）、大豆低聚糖（SOS）、菊粉（Inulin）。 3.益生菌+益生元组合。	1项	260			（1）开展原料来源研究 （2）开展原料安全性研究 （3）开展原料功能性研究 （4）开展原料质量技术要求研究 （5）开展产品质量技术要求研究 （6）开展原料目录信息列表研究

- **CFSA** won the bidding project
- **Duration**: Nov 1st 2018 - Jan 31st 2020

保健食品原料目录研究专项课题项目

中标结果公告

（采购编号：GXTC-18700106）

国信招标集团股份有限公司受国家中药品种保护审评委员会的委托对保健食品原料目录研究专项课题项目进行了公开招标，评标工作已经结束，现将中标结果公告如下：

采购人：国家中药品种保护审评委员会

地　址：北京市丰台区南四环西路 188 号 11 区 15 号楼

联系人：柳雨时、王进博

电　话：010-66230612、010-6623（0646/0776）

06 包：

中标供应商名称：国家食品安全风险评估中心、江南大学、中国食品发酵工业研究院有限公司、内蒙古农业大学、中国检验检疫科学研究院综合检测中心、中国食品科学技术学会

中标供应商地址：北京市朝阳区潘家园南里 7 号

中标金额：260 万元

合同履行日期：2018 年 11 月 1 日-2020 年 01 月 31 日共 15 个月

SAMR Project on Probiotics and Prebiotics Functional Ingredients for Health Food

No.	9 Probiotic Culture Species
1	*Bifidobacterium bifidum*
2	*Bifidobacterium longum*
3	*Bifidobacterium breve*
4	*Bifidobacterium adolescentis*
5	*Bifidobacterium Lactis* (*Bifidobacterium animalis* subsp. *Lactis*)
6	*Lactobacillus acidophilus*
7	*Lactobacillus plantarum*
8	*Lactobacillus reuteri*
9	*Lactobacillus rhamnosus*

No.	7 Prebiotics
1	Isomaltooligosacharide, IMO
2	Fructo-oligosaccharide, FOS
3	Galactooligosaccharide, GOS
4	Xylooligosaccharide, XOS
5	Lactosyl fructoside, LACT
6	Soybean oligosaccharides, SOS
7	Inulin

Expected outcome: format of functional ingredient list, with NCFM as an example

Name of ingredient	Origin	Function	Daily Dosage	Form	Target Population	Population not suitable
Lactobacillus acidophilus **NCFM**	**Human gut**	**Balance gut flora**	**≥1.0×10^{9}CFU/day**	**Powder**	**xx**	**xx**

Scientific Consensus on Probiotics

中国食品科学技术学会 Chinese Institute of Food Science and Technology **CIFST**

Probiotics Scientific Consensus (2019),
Launched on May 23th, 2019 on
"The 14th International Symposium on probiotics and health"

中国营养学会 Chinese Nutrition Society **CNS**

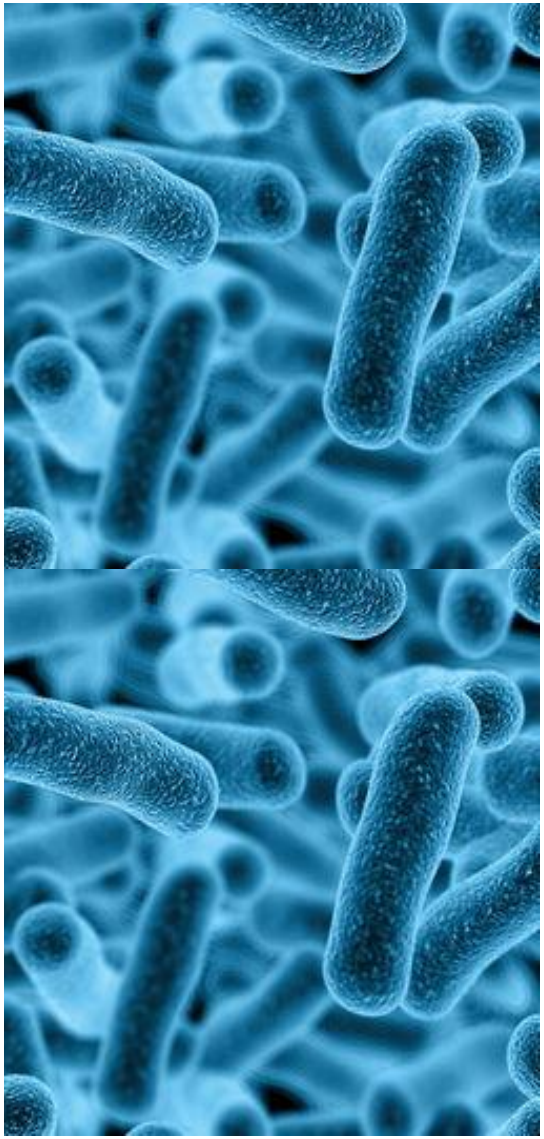
Probiotics and Health Experts Consensus,
Launched on May 29th, 2019

