Section 2. Thai FDA Regulatory Framework

Knowledge Empowers Business – Forum 2025

A Workshop on Compliance and Global Market Access

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THAI FDA REGULATORY FRAMEWORK FOR FOOD SUPPLEMENTS OVERVIEW & MARKET ENTRY

General Regulatory Landscape - Authorities & Scope

Thai FDA under the Ministry of Public Health Regulates **health supplements** under *Food Control Act*
Specific notifications, announcements, regulation on vitamins, minerals, and functional ingredients

Restrictions

No therapeutic claims (e.g., prevent, cure, treat) are allowed
Any "grey area" ingredient must be justified with safety data or scientific evidence
Novel ingredients not previously approved require separate review

Key Note: reading the Food Control Act **won't help you to understand the registration process**

THAI FDA – LIST OF FUNCTIONAL FOODS

13.0	foodstuffs intended for particular nutritional uses
13.1	infant formulae, follow-on formulae, and formulae for special medical purposes for infants
13.1.1	infant formulae
13.1.2	follow-up formulae
13.1.3	formulae for special medical purposes for infants
13.2	complementary foods for infants and young children
13.3	dietetic foods intended for special medical purposes
13.4	dietetic formulae for slimming purposes and weight reduction
13.5	dietetic foods
13.6	**food supplements**

THAI FDA – DEFINITION OF DIETARY SUPPLEMENT

"Supplemented food" refers to a food product that is intended to supplement the normal diet and contains one or more of the following:

- Vitamins
- Minerals
- amino acids
- fatty acids
- Fiber
- other substances with nutritional or physiological effects

provided in a dosage form such as capsules, tablets, powders, or liquids — and not presented for the treatment or prevention of disease or targeting any specific category of consumer

BASIC REQUIREMENTS FOR REGISTRATION

Finished Product

1. Manufacturer's Quality Standard Certificate (ISO, GMP, HACCP, others)
2. Notification or registration depending on product type
3. Thai-language labeling with permitted claims
4. Nutritional labels (now mandatory for almost all products)
5. Allergens (if mentioned in the original label)

Raw Material

You must hold an import license for food
The ingredient must be notified to the FDA as a raw material, not as a finished food product
Some substances (especially botanicals or functional extracts) may require a safety review

BASIC RULE FOR ALL FOOD PRODUCTS

When we register the product we pick all the ingredients to a list.
We MUST use exactly the same definition as in FDA system, that can't be changed

Fda Number	Name of substance	Cas No.	Ins No.	Type of substance
N-0022826	SODIUM ASCORBATE (PROVIDE VITAMIN C 88%)	134-03-2	301	NU
N-0015519	VITAMIN C (100%)	50-81-7	300	FA/NU
N-0021588	Vitamin C (98%)	50-81-7	P98	NU
N-0026139	SODIUM ASCORBATE (PROVIDE VITAMIN C 20%)	134-03-2	301	NU
N-0027295	NON-ACIDIC VITAMIN C (PROVIDE VITAMIN C 84 %)	-	-	AI
N-0030594	NON-ACIDIC VITAMIN C (PROVIDE VITAMIN C 80 %)	-	-	AI
N-0030769	Vitamin C (99%)	50-81-7	-	NU
N-0034567	LIPOSOMAL VITAMIN C* (Ministry of Public Health 1010/3355 dated 21 Feb. 2023)	-	-	NU
N-0034580	VITAMIN C (99.75%)	50-81-7	-	NU
N-0034800	LIPOSOMAL VITAMIN C* (Ministry of Public Health 1010/10601 dated 25 June 2024)	-	-	NU
N-0034885	LIPOSOMAL VITAMIN C* (Ministry of Public Health 1010/14858 dated 9 September 2024)	-	-	NU

COMMON ISSUES DURING REGISTRATION

1. Quality Certification can't be verified – need a certified true copy in paper
2. Product name is considered misleading or overclaiming
3. Ingredients are not in positive list of Thai FDA
4. Quantity of vitamins and minerals exceed the maximum daily intake
5. Claims are excessive
6. Product is not considered a dietary supplement

Takeaway note

Thailand has its own regulatory framework.
Avoid the common mistake of saying, *"But my product is registered in the USA…"* — that argument doesn't apply here.

COMMON ISSUES BY COUNTRY

USA: **R**egulation is weak compared to Thailand and 70% of products exceed Thai RDI
Some ingredients widely used in US are not allowed in Thailand

RUSSIA: Many herbal ingredient widely used in Russia are not allowed in Thailand
Quality Certificate are not compliant with international regulations

EUROPE: Many products classified as supplements in Europe are drugs in Thailand
Minerals often exceed the max allowed in Thailand

CHINA: Pharmacopoeia is different, and many herbal ingredients fall in the category of “herbal medicine“
Quality Standard Certificate are not compliant with international regulations

JAPAN: The quasi-drug are not existing in Thailand: or food or drugs or cosmetics

STEPS OF POST-REGISTRATION

1. Apply the Thai label on packaging BEFORE importing is generally safer
2. Undergo laboratory test before selling, including:
    1. Microbiological test
    2. Heavy metal test
    3. Vitamin/mineral test (only for those mentioned in the product name)
    4. Probiotic test (if any)