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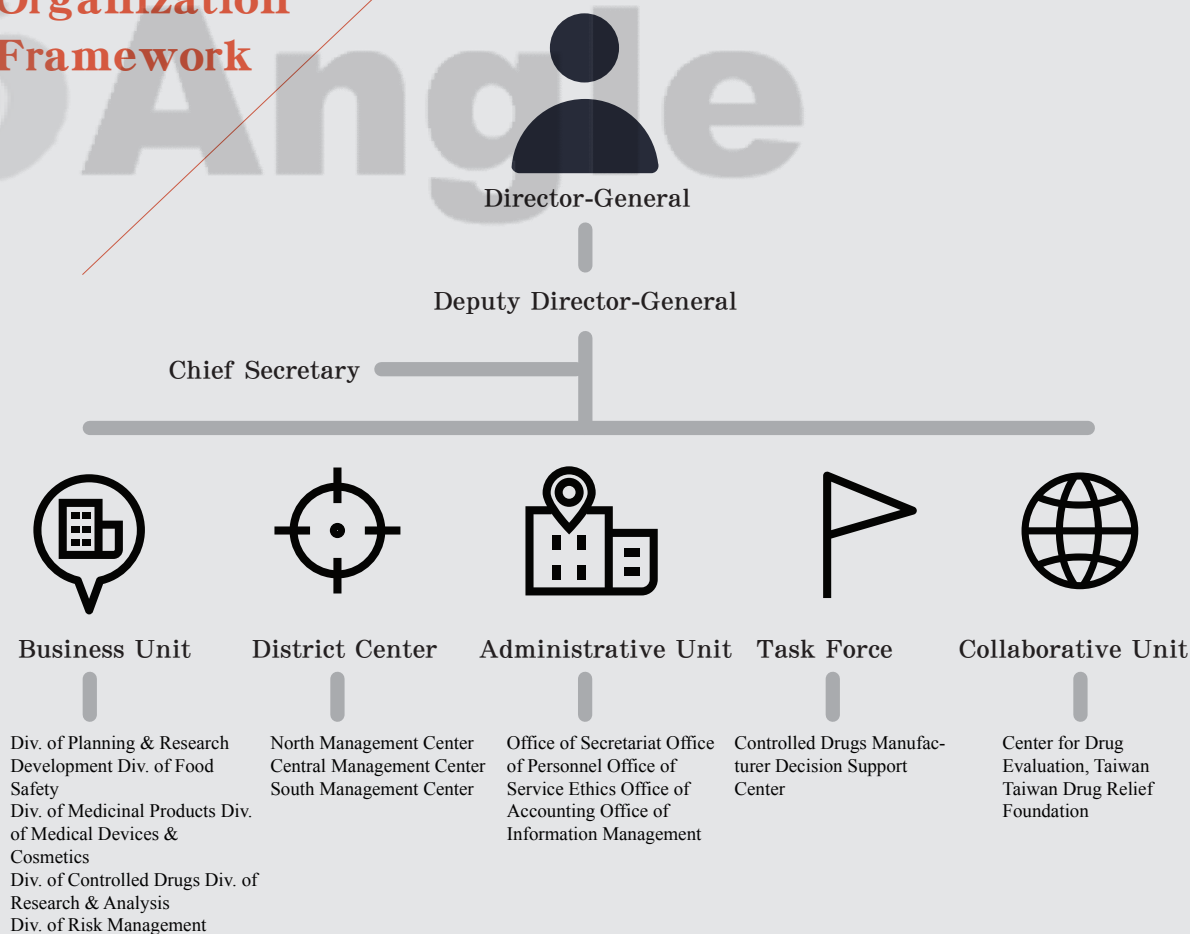
09

# Organization Introduction and Future Perspectives

Section 1. Organization Framework

Section 2. Business Perspectives

## Organization Framework



## 2016 Administrative Objectives

To strengthen food and medicinal products safety and safeguard public health



### Total product life cycle quality management

Promote total product life cycle quality management of food, medicinal products and cosmetics, and establish a modern policy and legal environment aligned with international standards based upon product quality and safety to restore the reputation of Made In Taiwan (MIT) food and medicinal products.



