



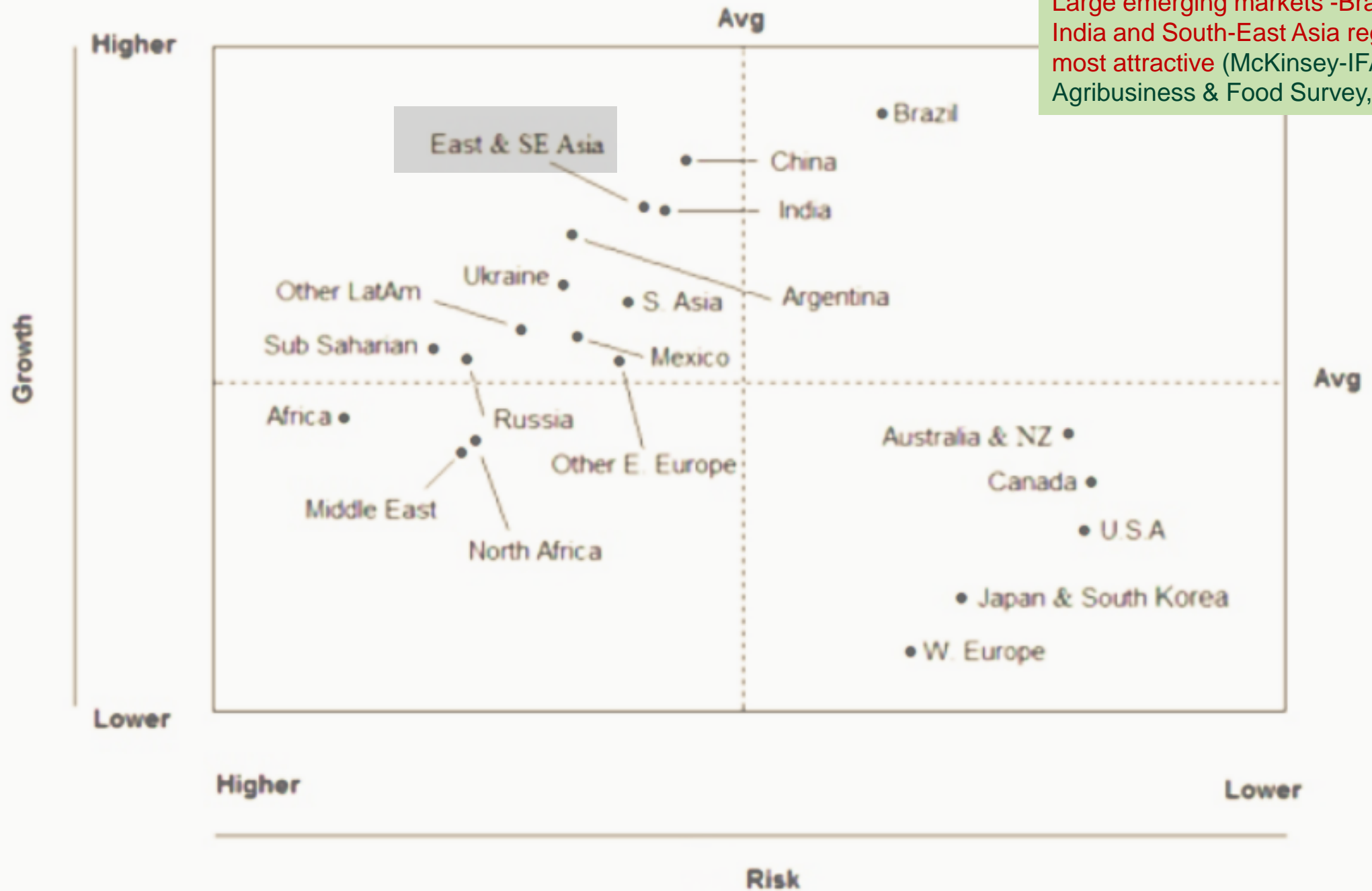
Regulatory Best Practices to Manage Food Innovation: Thailand's Food Innovation & Regulation Network (FIRN)

Prof. Pavinee Chinachoti
Chair, FIRN

2025 ASIA CODEX AND FOOD REGULATORY FORUM

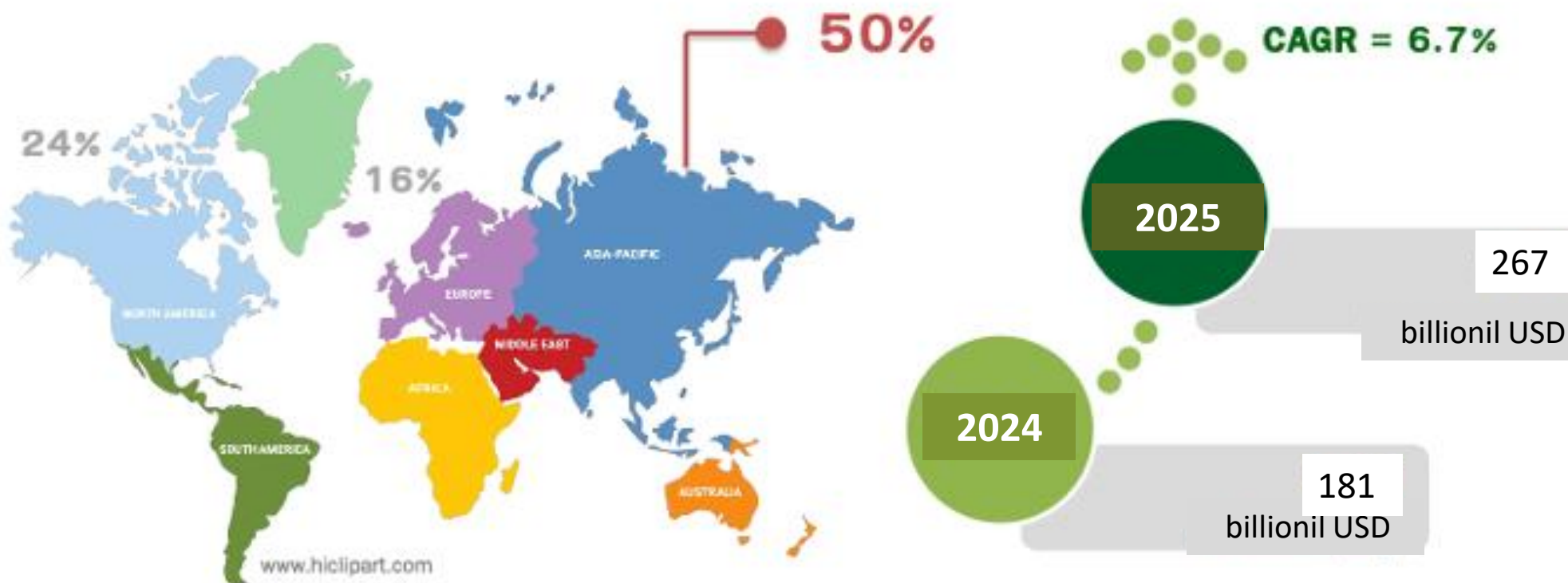
18-20 August 2025

Sheraton Royal Orchid Hotel and Towers, Bangkok, Thailand

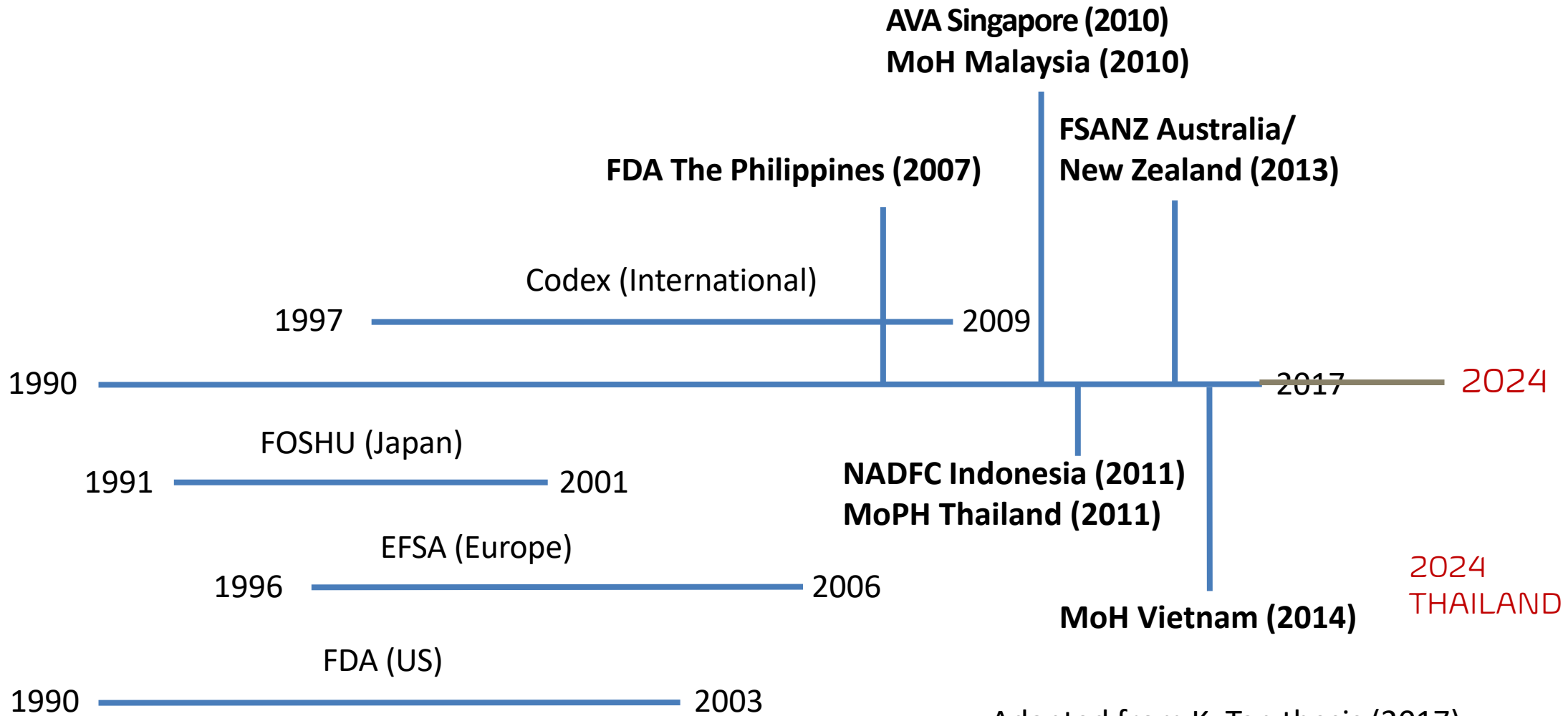


Large emerging markets -Brazil, China, India and South-East Asia regions are most attractive (McKinsey-IFAMA Agribusiness & Food Survey, 2012)