一、益生菌的定义与种类
二、益生菌的特性
三、益生菌安全性评价
四、益生菌的健康益处
五、益生菌消费者建议

CFIC 科信食品与营养信息交流中心 China Food Information Center

Probiotics Scientific Facts, CFIC

- Plan to launch in Nov 2019
- Collect scientific evidences on health benefits of probiotics
- Interpreter hot, rumor, misleading messages
- Strong media and consumers communication



Summary

- Food cultures and probiotics are highly regulated in China
- Many regulations are under revision or development by NHC & SAMR
- Important to have scientific voice to support regulatory changes
- Industry participation is essential
- Bright future ahead

Thanks for your attention!

Yan Wen
Head of Regulatory Affairs & Product Stewardship, Greater China
DuPont Nutrition & Biosciences
Tel: +8613901230707
Email: yan.wen@dupont.com

DUPONT

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

September 26-27, 2019, Penang, Malaysia

Allergen regulation update in Japan

11th BeSeTo Meeting 2019

ILSI JAPAN/Nagase&Co.,Ltd.

Global Regulatory&Pharmaceutical Affairs Office

Ms. Natsuki Matsuyama

Disclosure

I have no actual or potential conflict of interest in relation to this program/presentation.

Introduction

- History of labelling regulation in Japan
- Current labelling regulation
- National survey on health damage from allergic reaction 2019
- CODEX Committee starting a discussion on allergen labeling

History of labelling regulation in Japan

NAGASE

March 2002 Set the first regulation regarding the allergen labelling in the Food Sanitary Law.	Mandatory 5 ingredients (**Milk, egg, wheat, soba, peanut**) Voluntary 19 ingredients
December 2005	Added **banana** on voluntary ingredients
June 2009	**Shrimp and crab** upgraded on mandatory ingredients from voluntary ingredients.
September 2014	Added **cashew nuts and sesame** on voluntary ingredients.
April 2016 Enforcement of Food Labelling Act (with transition period)	

Current labelling regulation (1)

NAGASE

Specified Ingredients (7) Mandatory label	**Shrimp, crab, wheat, soba, egg, milk, peanut** 
Items equivalent to specified ingredients (20) Voluntary label	Abalone, squid, salmon roe, orange, cashew nuts, kiwi fruit, beef, walnuts, sesame, salmon, mackerel, soy, chicken, banana, pork, matsutake, peach, yam, apple, gelatin

NAGASE

1st option: Individual labelling (preferable)

Ingredients: Potato, Ham (contains egg and pork), Mayonnaise (contains egg and soy), Seasonings (amino acid)

