Introducing the FDA agency and general registration principles

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Food and Drug Administration

Vision

An internationally recognized organization for the regulation of health products to ensure quality, safety and effectiveness for the protection of public health.

Mission

Control and supervise health products to ensure quality, safety and effectiveness, including the provision of services. Legal and internationally compliant

Develop the potential of consumers to have knowledge, understanding and promote correct health product consumption behavior. And appropriate

Promote and develop entrepreneurs to have competitive abilities at the international level.

Objectives within 5 years (2017-2021)

1. People consume quality and safe health products.
2. People can take care of themselves in consuming health products.
3. Entrepreneurs can raise their business standards and have the opportunity to compete internationally.

Duties and Responsibilities under the Ministerial

Regulations of 2009: 1. Carry out the law on food, drugs, cosmetics, hazardous substances, psychotropic substances, narcotics, medical devices, the law on the prevention of the use of volatile substances and other related laws.

2. Develop systems and mechanisms to enforce the laws under its responsibility. 3. Monitor, supervise and inspect the quality standards of products, establishments and advertising, including undesirable effects of products.
Develop the country's chemical safety system and act as a central coordinator in cooperation with international chemical organizations, including monitoring.

Or monitor health product information from within the country and abroad . 4. Study, analyze, research and develop knowledge, technology, and systems for consumer protection of health products to be efficient and effective. 5. Promote and develop consumers to have the potential to choose health products that are correct, appropriate, safe, and worthwhile, including to enable consumers to file complaints to protect their rights. 6.

Develop and promote health product consumer protection operations through the participation of the government sector, local administrative organizations, private sector, citizens, and health community networks . 7. Develop international cooperation to ensure that health product consumer protection is beneficial to public health and welfare.
Of the nation

8. Perform any other operations as prescribed by law to be the authority of the Office or as assigned by the Minister or Cabinet.

Reasons for the necessity of restructuring

situation

- Thailand 4.0 policy towards an industry that creates value through innovation • Development of Thai herbs to create the economy • Intense trade competition, free trade, FTA (AEC,TPP etc.)

- Trade barriers (NTB such as safety standards)

- The health product industry is developing rapidly and using modern technology . •

Thai herbal products are being applied and developed in both form and research.

- Most health industries in the country are SMEs that need support from the government.

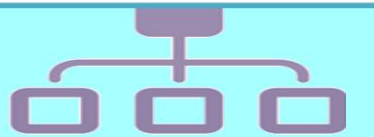
Challenges

- Adjusting the role of the FDA to support and promote the national economy • Safe health products that meet international standards
- Create security in medicine and health • Entrepreneurs are promoted and developed thoroughly by the government sector.

- Develop a regulatory system and staff capacity to keep up with technology and
- innovation, work quickly and respond to change, and build competitiveness for the private sector. •

Develop a regulatory system for herbal products that is international and does not hinder development.

