



Health Functional Foods and Evaluation System in Korea

2017. 5. 16.

식품의약품안전처

Ministry of Food and Drug Safety
Food Standard Division

Hae Jung Yoon, Director



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Ministry of Food and Drug Safety

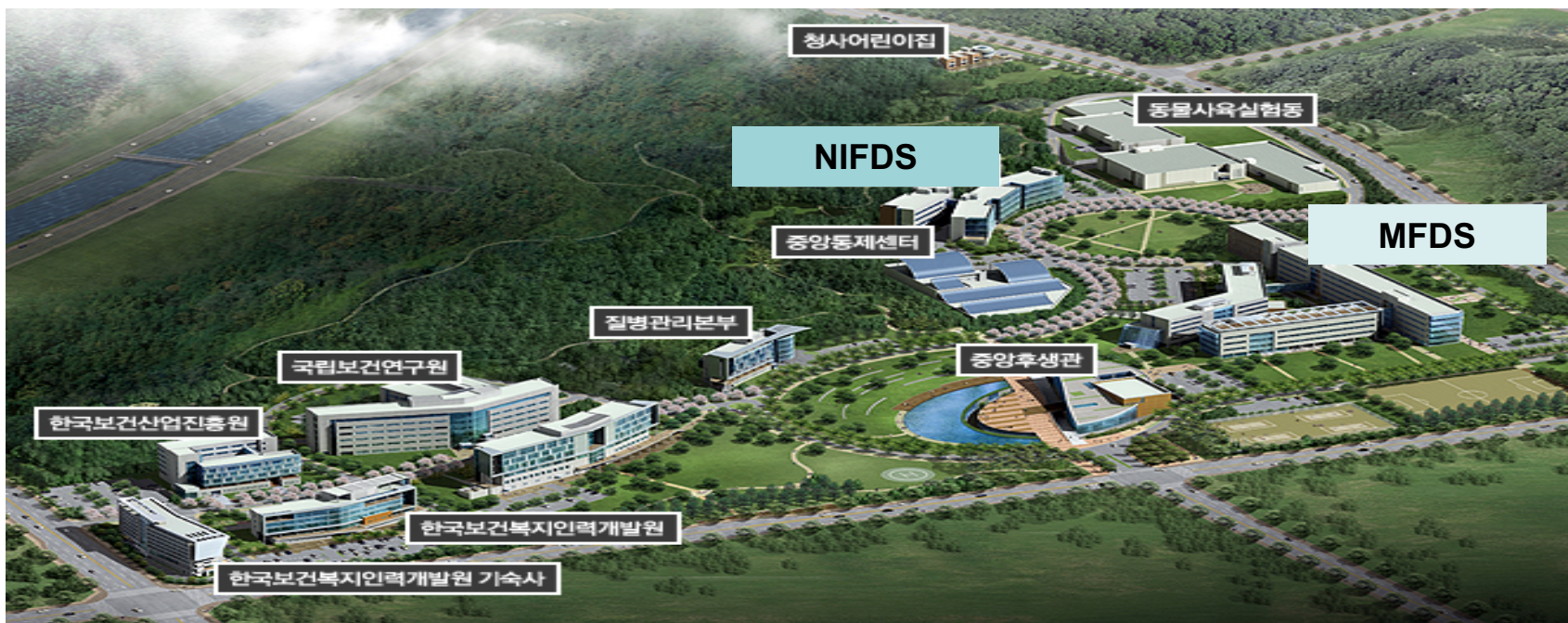




Ministry of Food and Drug Safety (MFDS)