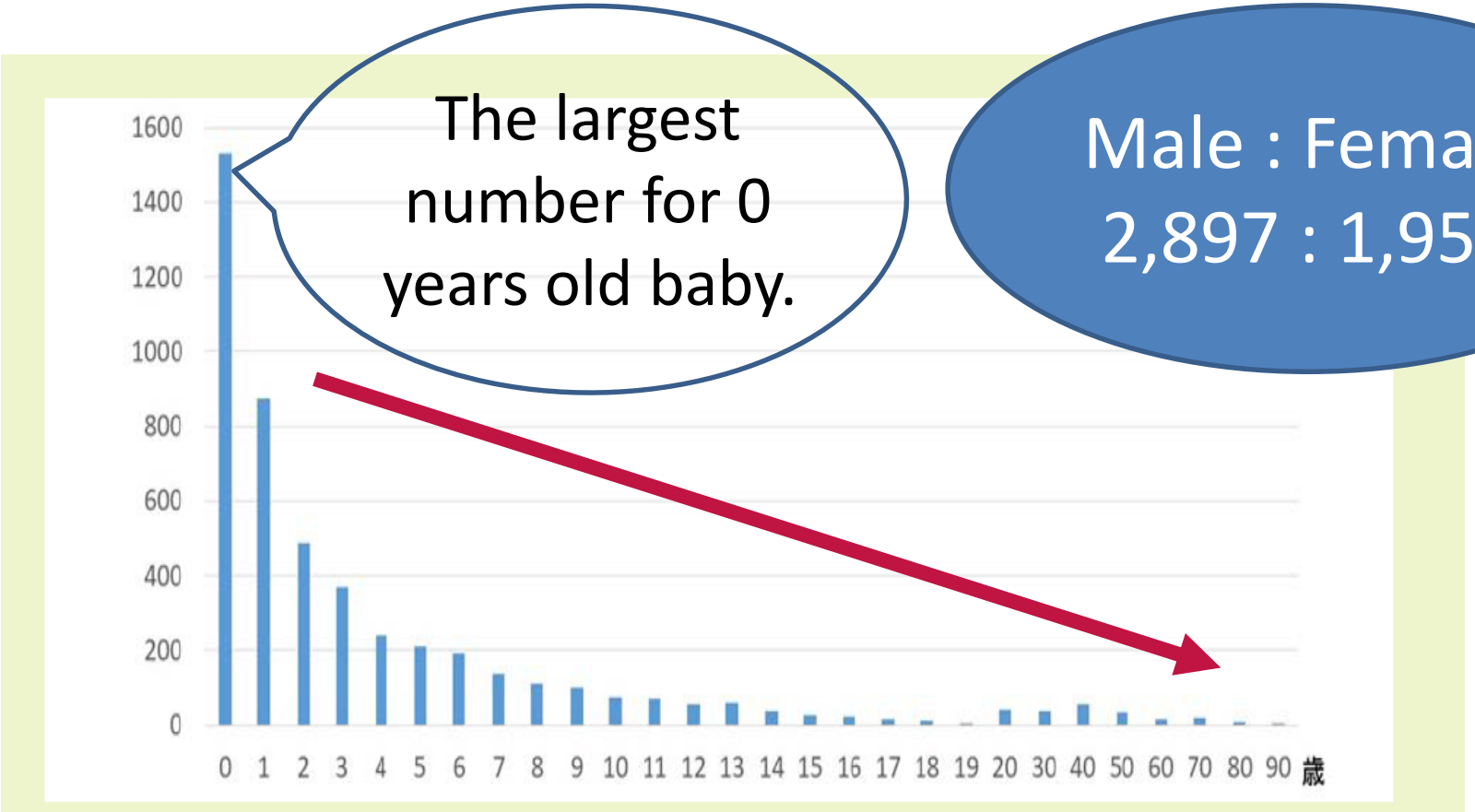
2nd option: Collective labelling

Ingredients: Potato, Ham, Mayonnaise, Seasonings (amino acid), (partly contains egg, pork, soy)

National survey on health damage from allergic reaction 2019 (1) Method and result

NAGASE

Asked the doctors (n=1,105) to report how many patients showed up for allergic symptom, every 3 month a year. In total, 4,851 cases are reported.