- Development of participatory work practices



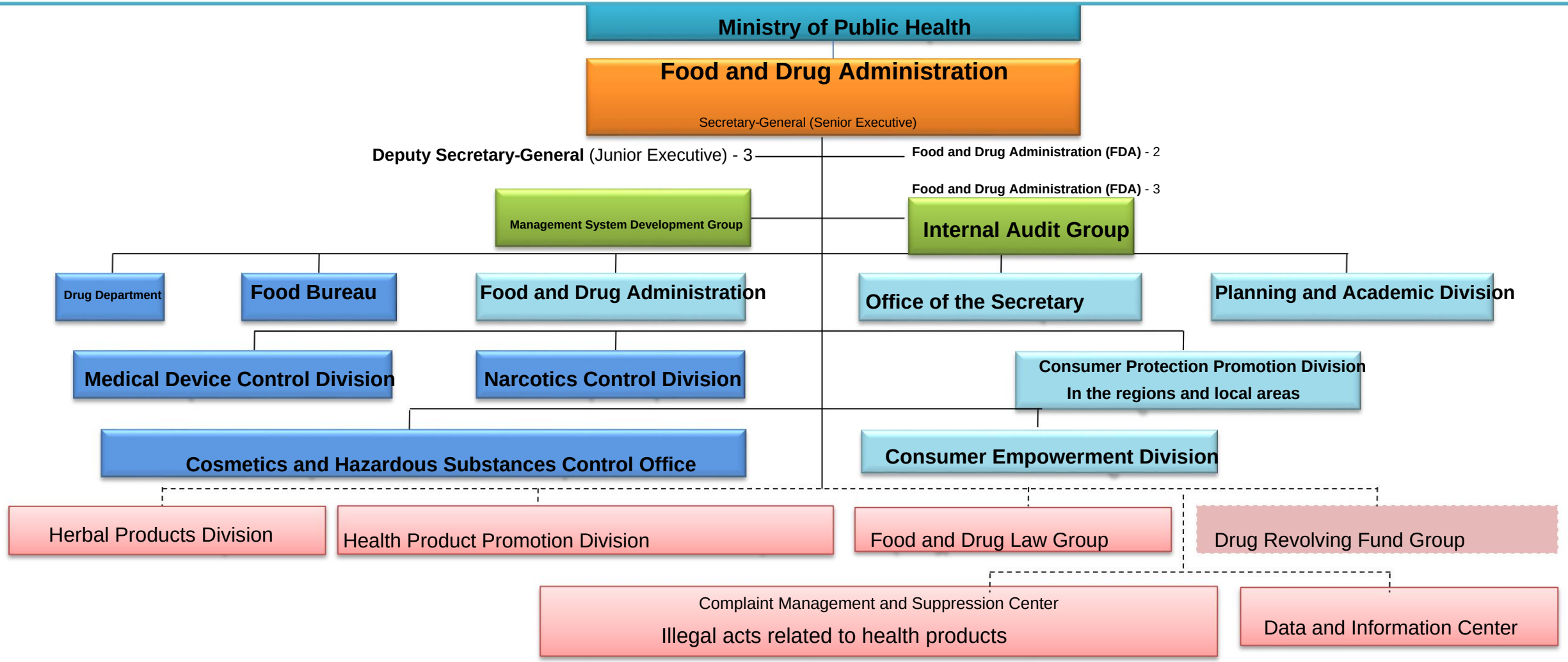
Agency 2 requests additional

1 product group

Herbs 2 Innovation

Division, Health Products and Service

Current structure

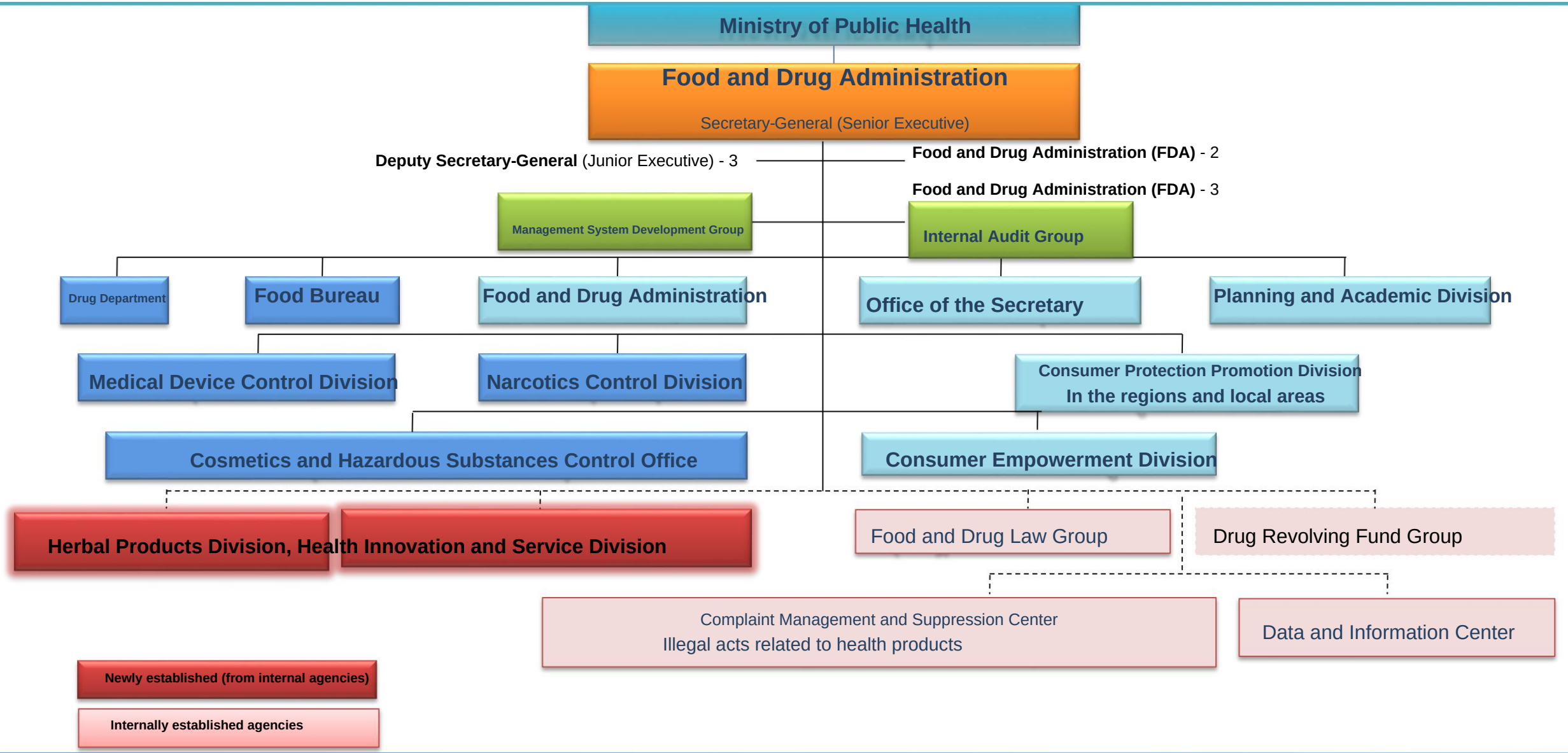


12 agencies listed in the Ministerial Regulations

6 internally established agencies

government officer	Permanent employees	Government employees
768	29	104

New structure



The Herbal Products Division was

established as an internal unit within the Office of the National Medicinal Products Policy and to conduct product evaluation and registration of research drug formulas and herbal products on January