FUNCTIONAL INGREDIENT MARKET - 1.81 BIL USD (2024)



FOOD HEALTH CLAIMS TIMELINE



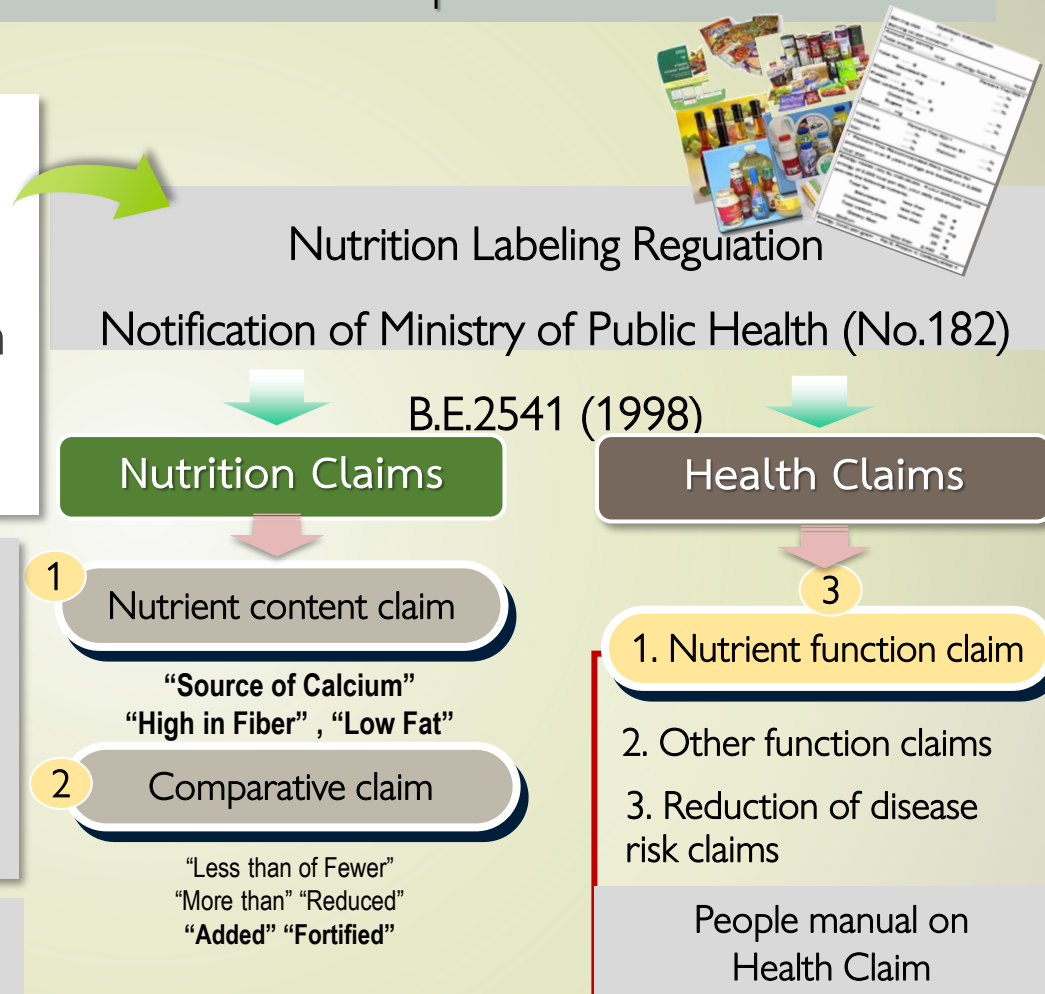
Adapted from K. Tan thesis (2017)

Regulations for health claims of food products

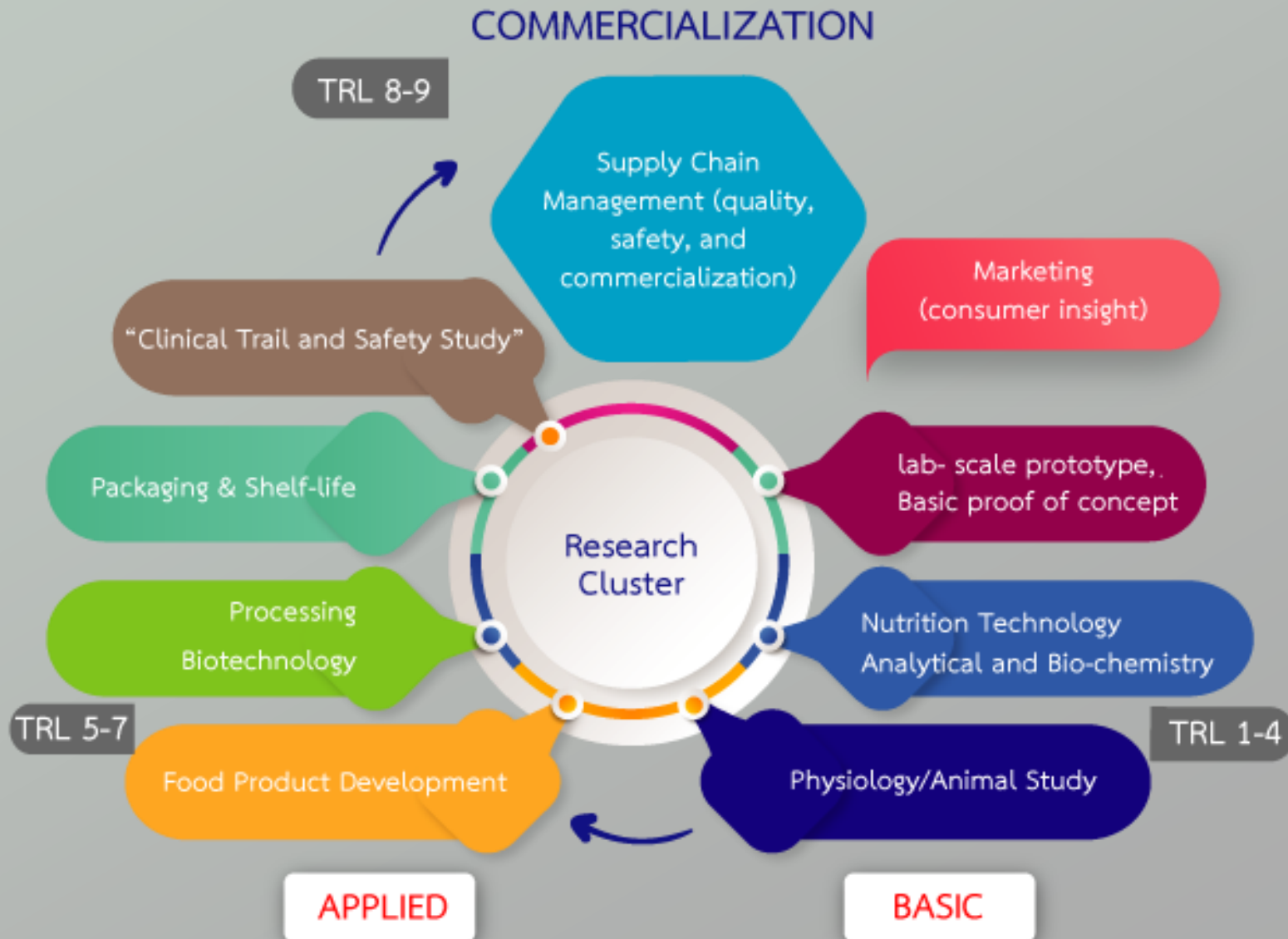
- Food Act B.E. 2522 (1979)
- Notification: Nutrition labeling (1998)
- People manual on Health Claim
- Food for Special Purposes/Medical Purposes

Nutrition labeling such as Healthier Logo;
Nutrient Function claims
Positive List of nutrients (nutrition) e.g. calcium
Positive List of functional ingredients
Announcement: Health claims