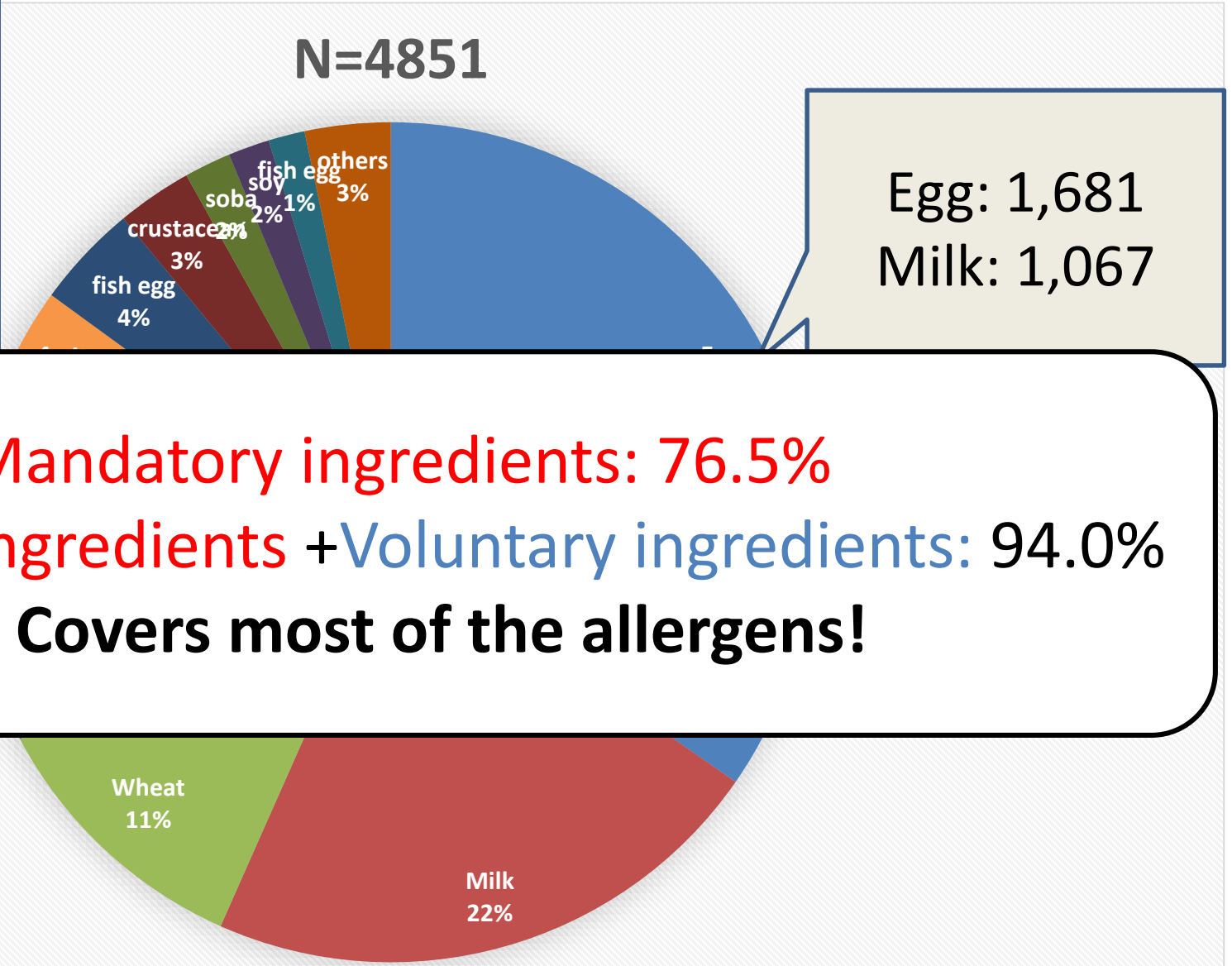


National survey on health damage from allergic reaction 2019 (2) Allergen

NAGASE

Nuts cases got dramatically increased!

Walnuts: 251



Mandatory ingredients: 76.5%

Mandatory ingredients +Voluntary ingredients: 94.0%

=> Covers most of the allergens!

NAGASE

☆UPDATE☆

September 19th, 2019

New Notification

Almond is listed in the

"items equivalent to specified ingredients"

Walnuts	Instant type	40	74	251
	Shocking symptom	4	7	42
Almond	Instant type	0	14	21
	Shocking symptom	0	4	1

Allergen discussion on CODEX Committee

CODEX Committee starts discussion on allergen labeling

NAGASE

CODEX ALIMENTARIUS COMMISSION

E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

REP19/FL

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-Second Session

Geneva, Switzerland

8 - 12 July 2019

REPORT OF THE FORTY-FIFTH SESSION OF THE

CODEX COMMITTEE ON FOOD LABELLING

Ottawa, Ontario, Canada

13 - 17 May 2019

Agenda Item 8

NAGASE

DISCUSSION PAPER ON ALLERGEN LABELLING (Agenda item 8)[11]