Later, it was established as the Herbal Products Division on September 29, 2017,

- **with the authority to control, supervise, and monitor herbal products, including production locations and processes, imports, sales, and advertising to ensure they meet standards and comply with the law.**

• Study, research and develop standards for herbal products, production processes, imports, sales, clinical research and product adver herb

• Support knowledge and information for formulating strategies for developing herbal systems and national policies on herbal products. • Promote and support the production, import, sale, and advertising of herbal products to meet quality and standards as required by law. • Provide herbal information services . • Develop laws, criteria, and regulations. Rationale and necessity: o Support the policy for Thai herbs to create the national economy, the National Master Plan on the Development of Thai Herbs, and the enactment of the Herbal Products Act B.E. .... o It is necessary to have an agency to regulate herbal products used for treatment, disease prevention, health promotion, and disease risk reduction, separate from the previous agencies under various product laws, including drugs, food, and cosmetics. There are limitations in licensing and product registration, which are not conducive to the development of Thai herbal products and the domestic industry. o There must be an appropriate, internationally recognized system and criteria for licensing herbal products to build confidence in Thai he

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Traditional medicine

- Traditional Thai

medicine - Other knowledge medicine

Drug Act

- GMP ?

- The criteria are not conducive to developmen

Medicines containing herbs that are not classified as

traditional medicines and have not been developed into modern medicines

?

Herbs that may not have enough history as food in the

country but have health benefits

Dietary supplements

- Herbs to be displayed

(health claim)

Food Act

- Evaluation criteria?

- standard ?

food

Traditional

medicine - Thai medicine

- Other knowledge medicine

Herbal products to be displayed

Other health benefits

Dietary supplements

- Herbs shown

Health-promoting properties

Herbal Products Act

Herbal medicine •

Thai traditional medicine / traditional medicine

• Medicines based on medical knowledge choice

• Herbal medicine

Herbal products • **Have health effects • Reduce disease risk factors**

สำนักยา

Traditional medicine - Thai medicine

- Other knowledge-based medicines, medicines developed

from herbs, medicines that contain herbs that are not classified as ancient medicines and have not been developed into modern medicines.

Herbs that may not have enough history to be used as food in the country but have health benefits

Food Bureau

Dietary supplements

- Herbs to be displayed (health claim)

Herbal Product Divisi

ÿ

Work system

Important

of

Herbal Product

Division

System for developing criteria, methods, and conditions

• ***Criteria must be modern and cover products that facilitate innovation.***

Risk Assessment, Approval/Permission System

• ***Fast, transparent, convenient***

Entrepreneurship development system supports research and marketing •

Entrepreneurs have high competence and

are competitive • Network of agencies supports research and marketing

A proactive, comprehensive **surveillance, deterrence and law**

enforcement system *focusing on advertising in social media and low-quality products*

Health Product and Service Innovation Division

Established as an internal unit of the Health Product Innovation Promotion Institute on December 30, 2016, and the Health Product Promotion Division on

September 29, 2017. • Serves as a service center providing advice related to health product licensing and research and development, classifying products, and

receiving health product applications. • Considering and granting applications that can be provided at one point, health products researched and produced domestically and innovative products. • Developing innovative

health product licensing processes via electronic means. • Conducting research to develop work systems and establishing standards for innovative

products, locations and production processes, importing, selling, clinical research, and advertising . • Developing policies, rules, regulations, criteria

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Rationale and

Necessity: o To support the innovation-driven economic policy, it is essential to establish a system development agency to promote health product and innovation research and development. A system and mechanism for licensing health products must be established to continuously adapt to market and technological changes. o An agency must develop a licensing system and establish standards for domestically researched and developed health products and innovations to support and promote the health product industry, enabling it to enter the market and gain competitiveness through innovation. o A consulting system must be in place for entrepreneurs and researchers to ensure that they can develop and create innovative health products domestically, ensuring compliance with standard criteria and credibility according to international standards. o To enhance the quality of public services and transform opera

Self-system Transportation type Registration Nata Rab Long Jii and innovation Karma results The picture

I'm here.

1. Product classification
2. Scientific Advice/Protocol assistant
3. Stepwise registration

Health and Wellness Product Innovation Division serve

1. Coordinate, manage, organize, screen requests and provide advice on registration of research drug formulas and products.
   Health innovation through e-submission system
2. Drive the development of the health product innovation registration system.

Subcommittee/Working Group for Evaluating Health Product Registration innovation

- Pharmaceutical products
- food
- Medical equipment

Develop criteria and regulations

- Academic guidelines and registration process
- Relevant policies, laws and regulations/
  It is an obstacle.