Control Tower for Food Safety in Korea

- Headquarter
- National Institute of Food and Drug Safety Evaluation



Ministry of Food and
Drug Safety

✓ MFDS Offices and Inspection Centers



● 6 Regional Food and Drug Administration Offices

● 18 Imported Food Inspection Center

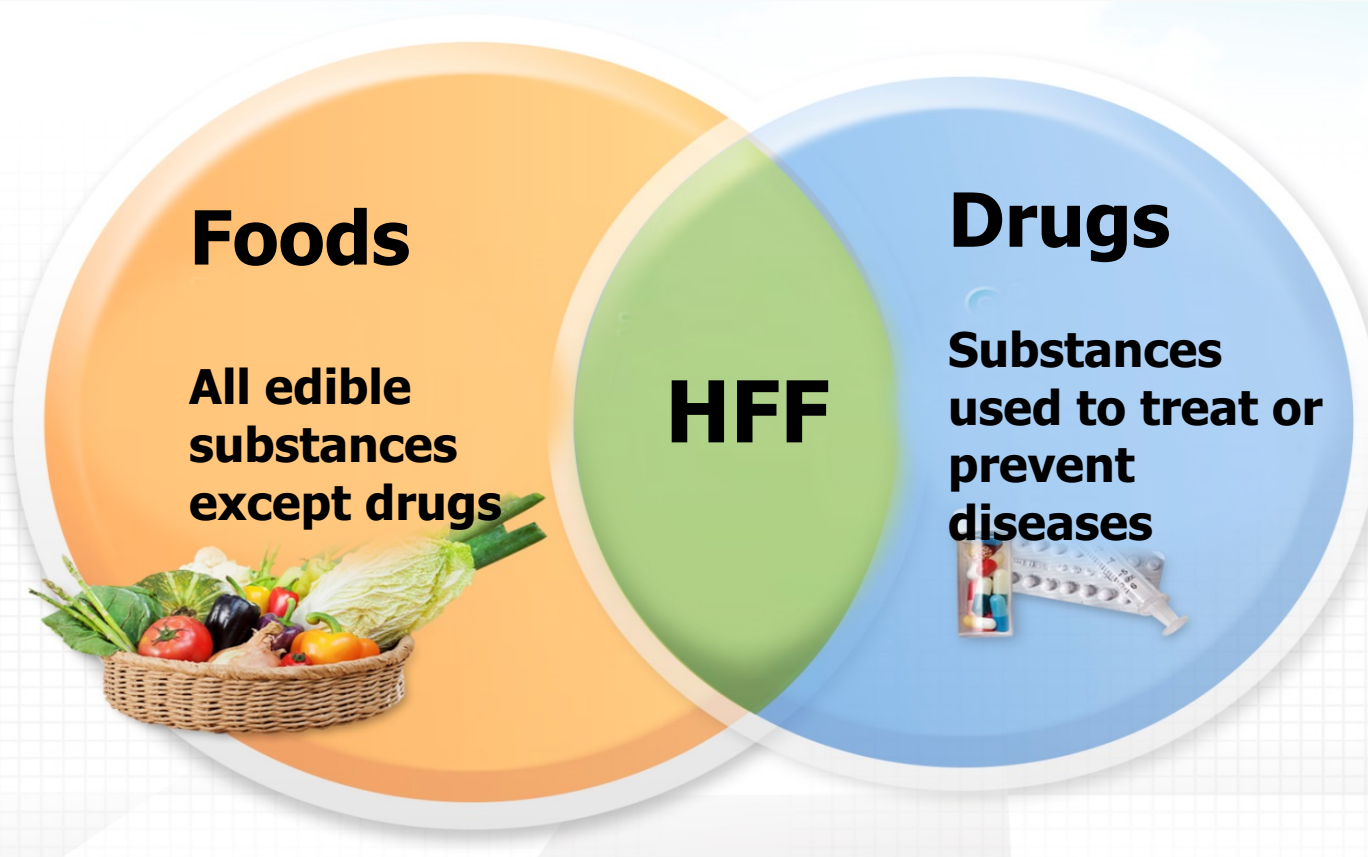
Total workforce : 1,759 persons



Health Functional Foods System and Status

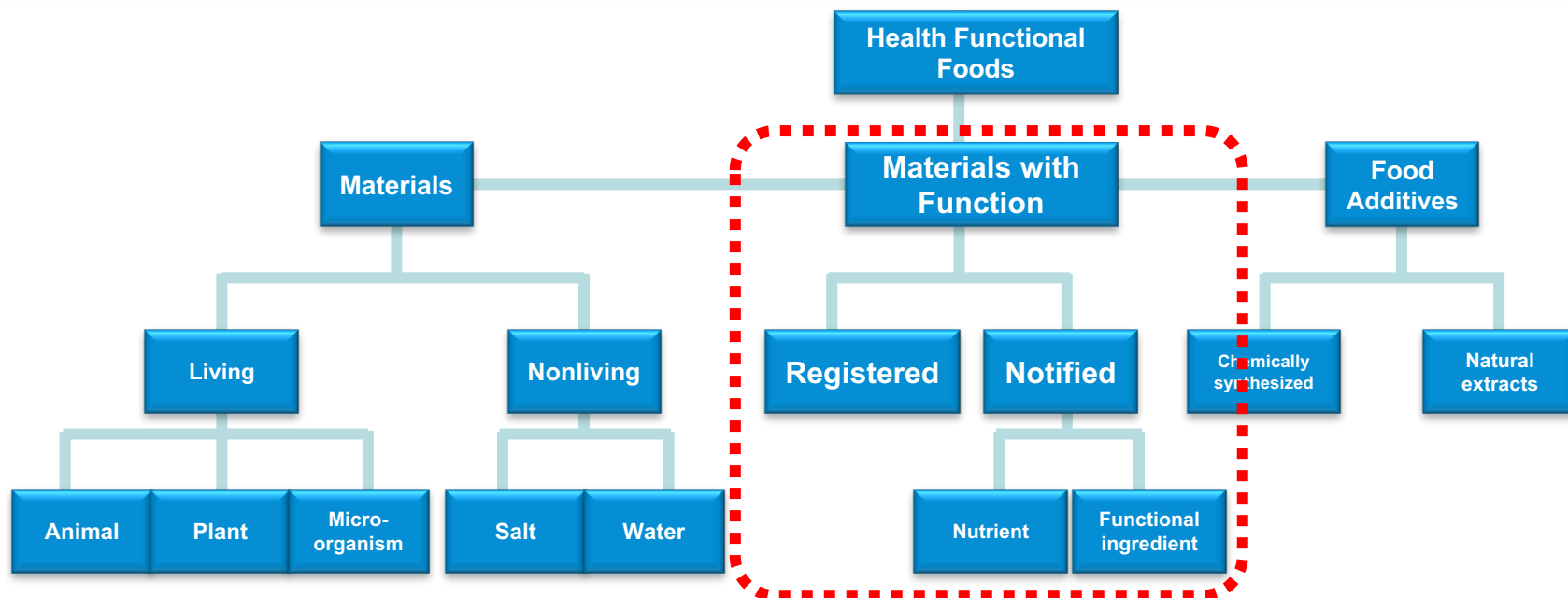


✓ Distinctions among Foods, HFF and Drugs



HFF : Foods manufactured using functional ingredients or components that are beneficial to human body to gain effects of preventing or treating diseases

✓ Ingredients for Health Functional Foods



Any HFF manufacturing business can use notified ingredients complying to the established specifications