93. Australia introduced the item, also on behalf of the co-drafters: United Kingdom and United States of America and recalled that CCFL44 had identified allergen labelling as a subject of possible new work, and had agreed to issue a CL to collect information on the current practices, issues and any potential role for CCFL in this area. She explained that the findings demonstrated support for work on reviewing and revising the GSLPF to amongst others: clarify the listed food and ingredients known to cause hypersensitivity, and potentially to update the current list to include new foods and ingredients, possible deletions or provide exemptions; need for further information on how allergens should be presented on food labels to ensure consumer protection and to provide more technical specifications for industry. She also noted that there was an increase in the use of "precautionary labelling" or "advisory labelling" and "free from" claims. All of this has

[10] CX/FL 19/45/7; CRD07 (Dominican Republic, European Union, El Salvador, Thailand, FoodDrinkEurope); CRD14 (Indonesia); CRD15 (Kenya); CRD 17 (South Africa)

[11] CX/FL 19/45/8; CRD8 (comments of Argentina, Dominican Republic, El Salvador, European Union, Malaysia, Nicaragua, Panama, Republic of Korea, Thailand, FoodDRinkEurope, FIVS, and OIV); CRD14 (Indonesia); CRD15 (Kenya) and CRD17 (South Africa).

led to allergen labelling that is not always clear or understood by consumers. In view of the current work in CCFH on the Code of practice on food allergen management and their proposal to FAO/WHO to provide scientific advice regarding threshold levels, it was timely for CCFL to also consider guidance for precautionary allergen or advisory labelling.

94. In view of the findings, she recommended that the Committee consider initiating new work as described in the project document; and to request scientific advice from FAO/WHO relating to the list of foods and ingredients in section 4.2.1.4 of GSLPF.

Discussion

95. There was general support to start new work and to request scientific advice from FAO/WHO.

96. Delegations also pointed out:

- The need to consider advice from social science experts on how consumers understand allergen labelling and advisory statements.
- The need to ensure that the work on precautionary allergen labelling is consistent with the ongoing work of CCFH on the Code of practice on food allergen management for food business operators.
- That any change to the list of 4.2.1.4 of GSLPF should be based on the scientific advice from FAO/WHO.

97. An observer referring to their comments in CRD8, drew the attention of the Committee to its allergen management guidance for food business operators (2013) and its non-paper on precautionary allergen labelling which could be useful for the new work.

Conclusion

98. The Committee agreed to:

a. Start new work to review and clarify the provisions relevant to allergen labelling in the GSLPF and develop guidance on precautionary allergen or advisory labelling, and to submit the project document (Appendix IV) for approval by CAC42.

b. Establish an EWG chaired by Australia, and co-chaired by the United Kingdom and the United States of America, working in English to:

- Prepare proposed draft revisions and guidelines for circulation for comments at Step 3 and consideration by CCFL46; and
- Take into account the scientific advice from FAO/WHO and evidence based consumer understanding of allergen labelling and advisory statements.

c. Request scientific advice relating to the list of foods and ingredients in section 4.2.1.4 from FAO/WHO on:

i. Whether the published criteria[12] for assessing additions and exclusions to the list is still current and appropriate.

ii. Subject to the advice on the criteria above:

- whether there are foods and ingredients that should be added to or deleted from the list.
- clarification of the groupings of foods and ingredients in the list.
- whether certain foods and ingredients, such as highly refined foods and ingredients, that are derived from the list of foods known to cause hypersensitivity can be exempted from mandatory declaration.

99. The EWG report shall be made available to the Codex Secretariat at least three months in advance of CCFL46.

For details with more clear sight,

click here!

↓

http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-45%252FFinal%252520Report%252FREP19_FLe.pdf

Thank you for your attention!