Service

- Product classification
- Quality consultation
- Non-clinical consultation
- Clinical trial consultation
  - Prior assessment consultation
  - Pre-Application consultation
- Review application & Re-evaluation

- Non-clinical Development
- Phase I
- Phase II
- Phase III
- Market Approval
- Phase IV

Technical

process guideline

Drug
Herbal Product
Food &HS
Medical devices
Cosmeceutical

- Quality
- Non clinical
- Clinical study
- Pre & Post- Marketing
  - Q
  - ACTD
  - NC
  - C
- Health Products development
- Risk plan Management

Administrative

- Financing
- Advisory Expert Panels
- Human Resources: Evaluators & staffs
- Infrastructure/Organization
- Policy, Legislation, Regulation

Benefits of restructuring

Policy, strategy, administration

o There are new entrepreneurs and innovative health products in the country

More licensing affects the economic value of health products.

Domestic and export

o There is development and improvement of herbal products and health products and increase the poten

International competitiveness

o Reduce reliance on herbal products, medicines and other health products from abro

o Improve working methods, use technology, be fast, flexible, and efficient.

More

oPeople have choices and access to quality health products.

And more secure

o Quality service, more convenient and faster

oPeople in the country earn more income from growing herbs.

Product laws for which the FDA is responsible

ÿ Drug Act B.E. 2510

ÿ Narcotics Act B.E. 2522 ÿ

Psychotropic Substances Act B.E. 2518

ÿ Medical Devices Act B.E.

2551 ÿ Food Act B.E.

2522 ÿ Cosmetics Act B.E.

2558 ÿ Hazardous Substances Act B.E. 2535

ÿ

Measures to prevent and control the spread of COVID-19

Control of drug use Market

(Pre-marketing Control)

ÿ Requesting

permission ÿ Drug formula registration

ÿ Advertising

Drug addiction control Market

(Post-marketing Control)