Relevant Divisions

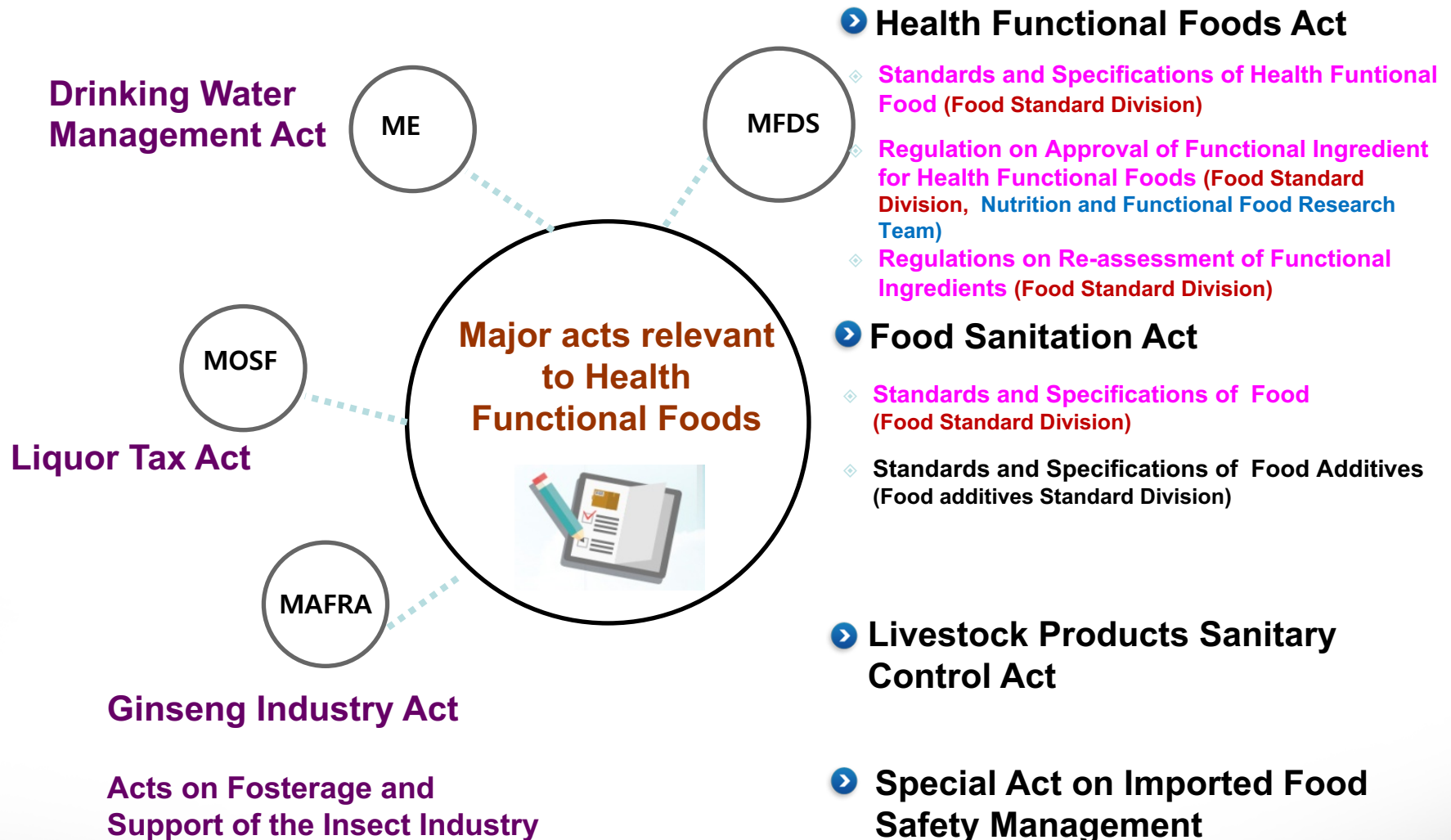
- **Food Standard Division** : Establish and amend standards & specifications and test methods of health functional foods, Reassess health functional foods and functional materials/ingredients
- **Health Functional Food Policy Division** : Develop policies and reform system of health function foods, amend and operate the relevant acts
- **Nutrition and Functional Food Research Team**: Review and evaluate documents and data for the approval of functional materials/ingredients