Herbal product announcement
Herbs and spices



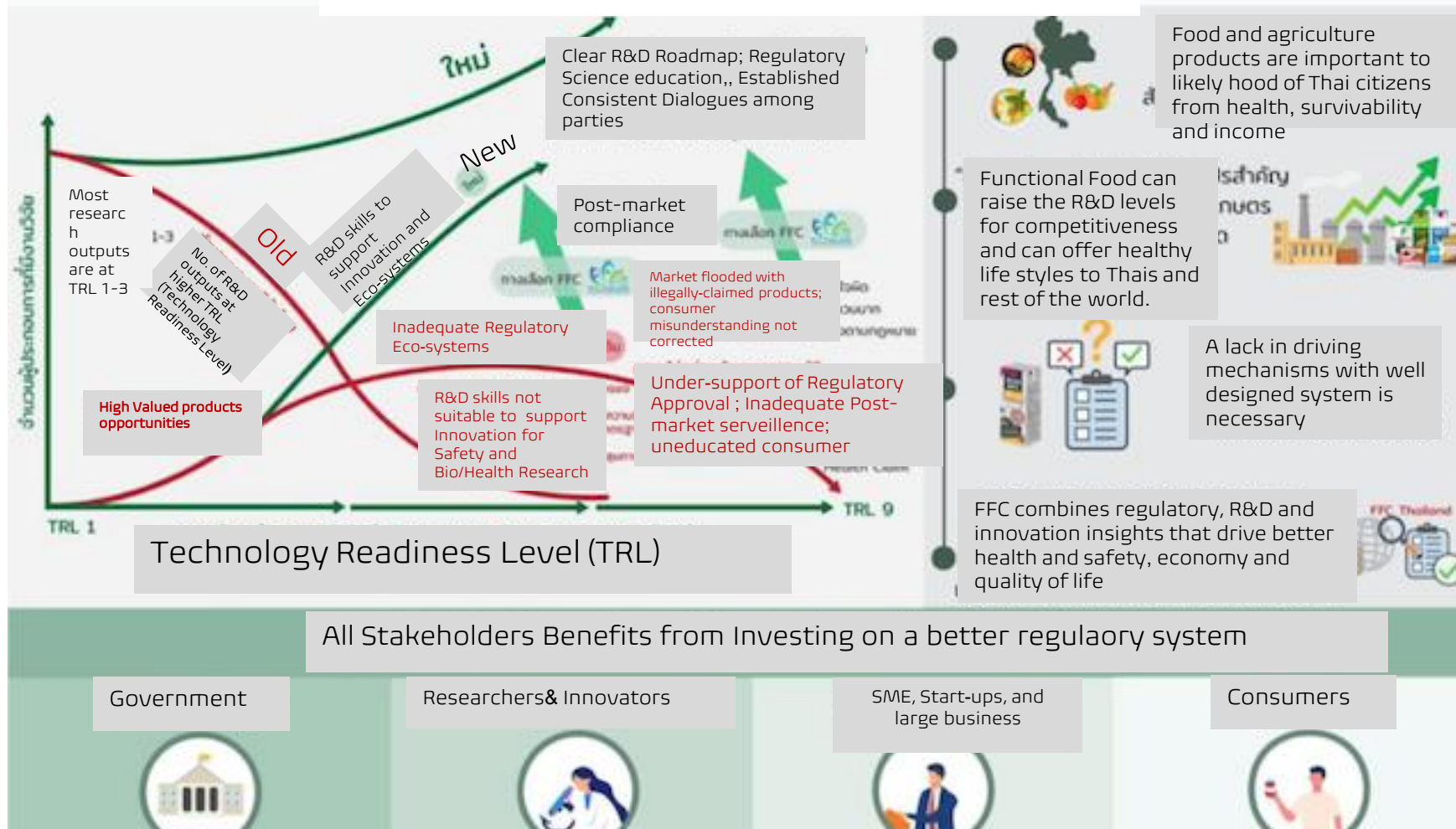
COMMERCIAL R&D SYSTEM





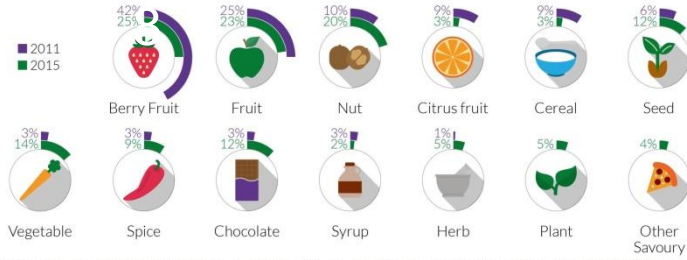
FFC Thailand is Knowledge (R&D)-Based Dossier Development and Regulatory Review Platform that Complies with FDA Requirements and Supports SMEs to Build Capability Positive List is Evidence-Based preapproval of bioactive compounds in which products can be labelled a HC statement at dosage level that had been proven to be safe.

WHY should we consider FFC SYSTEM?



PRODUCT INNOVATION VALUE CHAIN

TOP FLAVOR COMPONENT SUBGROUP IN GLOBAL SUPERFOOD* FOOD AND DRINK LAUNCHES, 2011 VS 2015



*Note: Superfood includes products that contain the words superfood or superfruit or supergrain with word variants in the product description. Source: Mintel GNPD

MARKET NEEDS



Regulatory
Approval

FDA

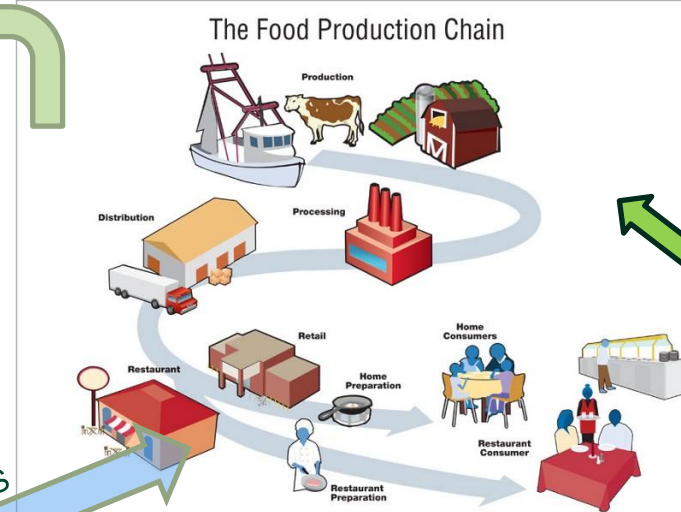
HEALTH
CLAIM
REVIEW

SAFETY
REVIEW

BUSINESS DEVELOPMENT
MARKETING AND SALE

Functional Foods and
their Design
PRODUCT FORMULATION-
PROCESS DEVELOPMENT

PLANT TRIALS



GAP. Organic
Trade secret



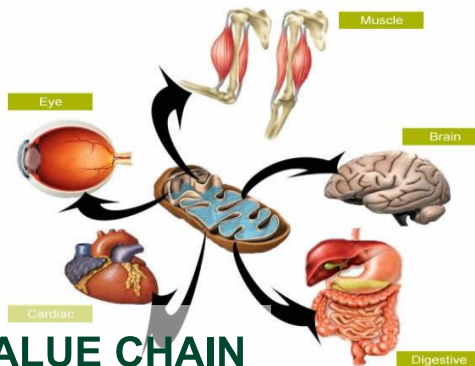
Photosynthesis

NO₃
Assimilation/
N₂ Fixation

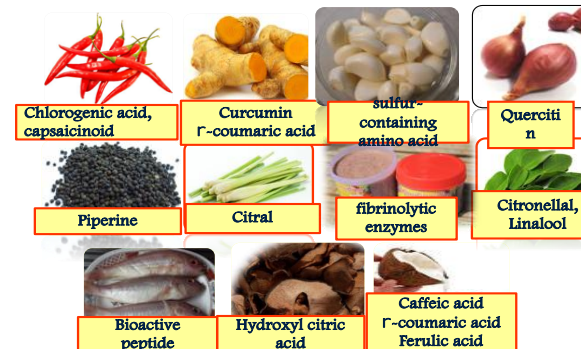
Local and Traditional Materials



MECHANISM KNOWLEDGE



Local bioactive raw materials



EFFECT ON HEALTH



Animal
and Clinical
Studies

RESEARCH VALUE CHAIN

ปริมาณสาร
สถานะที่เอื้อต่อ
การสะสม
สารสำคัญ

Types of Health claims in Thailand



Nutrient function claims



29 nutrient items, 131 claim statements

Other function claims



Reduction of disease risk claims

Foods with function claims (FFC) in Thailand



ACFS



FDA



Systematic review Intervention study



Calculation of recommended daily intake



Development of analytical method

Nutrient Function (Health) claims

29 Nutrients on Positive List



Foods in general

Positive List Other Function Claims



Other Function Health Claims Case-by-Case Review

Submit dossier

FFC

Food w Function Claim (support info. and roadmap provided)



Lack of proper Safety Efficacy Evidence



FDA



ACFS



Stakeholder Interviews



STAKEHOLDERS

Researchers

1. Prof. Dr. Krisana Kraisintu
2. Prof. Dr. Apichart Vanavichit
3. Prof. Dr. Chintanaporn Wattanathorn
4. Asst. Prof. Dr. Sujinda Sriwattana
5. Asst. Prof. Dr. Nuanpan Sirinuphong
6. Assoc. Prof. Dr. Cholat Santivarangkana
7. Prof. Dr. Aranya Manosroi
8. Assoc. Prof. Dr. Songsak SriAnuchart
9. Assoc. Prof. Dr. Chanipan Butyee
10. Prof. Dr. Visit Chavasit

Entrepreneurs

1. Mr. Ben Boonyalai (Medifoods)
2. Mr. Watanyu Boonyasitidej (AVA Plant)
3. Dr. Pakakrong Kwan Khao and Pharmacist Supaporn Pitiporn (Chaophraya Abhaibhubejhr Hospital)
4. Mr. Keskong Pornaveewat (Chiang Mai Bio Veggie Co., Ltd.)
5. Mr. Anan Chaikitwattana (Tipco Biotech)