### Prohibition of illegal products

Promote cross-departmental collaboration for the prohibition of illegal medicinal products, intentionally adulterated food products, and reduce drug abuse, and integrate central and local monitoring and work specialization systems to safeguard the rights and interests of fellow citizens relating to food and medicinal products.



### Based upon risk assessment

Continue to enhance source management of food imports based upon risk assessment, implement the three division strategy for food additives, and promote cloud-based management system for food products in order to achieve transparency of food information and build a food safety defense network.



# Organization Introduction and Future Perspectives

To effectively control food, medicinal products and cosmetics on the market, prohibit illegal matters, prevent and control drug abuse and align with international management standards. Food and Drug Bureau, Department of Health was recognized as Food and Drug Administration, Ministry of Health and Welfare on July 23, 2013.

Based on the administrative policies of Executive Yuan, TFDA aims to strengthen the control of food and medicinal products sources, production and distribution, the directions of raw materials and import products to achieve product transparency, protect consumer's safety and provide an environment of "safe drug and healthy food" for the consumers (Figure 9-1).



Figure 9-1 TFDA visions and missions

## » Section 1. Organization Framework

(1) TFDA comprises seven business units: The div. of planning & research development is responsible for the overall planning of the entire organization. Divisions of Food Safety, Division of Medicinal Products, Division of Medical Devices & Cosmetics as well as Division of Controlled Drugs are products and relevant provision management units. TFDA also has a Division of Risk Management, Division of Research & Analysis as well as Northern, Southern, and Central centers

for managing product quality assurance, factory management, distribution, and auditing. An additional five administrative offices were also established to support TFDA's administration and management, namely: Office of the Secretariat, Office of Personnel, Office of Service Ethics, Office of Accounting, and Office of Information Management (Figure 9-2).

- (2) TFDA also has two task force organizations of the Factory for Controlled Drugs and the Food and Drugs Intelligence Center to cater to changing social trends. The Factory for Controlled Drugs proposes relevant business activities according to the nature of its tasks and specific project requirements, and initiates close partnerships with professional consultants such as the Center for Drug Evaluation and Taiwan Drug Relief Foundation. The “Food and Drugs Intelligence Center” was established by TFDA on September 2, 2015 in order to acquire adequate information on food and drugs in Taiwan. This Center use big data analysis techniques to assess the risks and trends of food and drugs development in Taiwan and other countries, implement source management, and safeguard the health of the entire population.