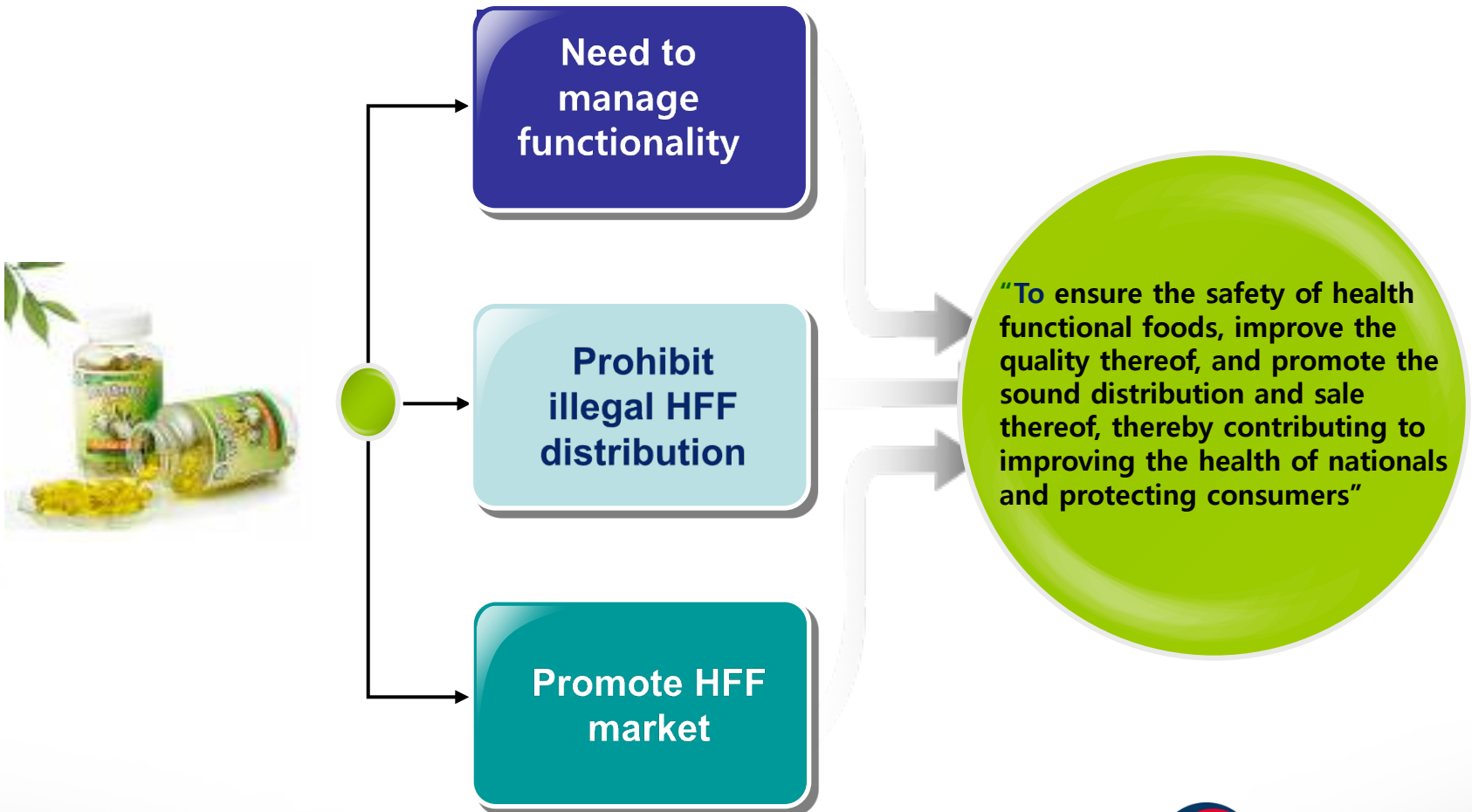


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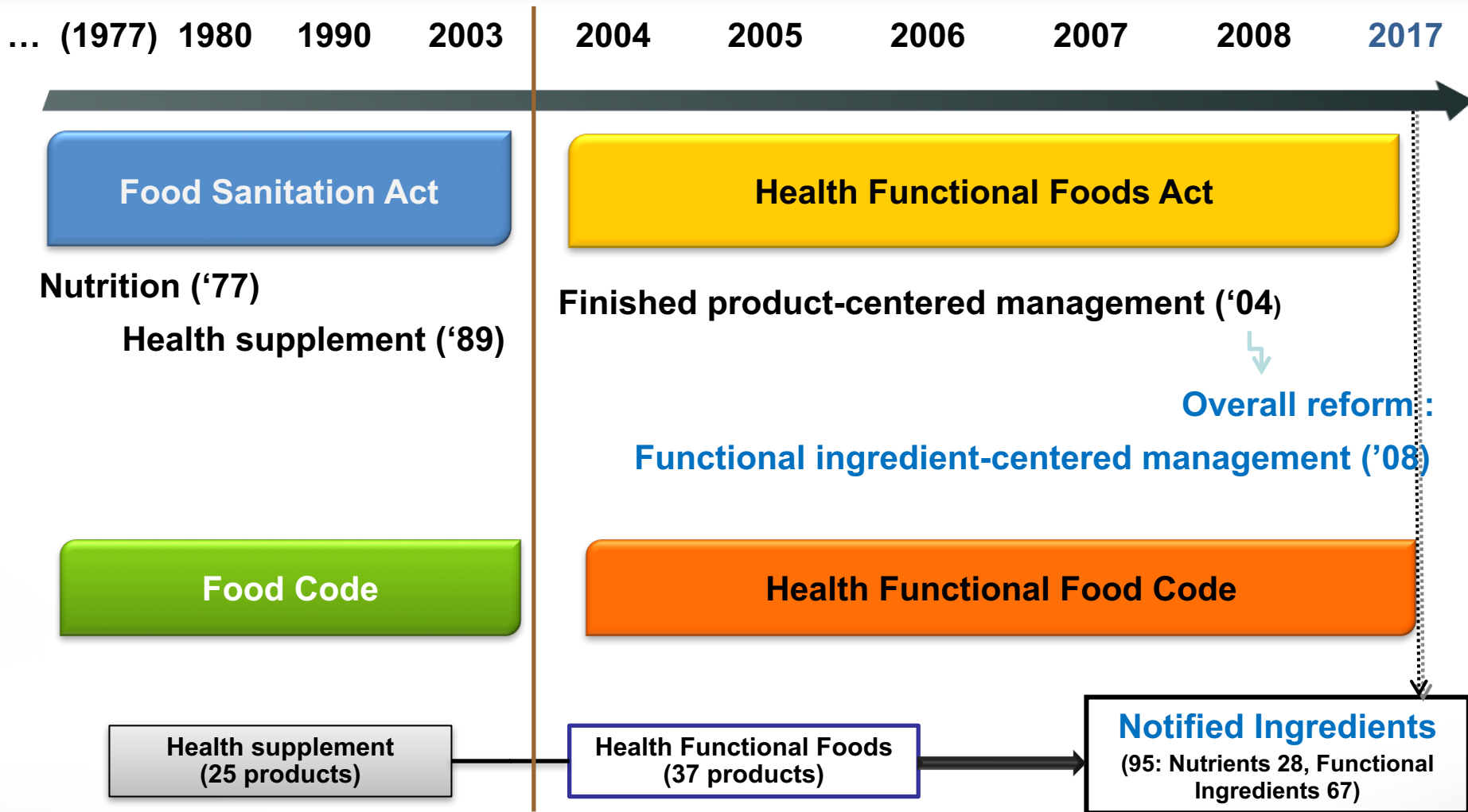
Major regulations relevant to HFF