Government sector

- Regulatory agencies
- Promotion and support
- Policy

1. Dr. Witit Saridsadeechaikul (Deputy Secretary-General of FDA)
2. Mr. Warawut Sermsin Siri (Director of Herbal Products Division)
3. Mr. Weerachai Nalawachai (Director of Food Division)
4. Mr. Phisan Pongsapitch (Secretary-General of ACFS)
5. Ms. Siriwan Chaisomboon (Director of the Research Institute Herbal Medicine)
6. Asst. Prof. Dr. Akkarawit Kanjana-Opas (CEO Food Innopolis)
7. Dr. Pathom Sawanpanyalert (Director-General of the Department of Science Service)
8. Dr. Yukol Limlamthong (National Food Committee)
- T.S. Dr. Kraisid Tontisirin, Chairman of the National Food Committee

Independent organizations

1. Chairman and committee members of the Biotech group, Federation of Thai Industries
2. Chairman and committee members of the Food group, Federation of Thai Industries
3. Mr. Nakorn Tawichawat Biotech Group
4. Mr. Wichian Cherdchutrakulthong Federation of Thai Industries, Chiang Mai
5. Thailand Center of Excellence for Life Sciences (TCELS)

Driving units Business and innovation

1. Eastern Economic Corridor of Innovation (EECI)
2. National Innovation Agency (NIA)

Research funding agencies Experts International

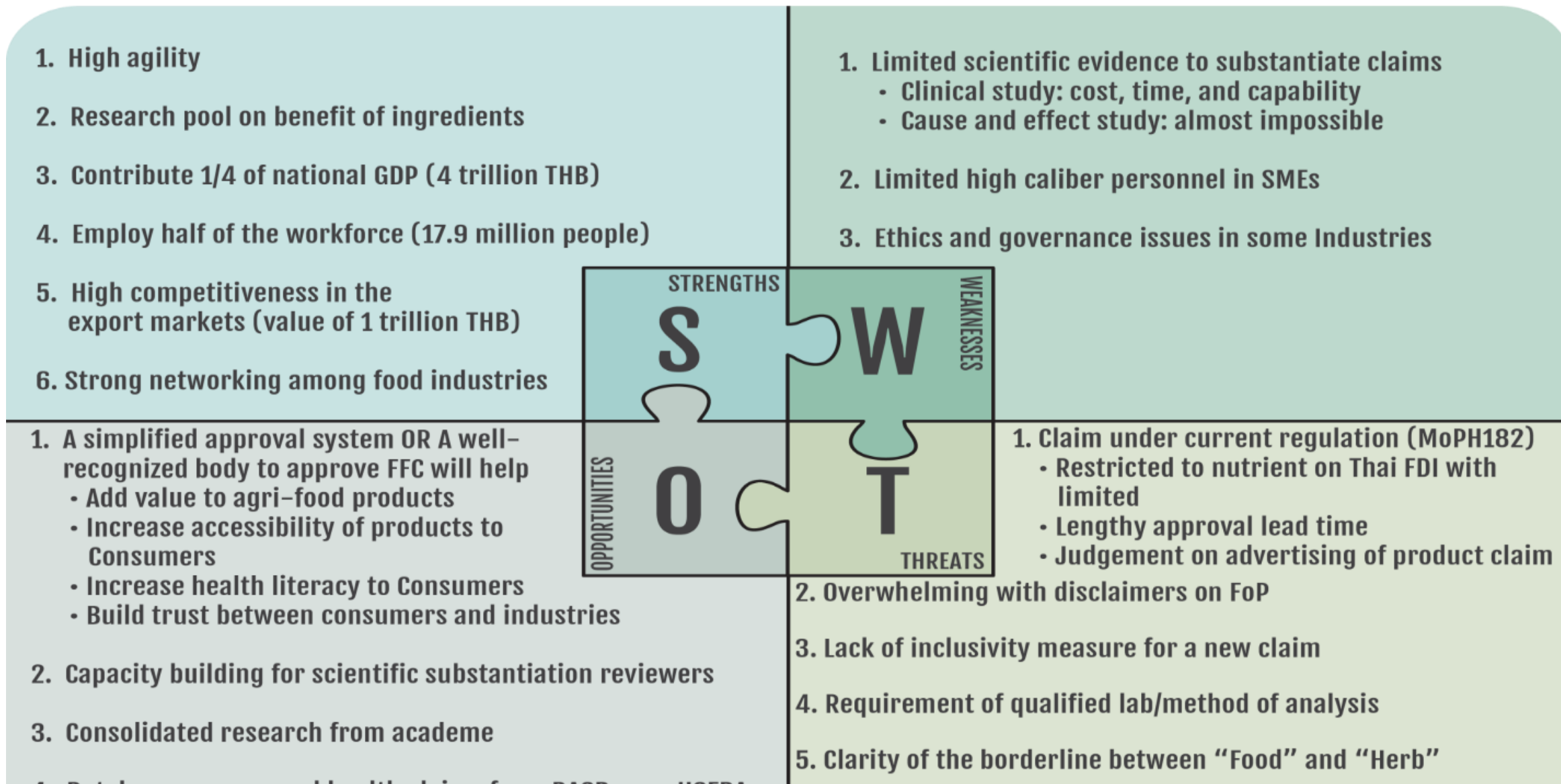
1. Dr. Suwit Chaikiattiyos (Director of ARDA)
2. Assoc. Prof. Dr. Siree Chaiseri (Director of PMUC)

1. Dr. Oran Kwon (Ewha Woman University)



SWOT Food Industry input

Agri-Food Sector and FFC

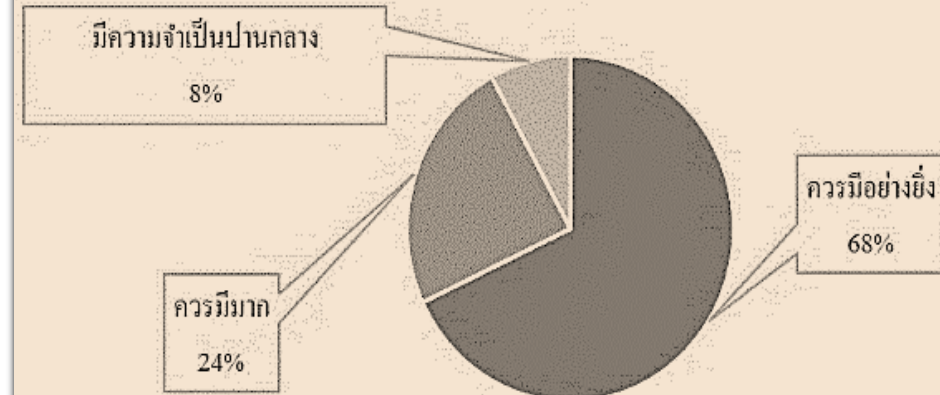


1. ระบบ FFC สามารถช่วยสนับสนุนเกษตรกรและผู้ผลิตอาหารของไทยได้ในระดับใด

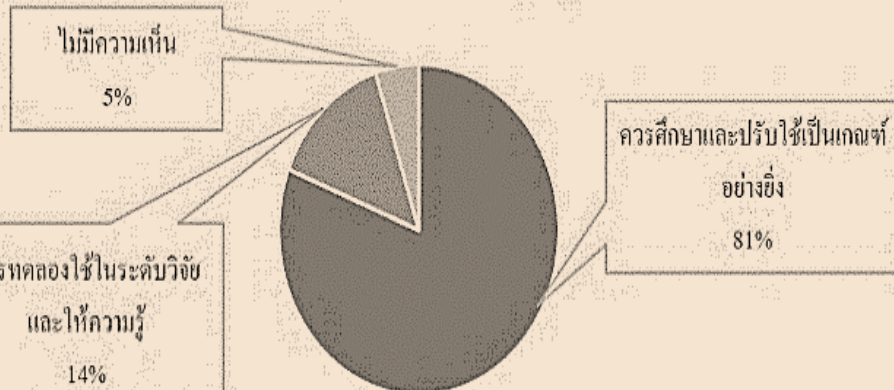
ระดับใด



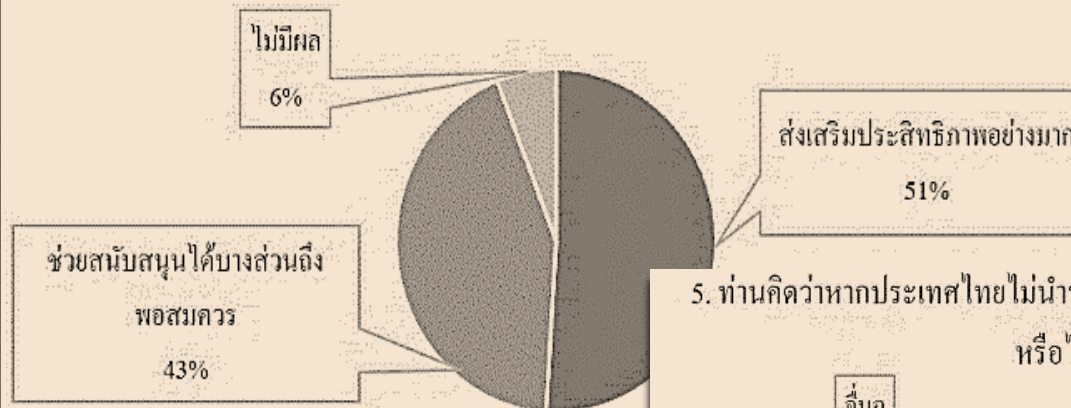
2. ประเทศไทยควรมีข้อมูลและระบบ FFC เพื่อช่วยสร้างธุรกิจ และช่วยในการตัดสินใจของผู้บริโภคหรือไม่



3. ท่านคิดว่าแหล่งทุนสนับสนุนงานวิจัยและผู้ประกอบการควรใช้ FFC เป็นเกณฑ์ในการดำเนินงานวิจัยของผู้รับทุนหรือไม่