ÿ The act of marking the frog

ÿÿ Entrepreneurship

ÿÿ Mahn The year of the 1970s Fall

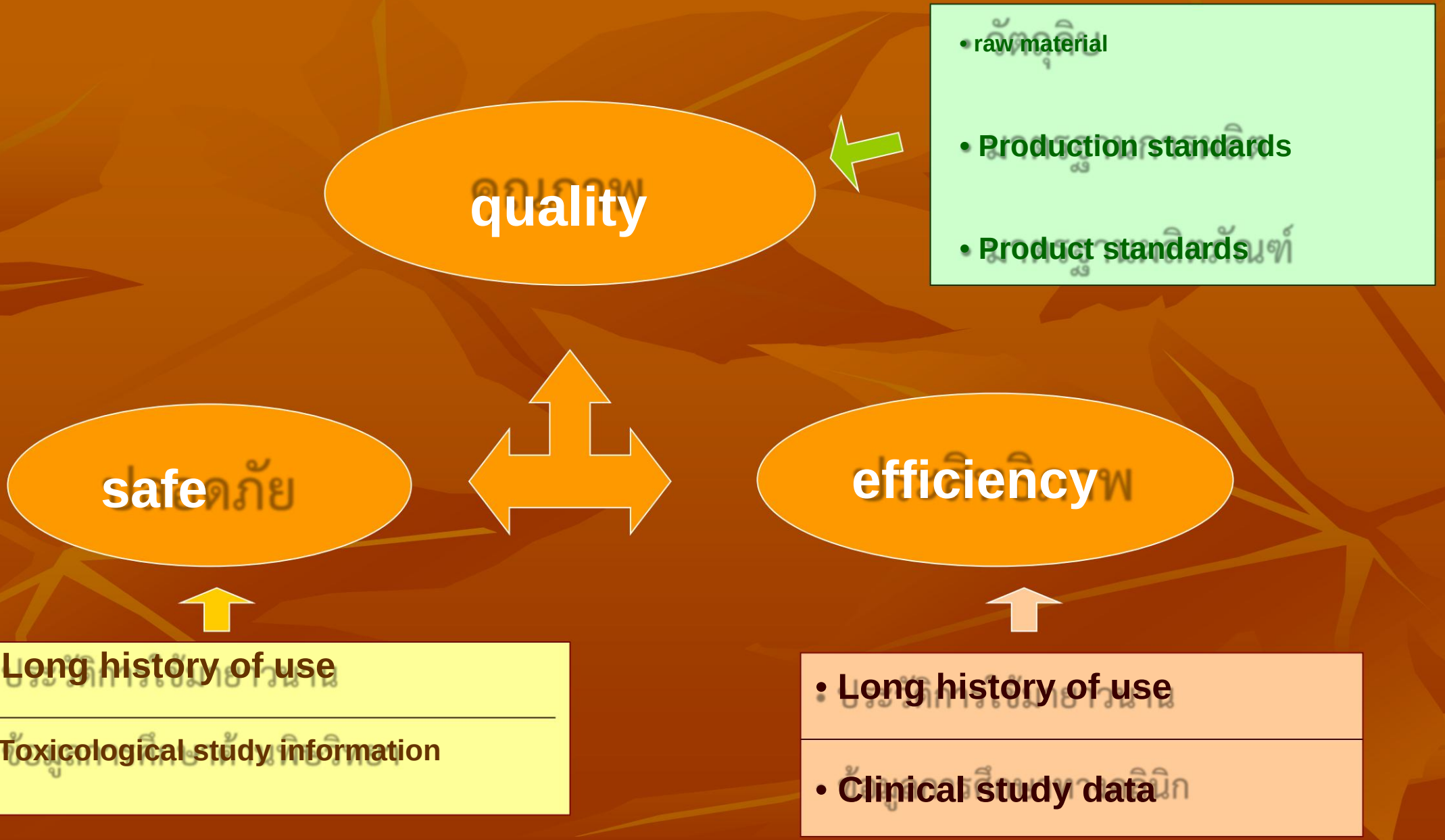
ÿProducts

Product Notification/Registration

- **objective**

- **Safety**
- **Efficiency**
- **Quality**
- **Claim**

Risk/Benefit Assessment



Definition/Classification

“Medicine” means

ÿ (1) Object I guarantee it in the eyes of the Lord Minister's announcement

ÿ (2) The object is intended for Used in the loop D.C.C. Treat, relieve, cure or prevent disease or pain My sickness A person who is a human being or a creature

ÿ (3) Objects It is a drug. Chemistry, Chemistry, Chemistry Gong Sarejorn I am PharA

ÿ (4) The objects that are intended for have Give it to me Ked Pholkaes Any condition, structure or function Of the human body or animal

Food Act B.E. 2522

“Food” under the Food Act means *food,*

Or Akeorongkham, until the end of the world including :

(1) All types of objects are interconnected. DMom or Ana he A

The body does not draw In any way or in any form, but

no including the length of the vehicle The brain and nerves or

Effectiveness of the drug

Narcotics under the law

Depending on the case

(2) The object that is intended for Use or Yes It is an ingredient in

Food production including food additives, colors and

Kre Organization Ginger S

Food type

- Special diet foods
- Food quality control or standard
- Foods that must be labeled
- Food go

Food ingredient safety assessment

Public Health Ministry (No. 376) B.E. 2016 regarding new food

New food

It has a history of use as food for 15 years or more.

Has a history of use as food for less than 15 years/
has a production process that is not the general production process of that food.

- Toxicity and mutagenicity testing
- Allergens,
- nutritional value,
- other

Assessor Risk

allow

- safe

x is not safe

Not allowed

Health Claims

ÿ **Displaying any pictures, images, invented designs, marks, trademarks or any text on the label related to food, food ingredients or nutrients related to h**

Direct and indirect

1. Nutrient function claims 2. Other function claims 3. Reduction of disease risk claims

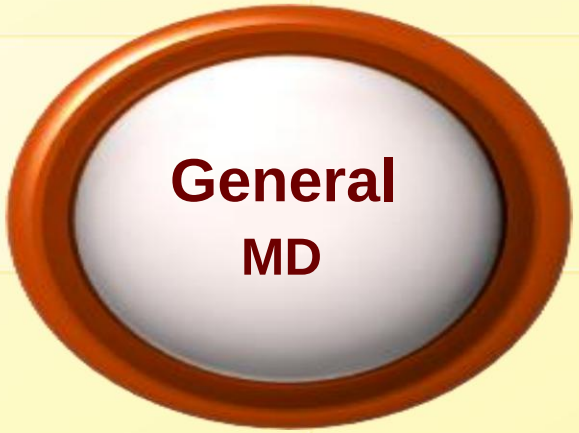
Scientific evidence to prove health claims

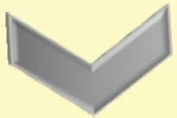
Nutritional function claims	Claims of other duties	Claims of reducing the risk of disease
Systematic review and meta-analysis **Published in a credible journal or**	**A full report of a well-designed human intervention study published in a reputable journal and one of the following documents :**	
Accepted and reliable academic opinions from **An agency, organization, or scientific expert group that** **Internationally accepted or**	**(1) A systematic review and meta-analysis published in a reliable journal or**	
Reports well-designed human studies **(Well-designed human intervention study)**	**(2) Academic opinions that are accepted and reliable from agencies, organizations or groups of experts** **Internationally recognized science**	

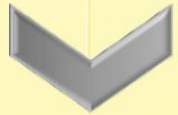
Supporting documents

- Academic papers published in reliable journals (Peer-reviewed published articles)
- Observational epidemiological studies (Observational evidence)
- Animal studies
- Academic texts, reference texts (Evidence-based reference texts)
- *In vitro* studies

Classification of Medical Device







Licensing

Notification

Importers intending to import these MD are required to submit CFS from the country of manufacturer (origin) to get FDA Certificate for Custom process

Classification of MD

I. Licensed MD

- Condom
- Surgical glove
- HIV test kit for diagnosis
- Contact lens

II. Notified MD

- Physical therapy device
- Alcohol detector
- Silicone breast implant
- Breast enhancement