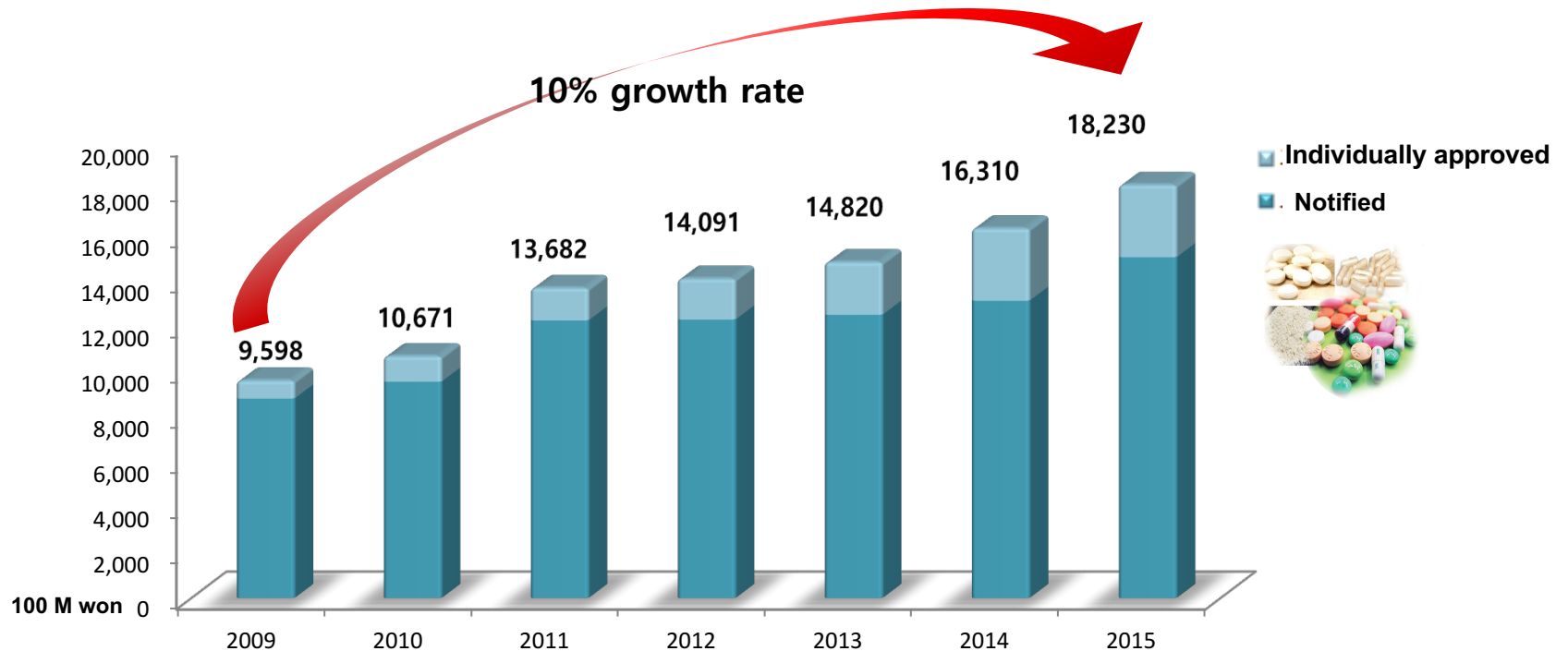


Chronological changes of HFF Management





Market Size of Health Functional Foods in South Korea



✓ Growth rate of 10% between 2009 and 2015

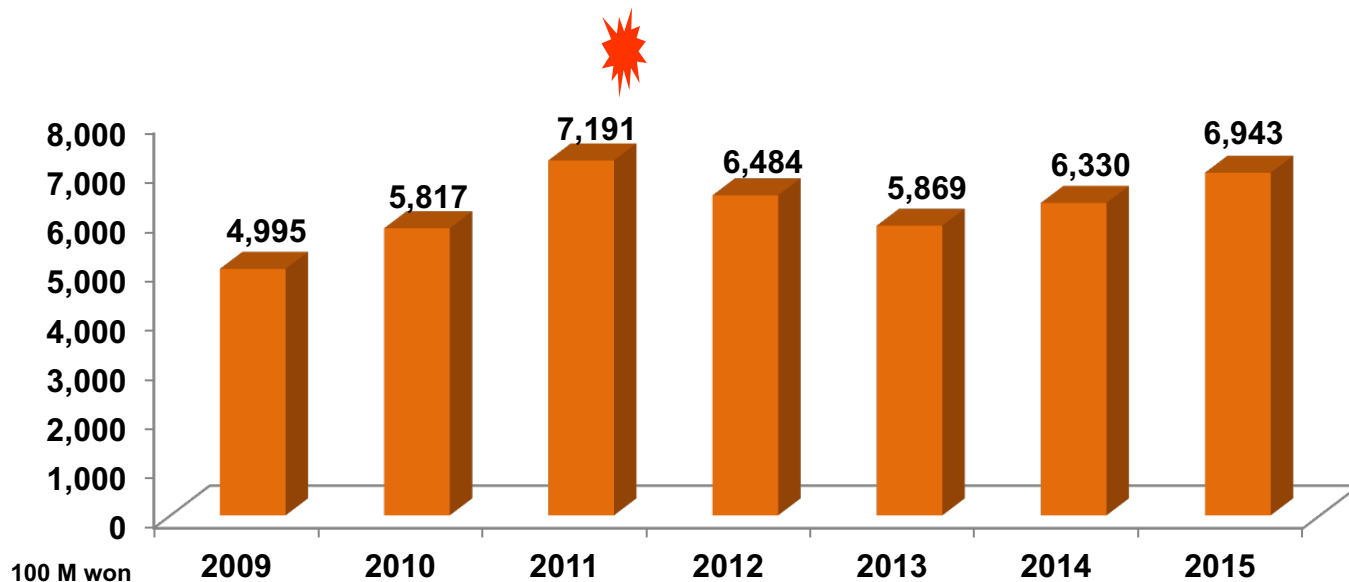
✓ Top four functional ingredients (red ginseng, vitamins and minerals, probiotics, aloe) account for about 80% of total production



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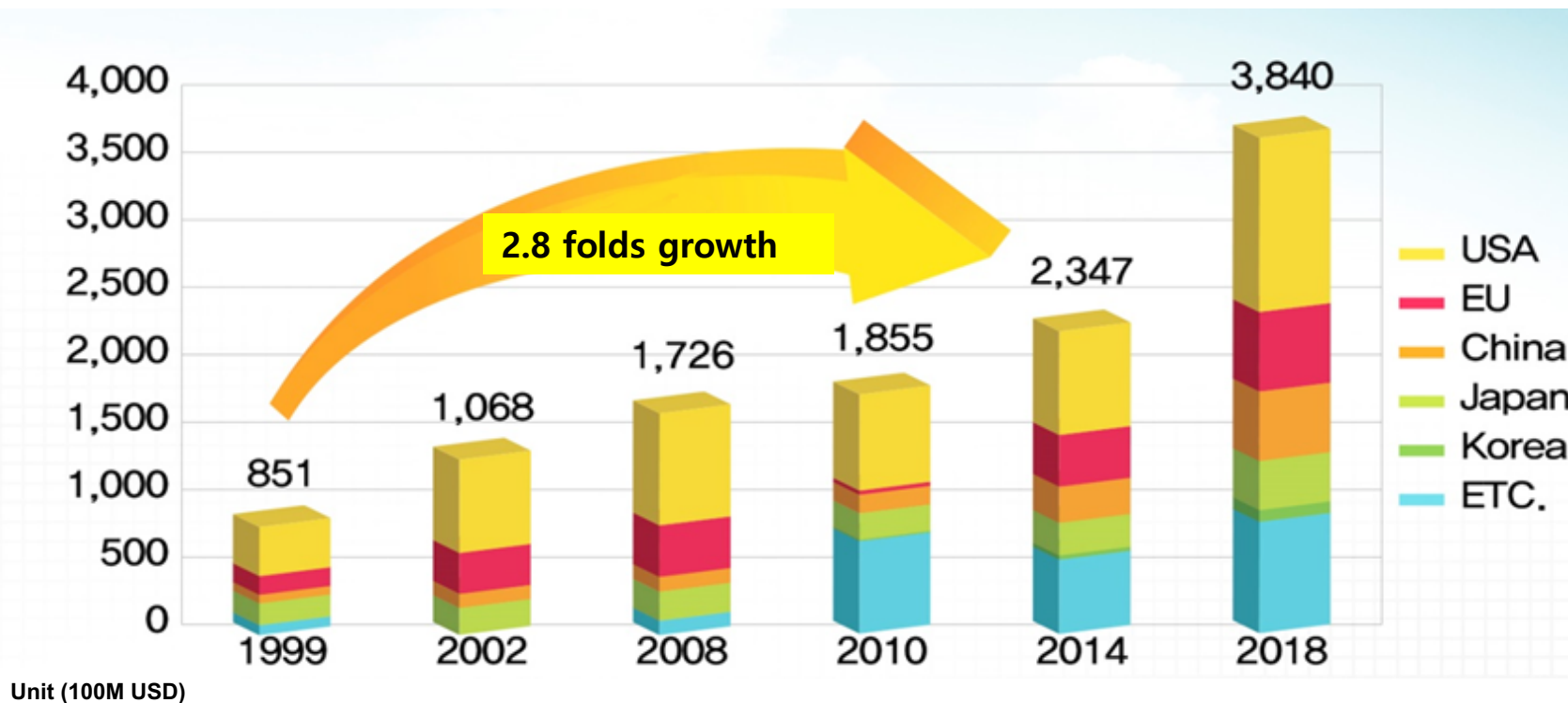