4. หากนำ FFC มาใช้ในประเทศไทยจะส่งผลกระทบต่องาน และภารกิจของท่านอย่างไร



5. ท่านคิดว่าหากประเทศไทยไม่นำระบบ FFC มาใช้จะเสียโอกาสด้านการค้าหรือไม่ อย่างไร

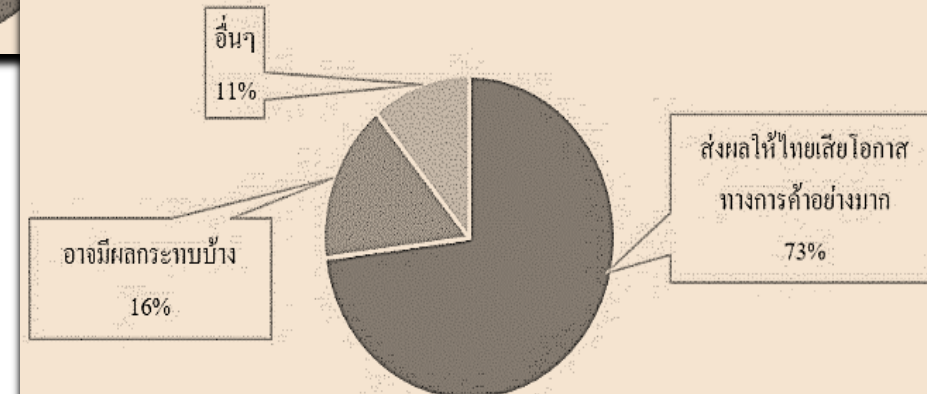


Figure 1. Summary of the questionnaire in the workshop on "Food with Function Claim (FFC) Thailand" on October 21, 2020

FEATURE - Applicants can know the status and have feedback to request additional documents or make corrections in real time

Guidelines for consideration before applying for FFC



Prepare documents to apply for FFC labeling

Consider whether the product meets FFC criteria

Assess product safety

Assess quality control and production standards

Gather data on the health effects of functional ingredients in the product

Evaluate functional claim statements based on scientific principles

FFC Labeling Application Process



Submit documents for labeling

Document verification

Receive notification number

Disclose relevant information on the CAA website

Incomplete or insufficient documents will be returned

Post-marketing samplig test

FAIL
remove company to blacklist


Sell products with notification number

What is FFC ???

Food with Function Claims

Is food with specific health function from bioactive compounds that uses scientific evidence to support health claims on product label and advertisement.

Scientific evidence obtained



Clinical trials of product containing bioactive compound of known quantity proven evidence of molecular-physiological function and level of safe use.



Scientific publication of Systematic Review of bioactive molecular on health function.



FFC Thailand is system developed in order to help manage evidence needed to be clearly understood, developed, and filed for health claim substantiation of functional food/product. This is to aid company's R&D capability in challenging steps and enabling them to be strong and more successful in competitive health markets. By way of documentation submission online and timely quality of evidence review process, Japan FFC has proven to be effective and improve time-to-market.



Why do we need a better system of FFC Thailand?



FFC Thailand is an alternative approach primarily for SME's to follow a regulatory roadmap with proper academic and industry R&D designed for functional claim substantiation. It also includes Q&A and training supports, databases of needed scientific databases, and on-line Health Claim Substantiation courses.



- FFC Thailand will help accelerate value-added agricultural, food and supplements products from Thailand towards health market opportunity.
- Systematic development of Thailand is long overdue and this may be a way to strengthen supply chains and stronger, more resilient and sustain the poor farmer livelihood for better second source of income from growing fresh products with functional ingredients, fresh fruits, vegetables, animals, or cultured products.
- Development is needed in several fronts to support research endeavors regarding standards, analyticals, clinical trials and FFC Thailand should offer a means the bridge to close as much gaps possible.



How consumers benefit from FFC Thailand?



- Consumers can differentiate FFC claim (and able to access some evidence informed)



- Increased understanding and know more about food choice for health



How FFC Thailand benefits Food Companies?

Policy study and intervention proposed with FFC Thailand model adopted by the Thai National Food Committee in 2022 with sub-committee formed to develop FFC Thailand system.



Proposed alternative FFC Thailand model for functional claims from farm to fork.



Current traditional functional food approval process (committee- based) remains the main stream process until sub-committee comes to a conclusion on approval criteria and format. Companies mostly agree on change towards more comprehensive model although some high-level of claims may still need this.



Food companies need to invest wisely and be more sure of productive and efficient outcome. Tougher for SME's who likely will use the new FFC Thailand model.



Other adds-on: systematic review documents, positive list of well-studied bioactive compounds, databases are important for companies R&D and product planning/design. SME are relying on academics as their R&D arms; therefore, developments of multi-disciplinary academic industry teams are vital to the success of start-ups and SME's

How FFC Thailand Benefits R&D Scientists?



Health Food Market value increase in last 5 years

- Small and Medium Enterprises (SME) less able to compete
- Functional food health claims regulation and process hard to understand
- FDA has limited resources information and decision criteria not known



FFC Thailand will support R&D scientists and companies (SME) will needed information, regulatory, guideline, roadmaps and document preparation.

How Government benefits from FFC Thailand?



Grants and business investments by the government can improve likelihood of successful use of public funds.



Expand BCG model of natural resource utilization and improve quality of life (health, income, etc.)



Create business incentives towards higher valued products to improve GDP.

Problem of unmet international standards → middle income trap

- improved company's ability to comply
- improved public R&D response time to company's needs
- clearer government planning and execution
- Gain public trust and safety on food supplies



How can FFC Thailand help?



FFC is alternative support system with compliance protocol clearly defined



Supports are fast, targeted, and clear



Reduce start-finish R&D cycle better approval rates



Establish approved product surveillance and consumer education

Ranking of possibility positive lists from 17 Functional Ingredients

Ranking number	Functional ingredients (nutrients, substances)	Number of countries that approve	Countries that approve the item in the positive list						Note
			EU	Canada	AUS-New Zealand	Korea	Singapore	Malaysia	
0	Beta-glucans	6	✓	✓	✓	✓	✓	✓	Appears in the new (draft) health claim
0	EPA and DHA	4	✓	✓	✓	✓			
0	Plant sterols and plant stanols (Phytosterols, phytostanols and their esters)	6	✓	✓	✓	✓	✓	✓	
1	Inulin	4	✓			✓	✓	✓	Approved 2024
2	Soybean protein	4	✓	✓		✓		✓	"
3	Fructo-oligosaccharides	3				✓	✓	✓	
	Resistant starch	2	✓					✓	
	Chitosan	2	✓			✓			
	Glucomannan (konjac mannan)	2	✓			✓			
	Guar gum	2	✓			✓			
	Live yoghurt cultures	2	✓		✓				
	Red yeast rice (Monascus purpureous)	2	✓			✓			
4	Alpha-linolenic acid (ALA)	1	✓						
	Oleic acid	1	✓						
	Olive oil polyphenols	1	✓						
5	Conjugated Linoleic acid	1				✓			
	Indigestible maltodextrin	1				✓			

KEY PAIN POINTS Functional Health Claims of Foods

Secretariat of the
Prime Minister

คณะกรรมการอาหารแห่งชาติ
THE NATIONAL FOOD COMMITTEE



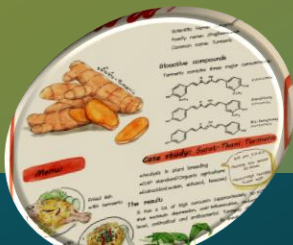
ACFS



FDA



National Innovation
Agency



Regulatory requirements, Proposed National Food Policy to develop comprehensive FFC Thailand and Positive List national agenda

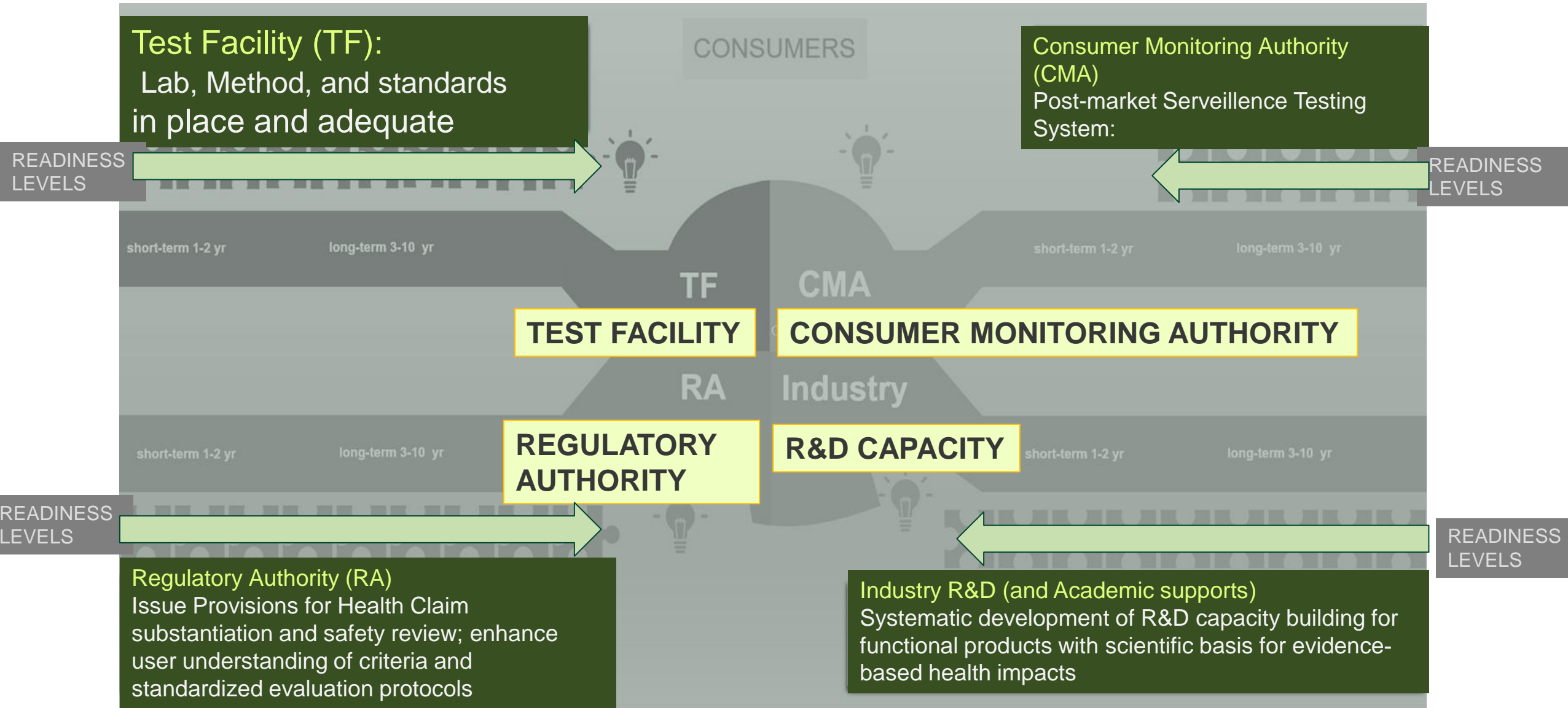
FIRN Co-Creates Positive List system that helps academics and stake holders preparation of evidence and dossier presenting to FDA