Organizer

ILSI Southeast Asia Region

In Collaboration With

ILSI Focal Point in China, ILSI Japan, ILSI Korea and ILSI Taiwan

11th BeSeTo Meeting

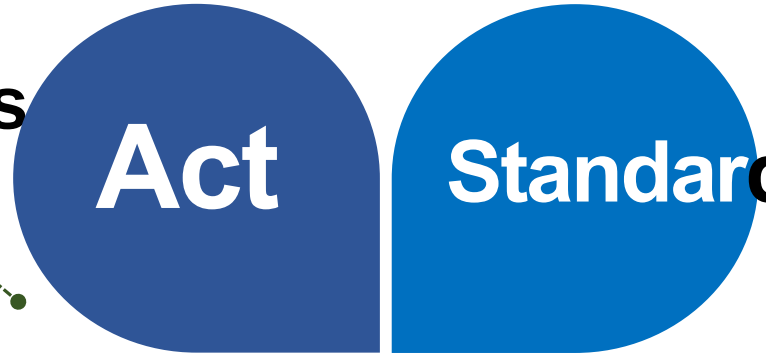
September 26-27, 2019, Penang, Malaysia

Update for New Food Labeling and Advertisement Act in Korea

Ji Yeon Kim, Seoul National University of Science and Technology

Why new food labeling act?

3 Acts and 8 standards



1) Food Sanitary Act
2) Livestock Products Sanitary Control Act
3) Health Functional Food Act

Comprehensive mandate in Notifications (not Law)
*Cosmetics Act
*Labeling Act of Origin for Agriculture and Marine Product

- Food Labeling Standards
- Livestock Product Labeling Standards
- Health Functional Food Labeling Standards
- Regulation for comparative labeling standard and method of sodium content
- Genetically Modified Foods Labeling Standard
- Labeling and Advertisement of Health Functional Food Review Standard
- Labeling and Advertisement of Food for Special Dietary Use Review Standard
- Regulation for Approving Reliability of Certification or Assurance Agency for Labels, Advertisement of Foods and Livestock Products

Because of too complex regulations

Consumer

- Need to protect from false or exaggerated labeling and advertisement

- **Administrative punishment for labeling: 552(2015) → 540(2016) → 341(2017)**
- **Quick shutdown in on-line labeling and advertisement:**
  18,431(2015) → 20,627(2016) → 41,435(2017)

Food Industry

- Too many regulations that are required by law (act)

  → Confusions in frequent revision of regulations

- Inconvenience for management by items

  (food/Livestock product/Health functional foods)

Purpose

Consumer

Consumer protection and health promotion

- Substantiation for labeling and advertisement
- Suspension order for false and exaggerated labeling

Industry

Consistent management

· Reduce cost and resources

Others

Consistency in food labeling regulation
Prevent for waste of administrative energy

2018.3.13 Enactment
2019.3.14 Enforcement

Article 1	Purpose	Article 12	Advice for regulation and management
Article 2	Definition	Article 13	Public relations and consumer education
Article 3	Relation to other acts	Article 14, 15	Correction order, Recall etc.
Article 4	Labeling standard	Article 16	Suspension of business
Article 5	Nutrition labeling	Article 17~19	Imposition of surcharge etc.
Article 6	Comparative labeling for sodium contents	Article 21	Official announcement for violation
Article 7	Advertisement standard	Article 22~24	Support of national treasury etc.
Article 8	Prohibition of unfair labeling and advertisement	Article 25	Legal fiction as public official (penalty)
Article 9	Substantiation of labeling and advertisement **Health Claims**	Article 26~29	Penalty
Article 10	Voluntary review for labeling and advertisement	Article 30	Joint penal provisions
Article 11	Establishment and operation of review board	Article 31	Fine

Article 8(Prohibition of unfair labeling and advertisement)

→ **Consumer protection from misunderstanding(Enforcement rule → Act)**

- ✓ Prevention or treatment of disease
- ✓ May cause the recognition of food as medicine
- ✓ May cause the recognition of food as health functional food
- ✓ False and exaggerated labeling and advertisement
- ✓ Labeling or advertisement for consumer deception
- ✓ Labeling or advertisement denouncing another company's product
- ✓ Labeling or advertisement that unfairly compared with that of another company's product without any substantiation
- ✓ Labeling or advertisement that significantly violates public morals or social ethics
- ✓ Labeling or advertisement not following the results of the review

Before New Act

Conventional Foods

Health Functional Foods

「**Food Sanitary Act**」

General improvement of body structure and function, authorized expressions related to health