Market size of Red Ginseng



Sales of red ginseng products rapidly increased in 2011 due to the influenza outbreak (Swine flu)

✓ Global Market Size of HFF



US (34%) , Western Europe (17%) , Japan (11%) and Korea (1.4%)



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Components of Health Functional Foods



Materials used in HFF

Nutrients

Physiological effects of nutrients for normal body functions or biological activities

Vitamins, minerals, dietary fiber, protein, essential fatty acids

Other minor ingredients

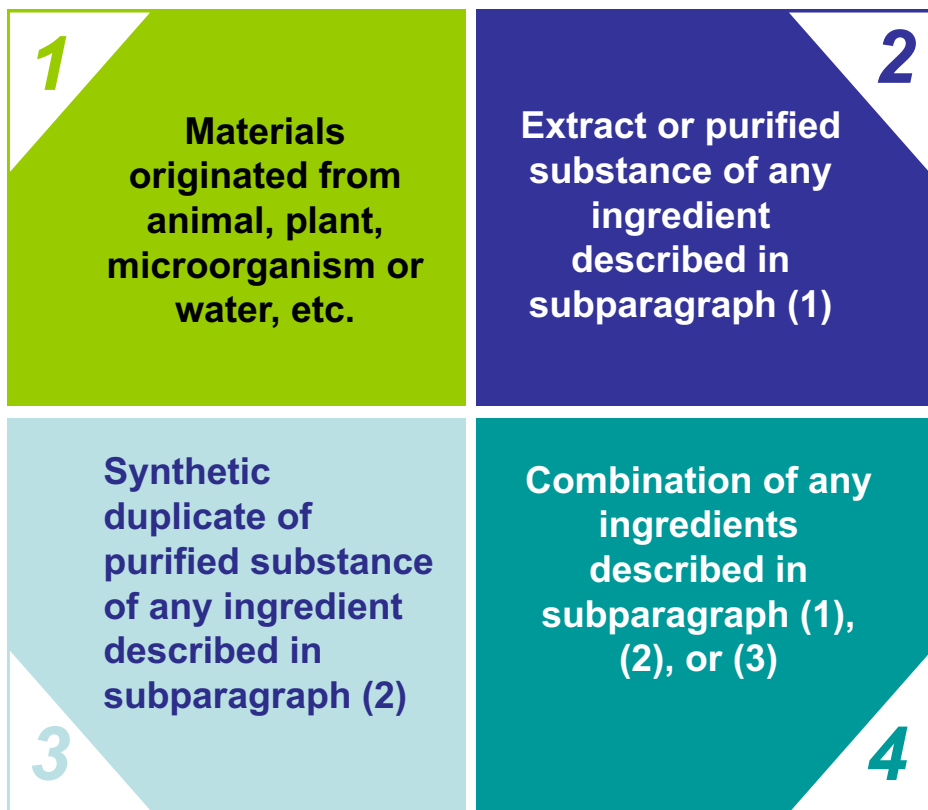
Any ingredient or component which can be used in manufacturing of health functional food, and which not claim to have functionality

- **Food additives**
- **Food materials**
- **Functional ingredients or Nutrients**



Materials used in HFF

Functional ingredients



Reduction of Disease Risk Functionality

- Contribute to reduce the risk of specific disease



Bioactive Functionality (except nutrients)

- Contribute to health, promote functionality or maintain and improve human health by providing special effects on normal body functions or biological activities





Notified Ingredients (~2010, total 75; nutrients 28, functional 47)

Nutrients(28)

- Vitamin A, Beta-carotene, Vitamin D, Vitamin E, Vitamin K, Vitamin B1, Vitamin B2, Niacin, Pantothenic acid, Vitamin B6, Folic acid, Vitamin B12, Biotin, Vitamin C, Calcium, Magnesium, Iron, Zinc, Copper, Selenium, Iodine, Manganese, Molybdenum, Potassium, Chrome, Dietary fiber, Protein, Essential fatty acid

2008

Functional ingredients(40)

- Ginseng, Red ginseng, Plants containing chlorophyll, Chlorella, Spirulina, Green tea extracts, Aloe whole leaves, Propolis extracts, Edible oil containing EPA&DHA, Edible oil containing gamma-linolenic acid, Lecithin, squalene, Phytosterol/Phytosterolester, Shark liver oil containing alkoxyglycerol, Edible oil containing octacosanol, Japanese apricot extracts, Glucosamine, N-acetylglucosamine, Mucopolysaccharide-mucoprotein, Guar gum/Guar gum hydrolysate, glucomannan(konjacmannan), oat fiber, Indigestible maltodextrine, Soybean fiber, Tree ear fiber, Wheat fiber, Barley fiber, Arabic gum(acacia gum), Corn bran fiber, Inulin/chicory extracts, Psyllium husk fiber, Polydextrose, Fenugreek seed fiber, Aloe gel, Ganoderma lucidum fruit body extracts, Chitosan/Chitooligosaccharide, Fructooligosaccharide, Probiotics, Red yeast rice, Soybean protein

2009

Functional ingredients(1) - conjugated linoleic acid

2010

Functional ingredients(6) - coenzymeQ10, soybean isoflavone, Garcinia cambogia extracts, lutein, Haematococcus pluvialis extracts, Saw palmetto extracts





Notified Ingredients(at present, total 95; nutrients 28, functional 67)



Gamma
polyglutamic
acid

2011
(8)

Guavarine leaf extracts, banaba leaf extracts, Ginko leaf extracts, Milk thistle extracts, evening primrose seed extracts, phosphatidylserine, theanine, MSM

2013
(1)

2014
(4)

Hyaluronic acid,
bilberry extract,
Garlic

2016
(7)

Raffinose, Gelidium amansil Lamourous Extracts, Creatine, Hydrolyzed milk protein, Phellinus linteus Extracts, tomato Extract s, Amorphophallus konjac Extracts

Notified Ingredients
(95: Nutrients 28,
Functional Ingredients 67)

✓ Registered ingredients (individual certified)

> Certified procedure



> Status of Registered Ingredients

# of Registered Ingredients (new material)	'08	'09	'10	'11	'12	'13	'14	'15	'16
	85 (17)	104 (30)	78 (20)	45 (13)	42 (10)	54 (22)	89 (26)	28 (11)	32 (2)