KNOWLEDGE GAPS. FIRN develops FFC Thailand digital platform; helps strengthening Manufacturers innovative approach from Upstream to Downstream

Advocate – Case studies (e.g. turmeric, catfish, color rice, Cordyceps) production of safe raw material standards; NQI (measurement standards and national labs), and Agricultural & Biotech Production Technology

Seminars, Workshops,
Books, Technical Bulletins
Grant grooming,
regulatory training

THE FOUR PILLARS for REGULATION EFFECTIVENESS



History of FIRN



2018 NXPO workshop by FoSTAT => **announce establishment of FIRN**

2019 **First workshop by former EFSA Directors**
<https://firn.or.th/2019/02/28/elementor-3335/>

Functional Food Dialog workshop by FoSTAT with **FDA Food Division Director (Dr. Tipvon Parinyasiri)**

EFSA former head of Health and Safety - Prof. Albert Flynn and Mr. Basil Mathioudakis



2020 ARDA grant –**Policy Roadmap for Functional Foods (FFC Thailand concept) with collaboration with NARO (Dr. Masuko Kobori)**

2021 TSRI (Thailand Science Research Innovation) grant to develop **online course for Functional Food Health Claims in collaboration with Thai FDA**

2022 **FFC Thailand Proposed to the National Food Committee and passed-** FDA and ACFS are to be Secretariate of Functional Food System Study ; Book published; 3-yr.Grant received from PMUC to develop FFC Thailand platform, 17 Positive List Monographs submitted to FDA

2023 **FFC Thailand Platform developed** https://ffc-thailand.in.th/th/ระบบ-ffc-thailand_draft/

2024 Positive List Policy Proposal for Future Foods - 150 compounds in 3 yrs approved by FDA Secretary General

2025 Functional Ingredients of Asia – new move to expand and strengthen FIRN commitment to harness local biomaterials for health and food security



FIRN now is located at the newly established Food and Health Security Foundation (FHS) 2025



FUTURE FOOD INNOVATION

IDENTIFYING TECHNOLOGIES OF CHOICE TO DEVELOP HEALTH PLATFORM

INDIGENOUS/TRADITIONAL FOODS



Phytochemicals -Antioxidants, antiinflammation, cholesterol lowering, reduced type 2 Diabetes

NUTRITION TECHNOLOGY AND INNOVATION

-e.g., micronutrient retention, fortification, reformulation, novel food medical food

FUNCTIONAL FOODS

ALTERNATIVE PROTEINS



FAO

คุณประโยชน์ของข้าวกล้องงอก
“ข้าวแสงแรกแห่งตะวัน”

1. มีสารกาบา (GABA) ที่มีส่วนช่วยกระตุ้นระบบประสาท และป้องกันโรคอัลไซเมอร์ได้อย่างดีเยี่ยม
2. ช่วยควบคุมระดับน้ำตาลในเลือด และป้องกันโรคเบาหวาน
3. มีสารต้านอนุมูลอิสระกลุ่มฟีนอลิก (phenolic compounds) ช่วยยับยั้งการเกิดฝ้า กระ ริ้วรอย
4. วิตามินอี (Vitamin E) ที่อยู่ในข้าวกล้องงอก ช่วยลดการเน่าเสียของผิว

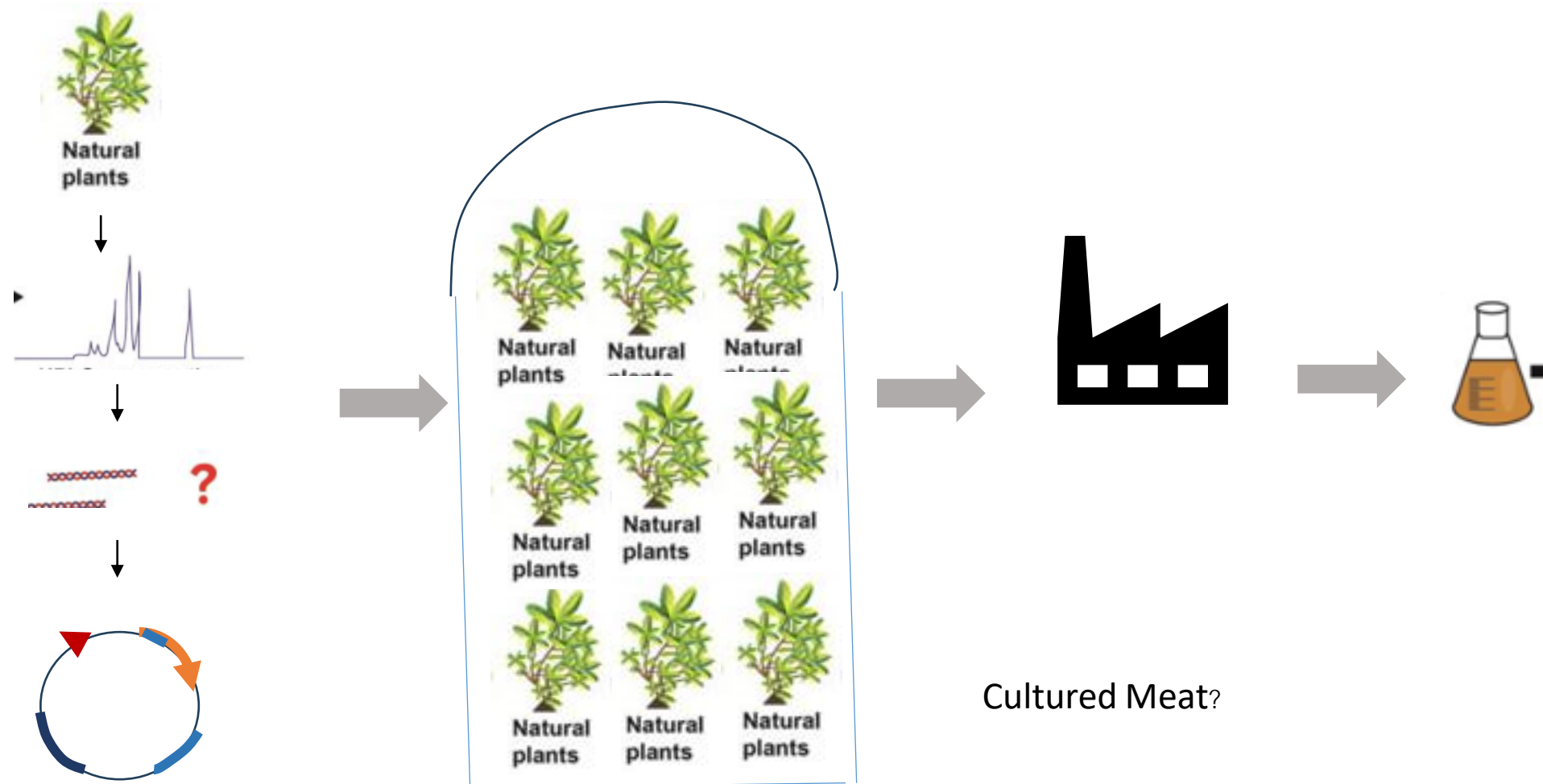
GOOD AND ABUNDANT

Special Report
HEALTHY BROWN RICE
 อร่อยอย่างมีคุณค่าด้วย “ข้าวแสงแรกแห่งตะวัน” และ “ปลากะพงขาว” คัดพิเศษ

biofortification especially to increase zinc, iodine and selenium density of cereals

“ข้าวแม่” KAO-MAE

Role of bioconversion- biotechnology natural extracts



MARKET OPPs

Functional Mushroom Market Size, By Application, 2017 - 2027

2027

13.6 Bn

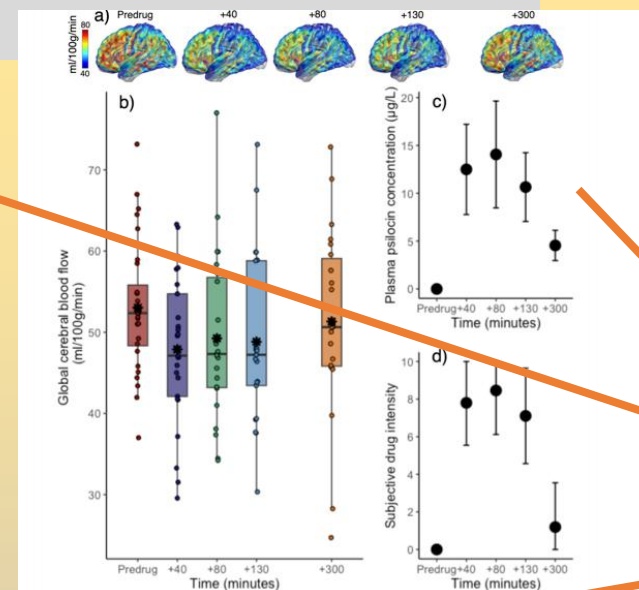
6.6 Bn

2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027

- Personal Care & Cosmetics
- Food & Beverage
- Pharmaceutical, nutraceutical & dietary supplements