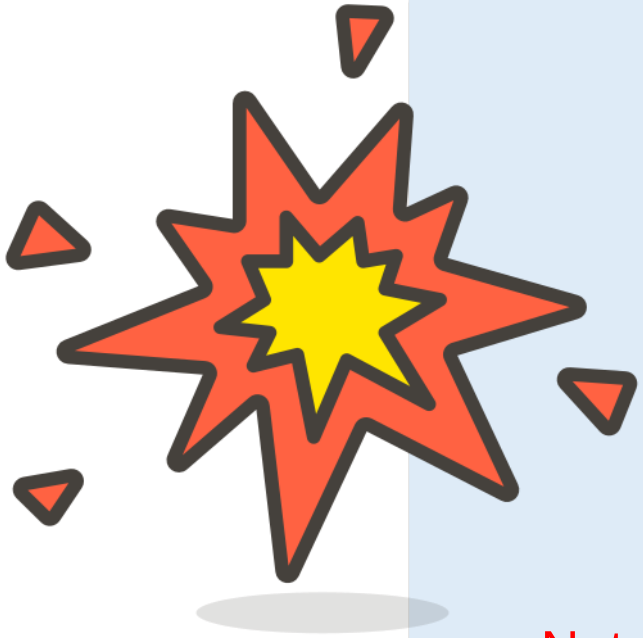
「**Health Functional Food Act**」

Foods manufactured (including processing; hereinafter the same shall apply) with **functional ingredients** beneficial for human body

So called 有用性

(general improvement of body structure and function, authorized expressions related to health**)**

→ **Similar to Health Claims**



Health Functional Food Act

Foods manufactured (including processing; hereinafter the same shall apply) with **functional ingredients** beneficial for human body

beneficial effects to health, such as physiological effects

Nutrient function/Physiological function/Reduction of disease risk

“Chance to be harmonized”

Efforts – Long Discussion

1. [Workshop by ILSI Korea: Health Claims for Conventional Food_2018. 7. 12]

Necessity

A comprehensive review of the direction of change in the ‘health claims on conventional foods’ according to the 'Act on Food Labeling and Advertisement’

Contents

1. **Held a shared seminar for various stakeholders, including examples of health claims for conventional food in excluded countries**
2. **Expert discussion on the introduction of health claims, including the current food hygiene law, and the impact of the (health claims) food industry, etc.**

- Identifying the health claim regulatory paradigm
- Share various cases, including current system and approval process and market trends in EU, Japan and the Unite

2. [Research Project supported by Ministry of Agriculture, Food and Rural Affairs 2018.6-2018.12]

발 간 등 록 번 호
11-1543000-002511-01

식품의 기능성 신고·표시제 도입·운영방안 연구

2018. 12

서울과학기술대학교 산학협력단

제 출 문

농림축산식품부 장관 귀하

본 보고서를 「식품의 기능성 신고·표시제 도입·운영방안 연구」의 최종보고서로 제출합니다.

2018년 12월

연 구 기 관 명 : 서울과학기술대학교 산학협력단
연 구 책 임 자 : 김 지 연 (서울과학기술대학교)
연 구 원 : 정 세 원 ((주)바이오푸드 CRO)
김 주 희 ((주)바이오푸드 CRO)
박 수 영 (전북대학교 법학전문대학원)
김 은 주 ((사)한국국제생명과학회)
고 명 규 (전 북 대 학 교)
연 구 보 조 원 : 김 윤 영 ((사)한국국제생명과학회)
이 하 림 ((사)한국국제생명과학회)
김 민 서 (서울과학기술대학교)
한 솔 (서울과학기술대학교)

[붙임1]

기능성식품 신고 등에 관한 가이드라인(안)

3. [Forum held by Ministry of Economy and Finance 2018.12]

홈 > 경제 > 경제일반

정부, '기능성식품 표시' 문턱 낮춘다...신고제 도입 검토

혁신성장 토론회서 규제완화 논의
일반식품에도 '기능성 표시' 허용 검토

기사입력 : 2018년12월07일 10:54 최종수정 : 2018년12월07일 10:54

가 + 가 -

일반식품 기능성 표시제 하세월인가

강민 기자 | 승인 2018.12.07 13:51 | 댓글 0

식약처, 내년 시행 '식품 등의 표시·광고 법률' 체계에 포함 불가 밝혀
기재부 주최 혁신성장 토론회

△'식품의 기능성 표시제도'에 대한 혁신성장 관련 분야별 토론회에서 업계는 내년 식품 등 표시·광고에 관한 법률 시행에 맞춰 가공식품의 기능성 표시 사전 신고제를 도입해야 한다고 주장했다.