✓ Registration of functional ingredients

➤ Documents required for submission

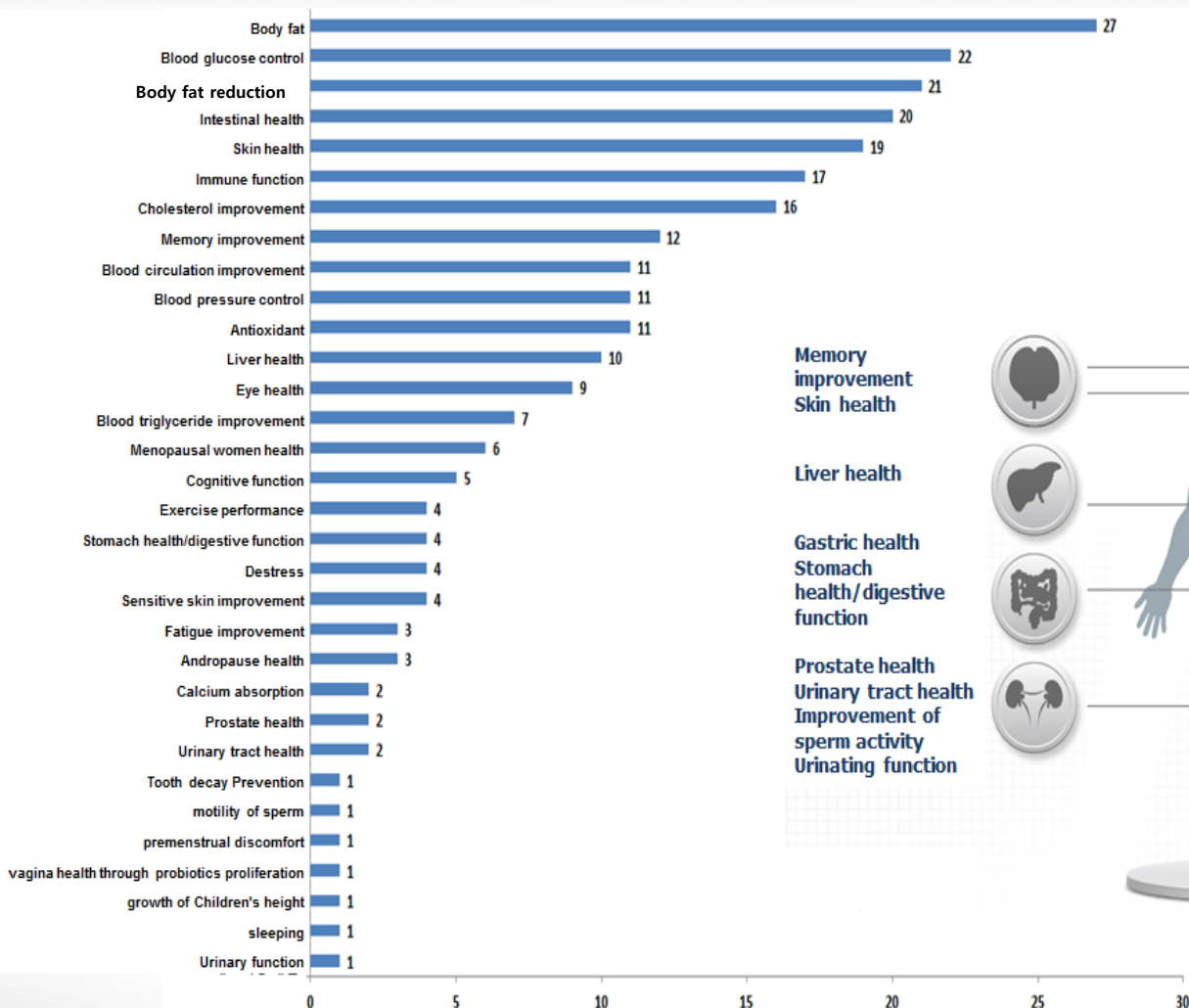
1. Executive summary of all submitted documents
2. Origin, development details, current status of approval and use in domestic and foreign countries etc.
3. Manufacturing methods and related data
4. Characteristics of the ingredient
5. Marker compound(Specification on functional component) and data on test method
6. Specification of harmful substance and related data on test method
7. Data on safety
8. Data on functionality of the ingredient
9. Consumption amount, consumption method, warning notice for consumption and rationales for setting them
10. Data on confirmation that the ingredient is not identical or similar to medical drugs

- **Processing time** : shall be **within 120 days** from the date of application.





Approved functionalities



Raw materials approved by function('04~'16, Number)

A total of 32 functionalities 190 functional ingredients

* In some cases, one ingredient has more than two functionalities.

Memory improvement
Skin health

Liver health

Gastric health
Stomach health/digestive function

Prostate health
Urinary tract health
Improvement of sperm activity
Urinating function



Eye health
Teeth health

Improvement of blood cholesterol
Improvement of blood triglyceride

Reduction of body fat

Joint/bone health
Enhancement of motor ability
Calcium absorption

Other approved functionalities

- > Immune function, antioxidant function, relaxation, and anti-fatigue effect
- > Health of menopausal men and women
- > Sleep quality improvement, and helpful for children's height growth
- > Helpful for vagina health of women through proliferation of lactobacilli



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Reassessment of Health Functional Foods



Disputes over safety and functionality of functional ingredients call for reassessment

➤ Controversy over **the adverse effects and effectiveness** of functional ingredients

(Safety) Garcinia cambogia extract : Liver damage

(Safety) Green tea extracts : Liver damage

(Function) Saw palmetto extract : Prostate health

(Function) Wild mango seed extract : Reduce Body fat



➤ Follow-up action (maintain, revise, or withdraw) be taken based on **the outcomes of reassessment starting 2017**

Complementary measures to apply to functional ingredients after approval of 10 years or new scientific information or data are available for the particular ingredients

👉 **caring out 19 periodic reassessments and 9 additional reassessments**





Reassessment of HFF

Review and assess the safety and functionality of functional ingredients (including products) that have been previously identified, as well as of functional health foods at the latest scientific level

Regulations on Reassessment of Functional Ingredients

Periodic reassessment

Subject	<ul style="list-style-type: none">● Ten years passed since approval
Ingredients	<ul style="list-style-type: none">● ('17) 18 ingredients including soybean oligosaccharides
Re-assessment	<ul style="list-style-type: none">● ('17) Identifying and notifying the subject ingredient and their products of reassessment, etc.● ('18) Reassessment



Additional reassessment

Subject	<ul style="list-style-type: none">● Risk information, social issues
Ingredients	<ul style="list-style-type: none">● ('17) 8 ingredients including green tea extract
Re-assessment	<ul style="list-style-type: none">● ('17) Identifying and notifying the subject ingredient and their products of reassessment and confirmation of reassessment results