Source: www.kbvresearch.com

SAFETY & CLINICAL TRIALS RESULTS -SYSTEMATIC REVIEW



FDA



Mushrooms from local areas



NATIVE

LOCAL PRODUCTION

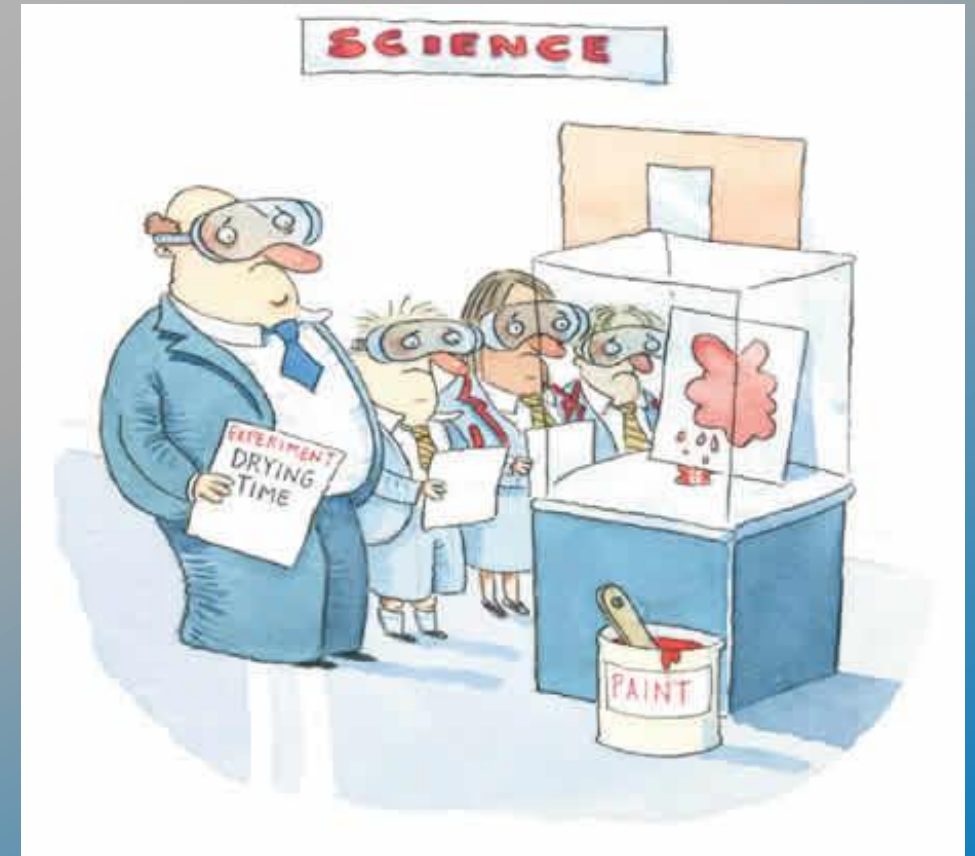
LAB EXTRACTION ? PILOT PLANT BIOTECHNOLGY

Innovation system for success in the private sector

1. How to and Management Tools

- a. Screening innovation and technology analysis
- b. Technology and development management for business
- c. Research and product development process

2. Intellectual property management



Roadmap for Functional Food Studies

Functional Foods

Market Analysis/Market Survey
/Segmentation

IDEATION

Preliminary

Proof of Concept

Feasibility

If that food in 1 serving contains
Total fat more than 13 grams or
Saturated fat more than 4 grams or
Cholesterol more than 60 milligrams or
Sodium more than 360 milligrams

1. SUPER-ADVANCE

There is a systematic literature review
(Systematic Review)

Yes

Yes

There is a human Randomized Control Trial (RCT) study

None, but can be reviewed

No

Must plan a study 2. ADVANCE

3. ALMOST BASIC

There has been epidemiological research
(Epidemiology Study)

Yes

Yes

There are clear key substances and quantities

No

Must plan a study 3. BASIC

There is a safety study. Unsafe substances. Substances that
often cause allergies. Pathogenic microorganisms, etc.

Yes

Yes

Preliminary feasibility study, patents and Freedom to Operate. If it
is a new food (Novel Food), it must enter the Toxicity Study
process according to FDA criteria.

No

Must plan a study

Must plan a study

No

Functional Foods cont.

R&D PROJECTS

Consumer Survey/Study

3. BASIC

There is a quality and safety management system for key substances such as HACCP, ISO and others.

Has a verification and transparency system e.g., raw materials, batch variation, farm location and quality (GAP, organic, or others)

Products are manufactured by actual manufacturing processes and have registration from the FDA.

- Manufacturing location
- Product

Secondary

Yes

Yes

Yes

Yes

Yes

Yes

In vitro Chemical laboratory studies

In vivo Animal tissue studies There are other research supports such as studies in experimental animals

Safety (Toxicity)
Structure-Function relationship

2. LAB + ANIMAL STUDY

There is a product usage formula with the amount of important substances that shows that it is an amount that has a positive impact on health or the biomarker that is actually claimed.
(GLP standard)

Tertiary

Yes

Focus Group Market Utility Trial

GAP = Good Agriculture Practice
GLP = Good Laboratory Practice
GCP = Good Clinical Practice

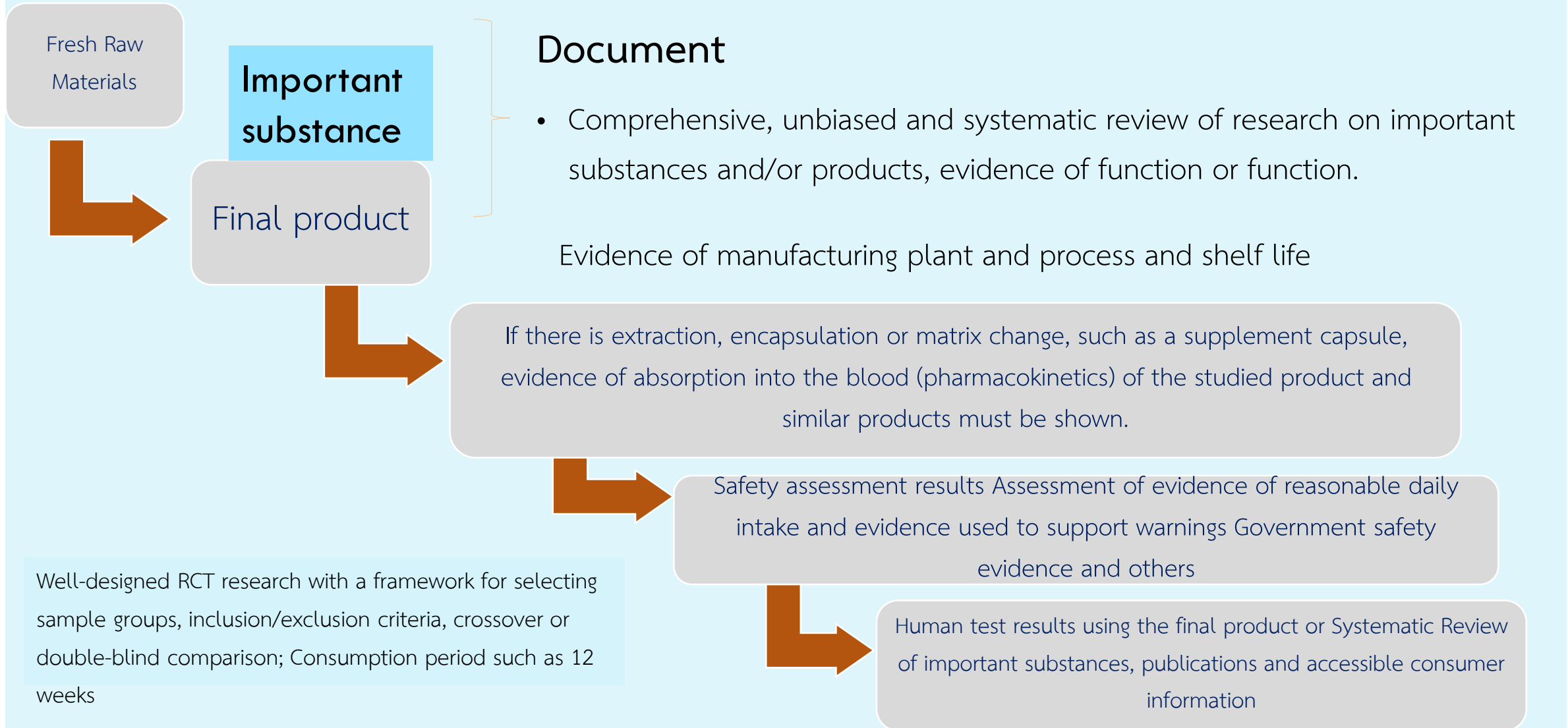
Clinical 1

- Human studies compared to +VE and -VE Control RCT model and statistically significant
- Published in a reliable journal (GLP, GCP)