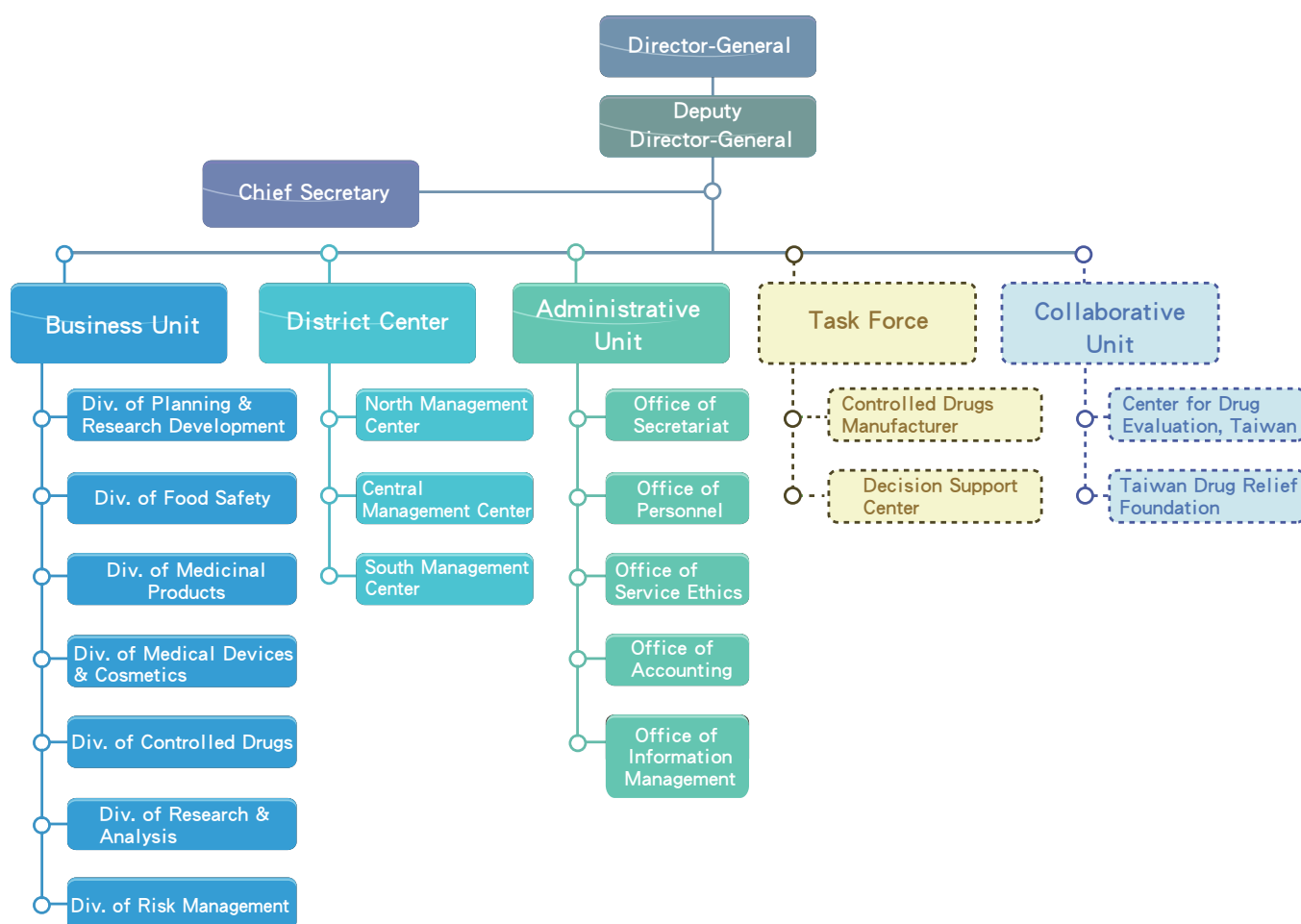


Figure 9-2 Organization framework

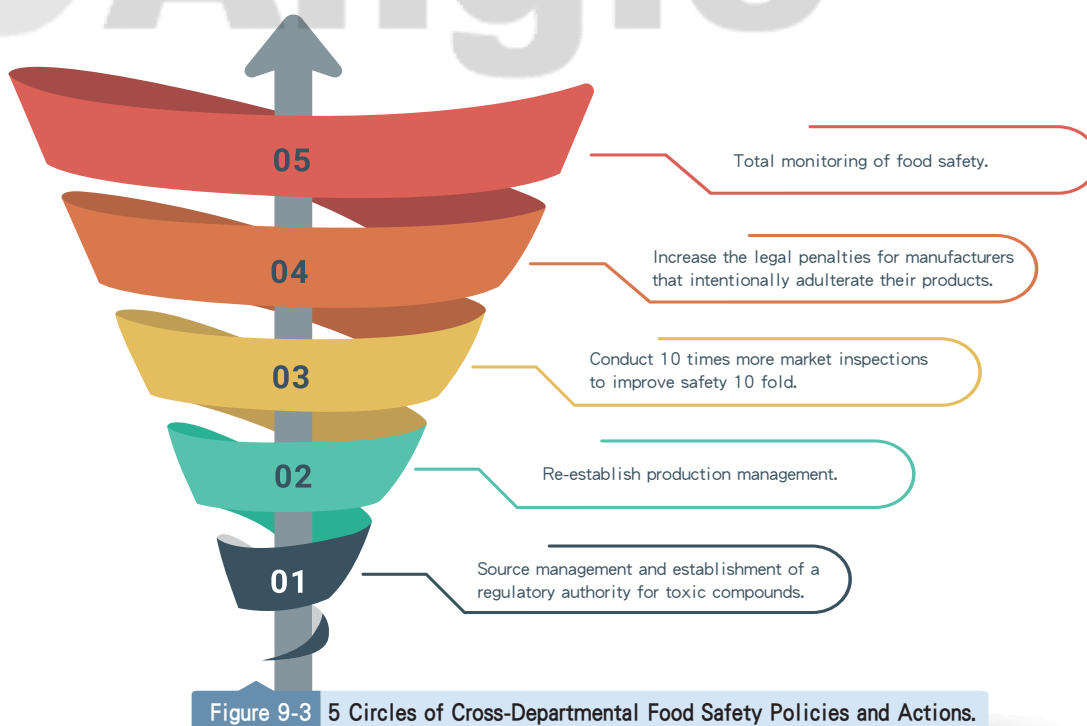
## » Section 2. Business Perspectives

### 1. Administrative goals

- (1) Promote total product life cycle quality management of food, medicinal products and cosmetics and establish a modern policy and legal environment aligned with international standards based upon product quality and safety to restore the reputation of Made in Taiwan (MIT) food and drug products.
- (2) Promote cross-departmental collaboration for the prohibition of illegal drugs, intentionally adulterated food products, and reduce drug abuse Integrate central and local monitoring and work specialization systems to safeguard the rights and interests of fellow citizens relating to food and drugs.
- (3) Based on the results of risk assessment, continue to enhance source management of food imports based upon risk assessment, implement the “three division strategy” for food additives, and promote cloud-based management system for food products in order to achieve transparency of food information and build a food safety defense network.

### 2. Administrative highlights

- (1) Promote Food and Drugs Management Capacity, Implement Source Management and Safeguard Consumer Safety:
  - A. Amendments for Product Management Regulations.
  - B. Strengthen Management of Product Manufacturing.
  - C. Comprehensive Product Review Management.
  - D. Strengthen Product Distribution Audits and Quality Monitoring.
  - E. Strengthen Laboratory Testing Capabilities.
  - F. Strengthen International Collaboration and Cross-Straits Exchanges.
  - G. Reinforce Risk Management.