Reassessment of HFF

Periodic reassessment (19)

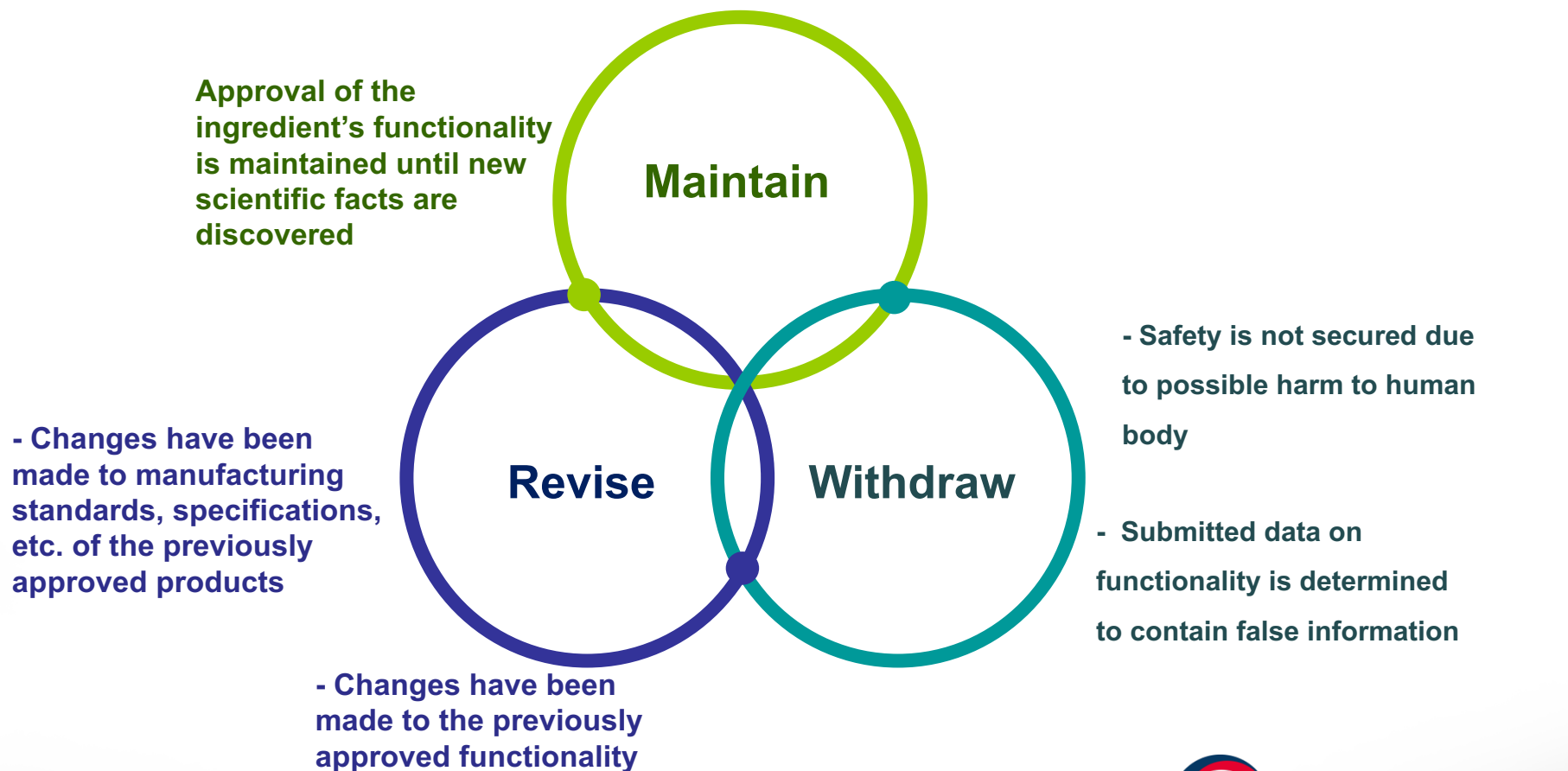
Gastrointestinal peptides, Sugarseed wax alcohols, Plant stanol ester, Olive leaves extracts, Sardine peptide, Casein hydrolyzate, French seaweed extracts, Green lipped mussel extracts oil, Complex extracts golden root, Angelica gigas Nakai root extract powder, Fibroin enzyme hydrolyzate, Hibiscus extract, Complex extract mixed Angelica gigas Nakai, Soy oligosaccharide, Isomaltooligosaccharide (3), Xylitol, Grape seed extracts

Additional reassessment (9)

Garcinia cambogia extracts, Green tea extracts, Probiotics, Aloe whole leaves, Green matte extracts, Complex green tea extracts and Theanine, Wild mango seed extracts, Polygala tenuifolia Willdenow extract powder, Complex extracts Astragalus membranaceus Bunge



✓ Follow-up Actions from the Reassessment



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Directions for Health Functional Foods



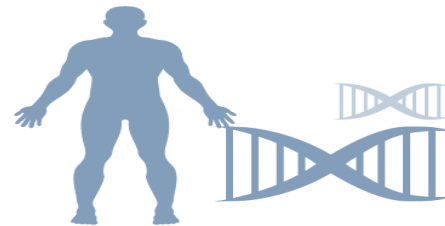
Policy Directions for HFF

Solidifying consumer-centered foundation

- Conduct case study of abnormal functional foods (full-scale)
- Introduce a request system for consumer administrative inquiry
- Enhance overseas sales inspection
- Conduct targeted management through analysis on commencements from consumers

Scientific evidence based evaluation of functional ingredients

- Implement systematic approval of functional ingredients
- Reassess safety and functionality of previously approved functional ingredients



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Supporting System for HFF Industries - From ingredient approval to commercialization

Explore new functional ingredients

- ✓ Develop new functional ingredients support system
 - Establish database for nutrients and functional ingredients of domestic foods and make it available to the public including industries

Standardization of functional ingredients

- ✓ Develop analytical methods for functional markers/indicators
- ✓ Operate open manufacturing facility and laboratory facility

Safety evaluation and Identification of functionality

- ✓ Provide consulting system to develop a comprehensive test plan including animal experiment, human study, etc.
- ✓ Establish Functionality Evaluation Support Center

Individual approval

- ✓ Prior support including consulting for functional recognition
- ✓ Promote CRO(Contract Research Organization)

Commercialization

- ✓ Provide support for product manufacturing, declaration consulting, etc.
- ✓ Establish export support center



Thank you