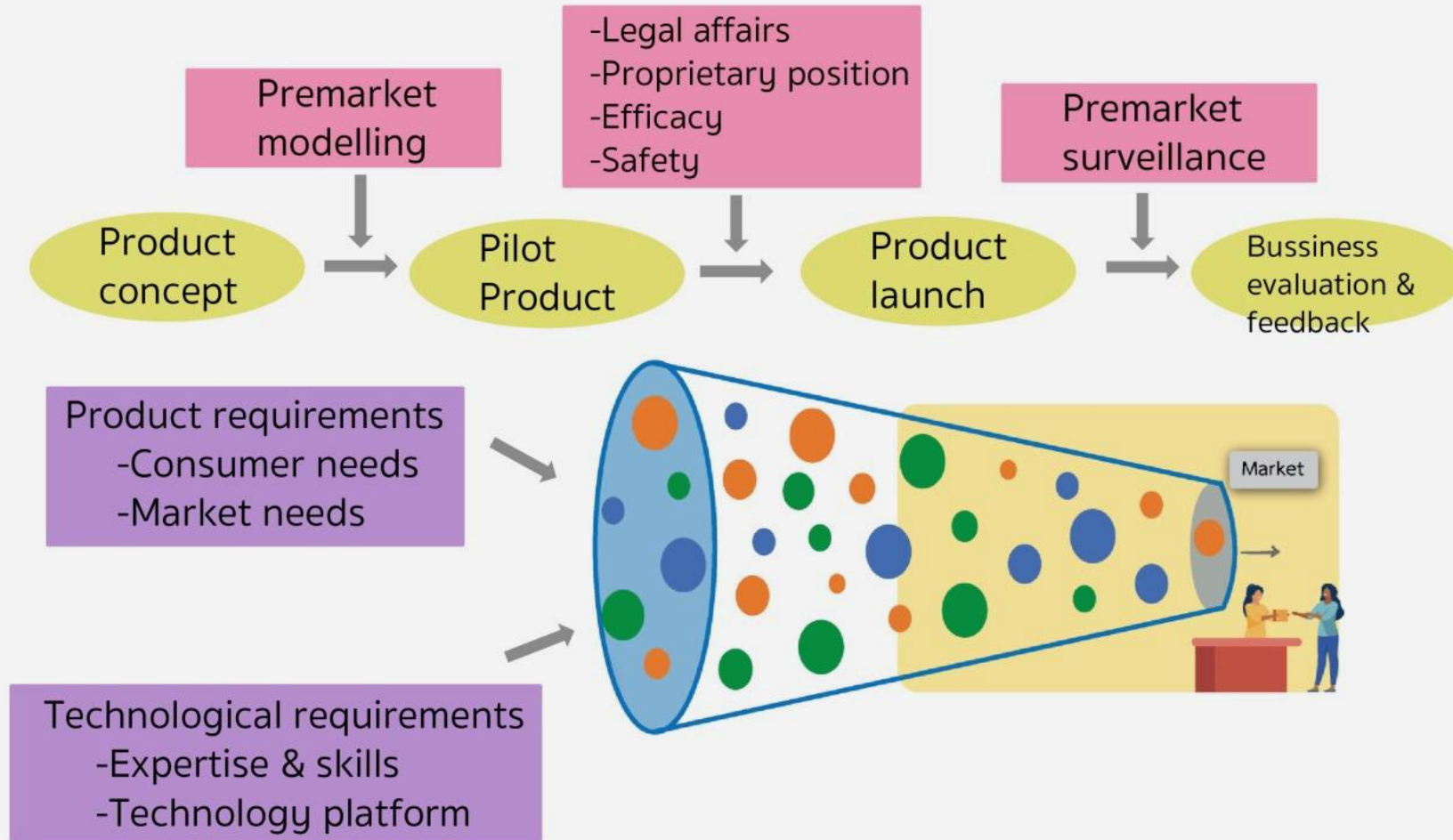
Clinical 2 Large RCT human studies (Target group) showing effective dose

**FDA gives the most weight
Does not accept results from in vitro**

Preparing evidence and reviewing literature to submit HC



COMMERCIAL R&D SYSTEM



Cross-Functional Collaboration: A Critical Success Factor for DevOps

Industrial-era thinking



From Silos,
Lack of Communication,
Multiple Handoffs

To ➡

Cross Functional Roles,
High Collaboration,
Results Oriented

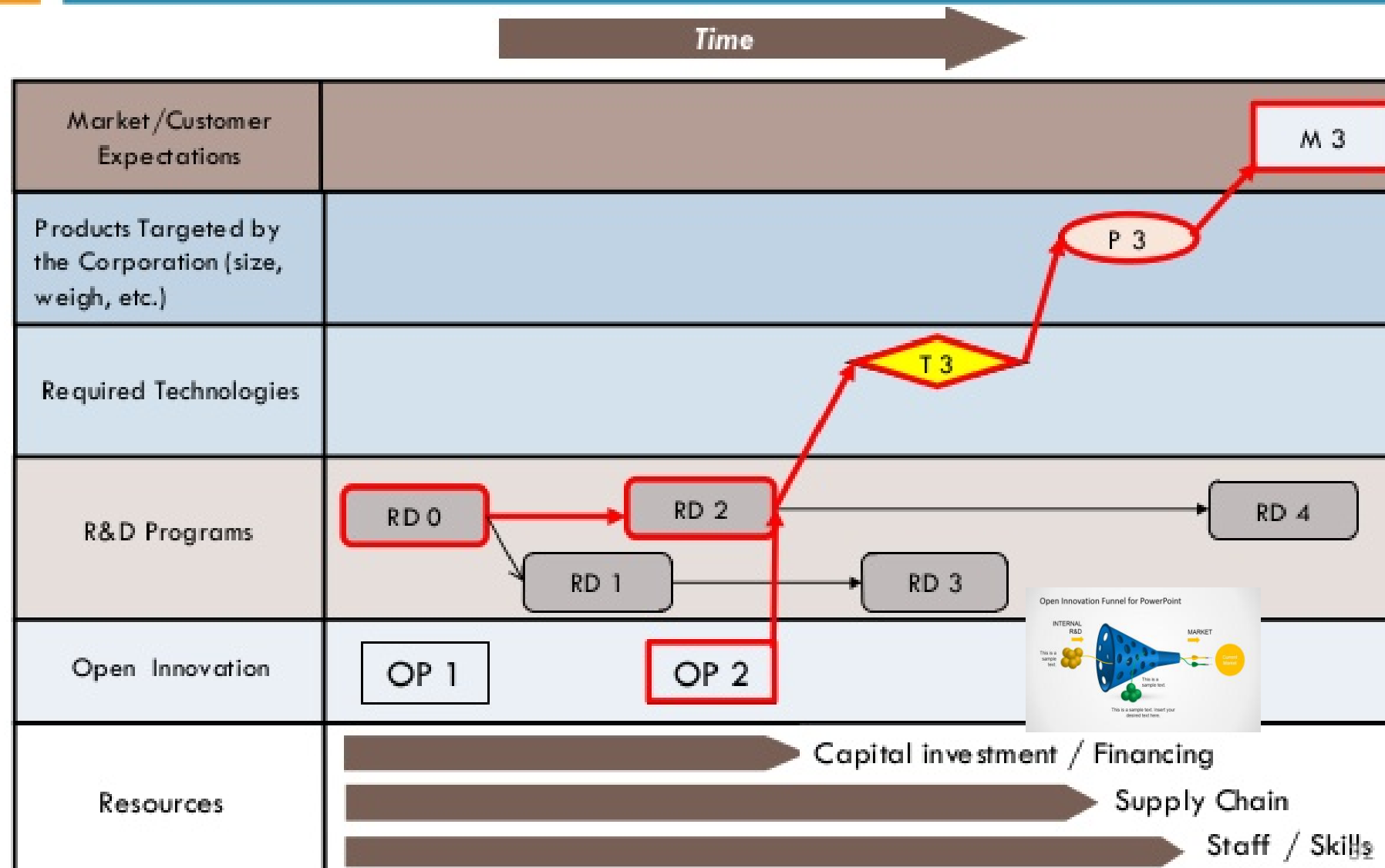
Knowledge-era thinking



Cooperation to Collaboration

- ◆ No single Function creates business value for Customer
- ◆ Business value is created only by the contribution of all the Functions

Innovation-driven technology roadmap

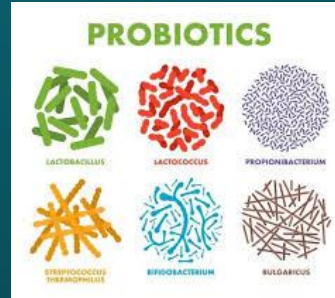


SOME THOUGHTS ON NEW CODEX ROLES ON INNOVATION OF ASIA



Plant-Based and Novel protein

- Levels and battery of tests required for safety – crude, purified, synthetic, Synbio
- Efficacy of bioactive compounds – crude, purified, synthetic, Synbio
- Analytical methods verification and required protocols
- Fortification – e.g., nano-particles (bioavailability, stability, etc.); tests required



Probiotics Health Claims

- “Probiotics “may be viewed as health effects but not clear to the consumers
- Burden of proofs to declare additional HC
- New/traditional species , post biotics, etc.
- Regulatory control of production operation to assure safety (from source and maintenance of culture to scale-up)



Traditional local Herbs and others

- CODEX and local enforcement coordination/ cooperation may need aggressive enforcement to prevent illegal products (heavy metals, steroid-tainted products, etc.)
- How can CODEX work with country operation or advocate required country systematic programs ?
- Thai FDA Health Claims example , “Low-Risk Medicine” – includes several herbal products which must meet pharma standards; whereas the Division of Herbal Products issue “Positive List of traditional Herbs”. How can CODEX engage in the safety protocols of producers?

THANK YOU



*Better
Together*

CHAIR@FIRN.OR.TH