III. General MD

- Other than I & II

	United States	European Union	Canada	Singapore
Philosophy	Risk based Classification	Risk based Classification	Risk based Classification Risk	based Classification
Regulatory Framework	• Food, Drug & Cosmetics Act • Code of Federal Register (CFR)	• 90/385/EEC • 93/42/EEC • 98/79/EEC	•Food & Drugs Act •Medical Device Regulations	•Health Products Act •Medical Device Regulations
Classification Systems	Class I (Exempt + General Controls) Class II (Gen + Special Controls) Class III (Gen + Special Controls + PMA)	Class I, IIA, IIB, III (4 Classes)	Class I, II, III, IV (4 Classes)	Class I, IIA, IIB, III (4 Classes)
Conformity Assessment	• Premarket Approval (PMA) by FDA • Premarket Notification (510k) by FDA and 3rd parties accredited by FDA • Quality System • Vigilance Reporting	• Evaluation by Notified Bodies • Quality System / Type Testing • Vigilance Reporting	• Evaluation by Health Canada • Quality System (ISO13485 mandatory) • Vigilance Reporting	• Full Evaluation by HSA (1st Country) • Abridged Evaluation by HSA (Benchmarked GHTF) • Quality System • Vigilance Reporting

Direction of MD Reclassification

Situation Base Classification		Risk Base Classification
• General MD	→	• Low risk
• Notified MD	→	• Low-moderate Risk • Moderate-high risk
• License MD	→	• High risk

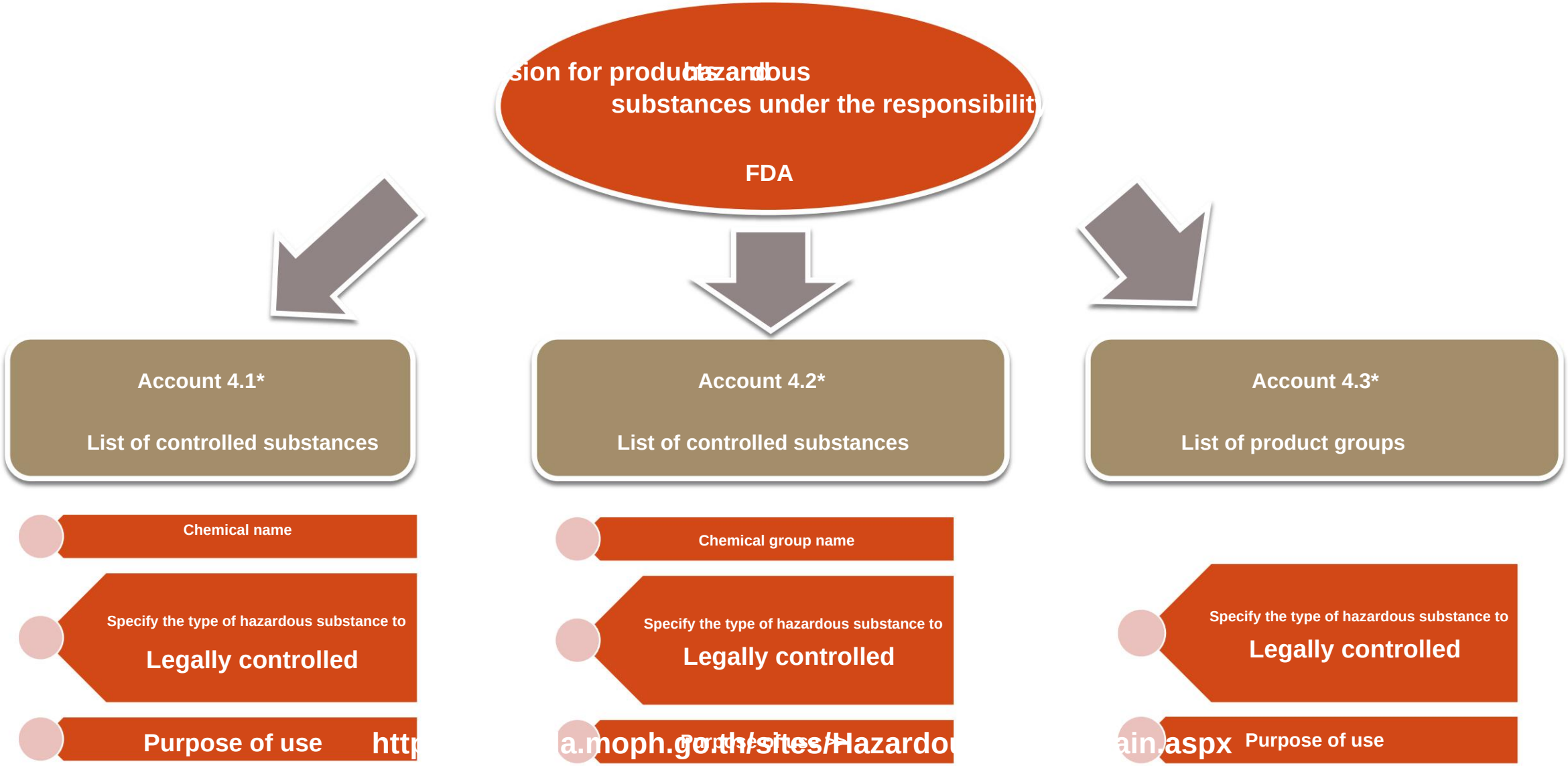
products and hazardous substances

Under the responsibility of

FDA

Products used in households or public health

- Prevent/repel/control/ eliminate insects and other animals
- Eliminate rodents (e.g. rats)
- Disinfect/ clean floors, walls, sanitary ware and other materials or fix blockages. Clogged pipe or drain Waste
- Washing white clothes , disinfecting or eliminating odors in swimming pools
- Products for erasing or correcting mistakes or for dissolving chemicals used for erasing o Wrong word or dry cleaning of fabrics or other textiles