- (2) Enhance and Strengthen the 5 Circles of Cross-Departmental Food Safety Policies and Actions (Figure 9-3).
  - A. 1<sup>st</sup> Circle: Source management and establishment of a regulatory authority for toxic compounds.
  - B. 2<sup>nd</sup> Circle: Re-establish production management.
  - C. 3<sup>rd</sup> Circle: Conduct 10 times more market inspections to improve safety 10 fold.
  - D. 4<sup>th</sup> Circle: Increase the legal penalties for manufacturers that intentionally adulterate their products.
  - E. 5<sup>th</sup> Circle: Total monitoring of food safety.



(3) Continue developing the biotechnology and pharmaceutical industries:

- A. Ensure comprehensive development of the biotechnology sector and establish systems to promote drugs safety and quality.
- B. Establish and harmonize legal environments for medical drugs trade and commerce.

### 3. Future perspectives

With the trends of global trade and the development of technology, problems relating to food safety and sanitation become more and more complicated. Therefore, management with higher perspectives is required to establish several control gates. In the meanwhile, inter-departmental streaming can enhance the responsibility of management among businesses to ensure the safety of products and protect the rights and interests of the consumers.

It is the government's duty to protect the safety of food and medicinal products. TFDA integrates different departments and businesses and expand the participation of the public to construct a safe protection network for agriculture and food industry, establish an excellent "safe medication and healthy food" environment.