기획재정부 **보도자료** 혁신성장 오늘을 바꾸고 내일을 만든다

보도일시	12. 7.(금) 09:00	배포일시	2018. 12. 7.(금) 10:00
담당과장	기획재정부 산업경제과 이상윤 (044-215-4530) 농림축산식품부 식품산업진흥과 이용직 (044-201-2131) 식품의약품안전처 건강기능식품정책과 강대진 (043-719-2451)	담당자	김선아 사무관 (044-215-4534) seonahkim@korea.kr 김성만 사무관 (044-201-2132) bomipapa@korea.kr 신승철 사무관(043-719-2452) scshin1210@korea.kr

혁신성장 관련 분야별 토론회 (식품의 기능성 표시제도) 개최

□ 기획재정부는 '18. 11. 28일(수)부터 약 3주간 **새로운 산업과 서비스 창출**을 위하여 **관련 업계**와 **민간 전문가, 정부 담당자**가 함께하는 **'혁신성장 분야별 토론회'***를 개최

* ①공유경제(11.28.), ②핀테크(11.28.), ③규제샌드박스법(12.5.) ④**식품의 기능성 표시제도 (12.6.)**, ⑤화학물질 규제합리화(12.7.), ⑥혁신성장 향후추진방향(Wrap-up 세션, 12.12.)

○ **네 번째 세션**으로 **식품의 기능성 표시제도 개선방안**에 대해 논의

< 혁신성장 분야별 토론회(식품의 기능성 표시제도) 개요 >

○ **일시·장소**: 12.6(목) 14:30~16:30, 서울 코엑스

○ **참석자**

- **(정부)** 기재부 산업경제과장, 농식품부 식품산업진흥과장, 식약처 건강기능식품정책과장, 식품안전표시인증과 연구관
- **(기업)** 롯데, 풀무원, 매일, 식품협회, 건강기능식품협회, 소비자연맹 등 6인
- **(전문가)** 남부대 황권택 교수(발제), ILSI 김은주 사무총장 등 전문가 4인

4.

[4th Industrial Revolutionary Committee Hackathon discussion 2019.3]

Activation of food industry by improving functional labeling system of food

Debaters draw two issues with regard to innovation in regulation of the marking of functionality of food

-Legislation to health claims on conventional foods

-Promote health & enhance the consumer choice by providing them right information.

-Recognizing the effective implementation measures to bring new vitality to the food industry

Agreement:

Clarify content in sub-regulations in accordance with Codex Guidelines

- The consensus means “health effect” that can help to improve body tissues and its functions

“Chance to be harmonized”

[Enforcement Decree of the Labeling and Advertising of Foods, etc]

Article 3 (Content of Unfair Labeling or Advertising)

1. The details of unfair labeling or advertising under Article 8 (1) of the act shall be as shown in appendix 1.
2. In addition to the matters stipulated in paragraph 1, the details of unfair labeling or advertising shall be determined and notified by the Director of the Ministry of Food and Drug Safety (MFDS).

[Appendix 1] **Contents of unfair labeling or advertising** (Article 3, Clause 1)

3. Labels or advertisements that may be recognized as health functional foods that are not health functional foods : labels that expressed as having functionality under article 3, paragraph 2 of the Act on health functional foods. However, display advertisements falling under any of the following items will be excluded

- Label or advertisement indicating the function and content of nutrients as defined in the standards and specifications of health functional foods pursuant to Article 14 of the Health Function Food Act

- The Director of the Ministry of Food and Drug Safety specifies and discloses the health claims that can be permitted in conventional foods

Public-private joint task force 2019.4

Public-Private Joint Task Force

◈ Generals

· Permitted health claims

· Not permitted foods bearing health claims

· Balance to health functional foods

· Nutrient profiling

◈ Meetings

• 6 times meetings (April ~)

• Governments, Industry, Academia, Consumers Union

THANK YOU

jiyeonk@seoultech.ac.kr, http://www.mfds.go.kr