*List of hazardous substances attached to the Ministry of Industry Announcement on the List of hazardous substances B.E. 2556 and the revised editions (No. 2 B.E. 2558, No. 3 B.E. 2559 and No. 4 B.E. 2560, List 4 for which the Food and Drug Administration is responsible.

Requesting permission for products based on the type of hazardous substance

Type 1 (W.1)

Report facts about the object

Type 1 hazard

Type 2 (W.2)

Product registration

Production/storage location

Notification of action

Production/Import

Type 3 (W.3)

Product registration

Production/storage location

excuse me

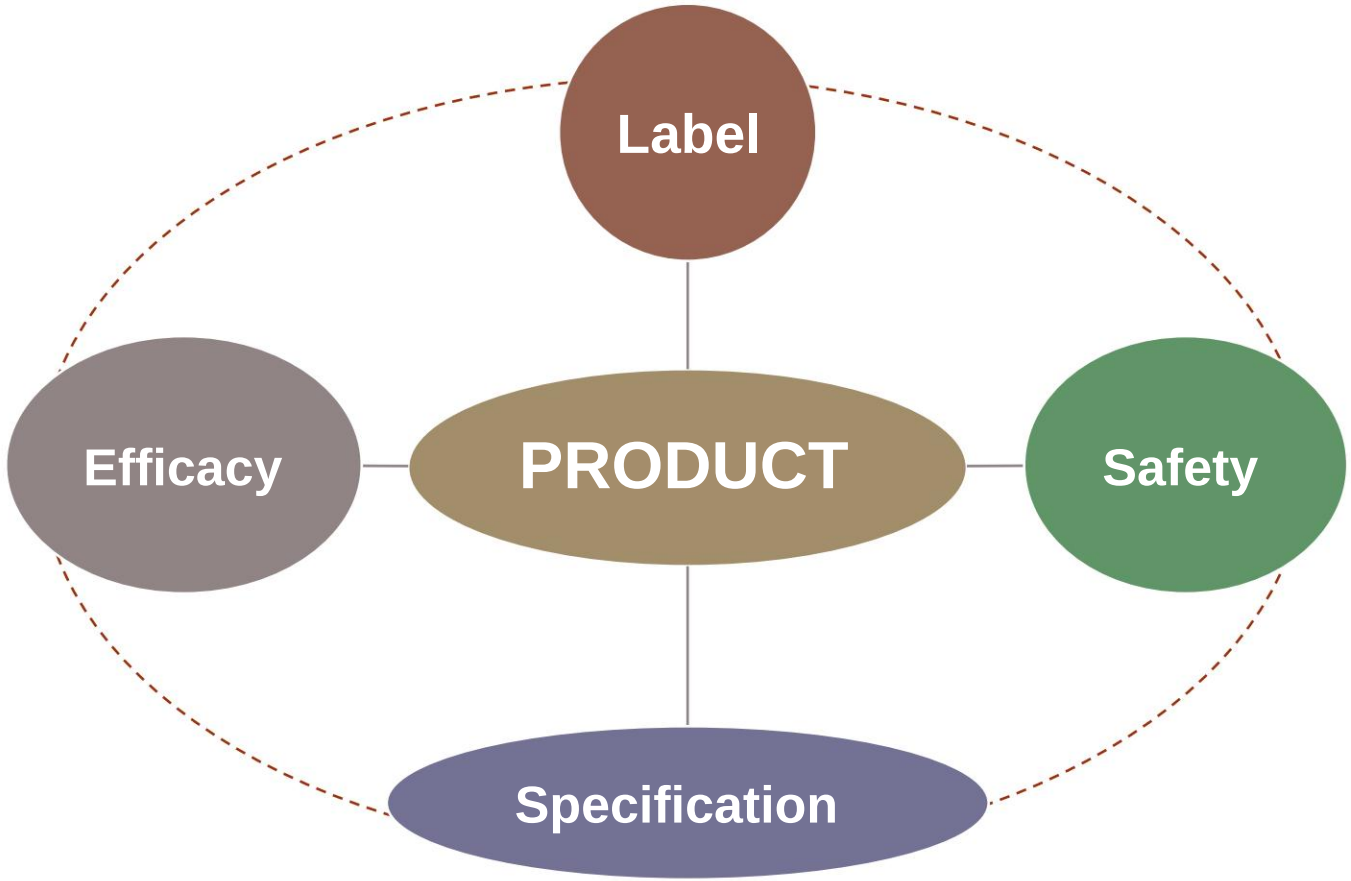
Production/Import

Type 4 (W.4)

Prohibited for production, import, expor

In possession

Registration of hazardous substances



Things to know about cosmetics

According to the Cosmetics Act 2015, “cosmetics” means

- **Objects intended** for use in applying, rubbing, massaging, sprinkling, spraying, dropping, inserting, fumigating or performing any other action on a part.

  Any part of the human body including the use of teeth and oral mucosa

- **The purpose is to clean,** beautify, or change the appearance, or prevent body odor,

  or protect and maintain various parts in good condition, including various cosmetics for the ski

  too

- **But does not include** jewelry and clothing which are external devices of the body, objects intended

  for use as ingredients in the production of cosmetics specifically, or objects specified by the

  Ministerial Regulations as cosmetics.

Cosmetics registration

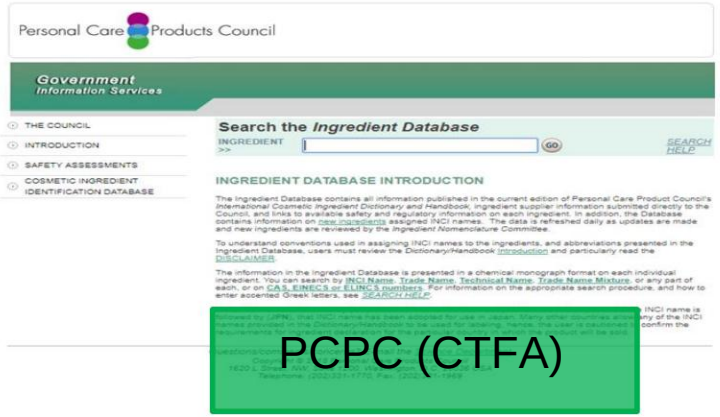
Anyone who wishes to manufacture for sale, import for sale , or contract to manufacture cosmetics must notify the registrar of the details of the cosmetics. Only after the registrar issues a notification receipt can the cosmetics be manufactured or imported." (Section 14 of the Cosmetics Act) 2015)

Filing a notification application

- **Submit application documents**
  - **• FDA (OSSC) / Provincial Public Health Office**
- **Submit via computer network**

A registration certificate is valid for three years from the date of issue. Renewal of a registration certificate must be submitted before the expiration date. If the registration certificate has expired within one month, an application for renewal and an extension may be submitted, stating the reason and paying the renewal fee (Section 15 of the Cosmetics Act 2015).

Notification of substance names in the cosmetic notification system

Substance Notification System	International Cosmetics Guide
International name : INCI Name	 Cosing
Color: CI Number	 PCPC (CTFA)
plant : Botanical Name + part of use + preparation	

New substances have no data in the cosmetic system.

The Director of the Office of the Public Sector Development Commission (OPDC) wrote a letter to the Director of the Office of the Public Sector Development Commission requesting the addition of a new name.

Submit the document at the Office of the Attorney General (Building 4, 4th Floor)

There is information in the cosmetic textbook.

Attach reference documents:

- Cosing
- PCPC (CTFA)

Fee: None

The officer added the information into the system (within 10 business days).

There is no information in the cosmetic formula.

Attach academic documents regarding safety information and past use history.

Fee ÿ 30,000

baht (chemicals or herbs without research) ÿ
15,000 baht (Thai herbs with research but not yet published in a reliable journal) ÿÿ No fee (Thai herbs with research published in a reliable journal)

The officer added the information into the system (within 60 business days).

In the case of using herbal ingredients that do not have information in the **cosmetic**

formula (international) ÿÿ **Follow the safety assessment criteria for herbal ingredients used in ASEAN cosmetics.**

ÿÿIn cases where the characteristics of the herbal ingredients are incomplete, toxicity testing should be considered. However, toxicity testing may not be necessary for herbal ingredients used according to traditional wisdom. ÿÿIn

cases where there is complete and sufficient safety data on the use of herbal ingredients as food and they are widely used, clinical safety data may be sufficient to support the use of the herbal ingredients in cosmetics.

การประเมินความปลอดภัยของวัตถุดิบสมุนไพรที่ใช้ในเครื่องสำอางอาเซียน

Characteristics of raw material

- Source of raw materials
- Physical characteristics
- History of use according to region
  Traditional wisdom
- Preparation method
- Chemical characteristics (if any)
- Contamination

Exposure

- Product type
- Amount used
- Population group
  Targets such as children and adults
- How to use

Testing Toxic

- The creation of Mutation
- UV absorption
- Sensitization
  Stimulates allergic reactions skin
- Irritation
- Toxicity
  Body systems

Assessment of risk

- History of use safe
- Assessment compare
- Evaluation by method TTC
- Allergy assessment
  Only in the body

Overall Summary

• **Production site standards :** ISO, **GMP** ASEAN/ PICs • **Registration**

• Document formats:

CSDT, ACTD, eCTD • Quality • Raw material

Specification

• GAP,GMP,GTP • Active ingredient •

Finish Product

Specification • Active

Ingredient • Microbial contamination

• Heavy Metal

• Stability

• Safety / efficacy •

GCP, GLP, ISO