



Organization Introduction and Future Perspectives

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Public Trustworthy Guardian of Food & Medicinal Product Safety Creating a Safe Food & Medicinal Product Customer Environment

Regulations and management will continue to advance with the times

Strengthen the management of the imported products and their raw material

Improve the quality of manufacturing processes and management

Master the distribution of products and their raw material

Protect food, drug, and cosmetic safety for the consumers



Future Perspectives

Execute the perspective plan on Food Safety Establishment

Improve food safety management, and implement Five-point Food Safety Policy

Establish a traceability and follow-up system for medicinal products to prevent counterfeits from entering the legal supply chain.

Expedite the stipulation of medical device exclusive laws and the addendum / amendments on sanitary management regulations for cosmetics.

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Organization Introduction and Future Perspectives

Nowadays, with the development of society and economy as well as the increase of public health awareness, the quality and safety of food, medicinal products and cosmetics have become one of the focused livelihood issues. To be in line with international management trends, and effectively strengthen the control of food, medicinal products, and cosmetics, Food and Drug Bureau was established on January 1, 2010, which integrated relevant units in Department of Health (former “Ministry of Health and Welfare”). Afterward, in response to the organizational reform project proposed by Executive Yuan, Food and Drug Bureau was officially renamed as “Taiwan Food and Drug Administration, Ministry of Health and Welfare” (“TFDA”) on July 23, 2013. TFDA aims to establish a complete and safe food and medicinal product management system to achieve the vision of “Being a reliable guardian on food and medicinal product safety” and “Creating a safe food and medicinal consumer environment.” (Figure 7-1)

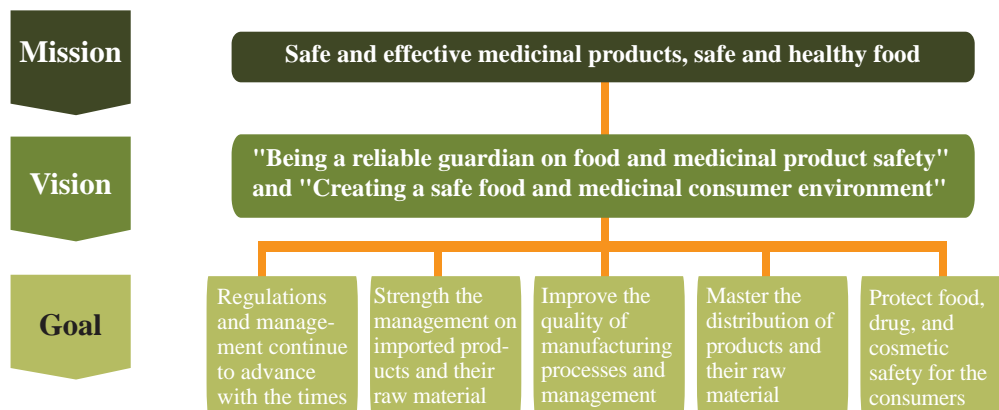


Figure 7-1 TFDA visions and mission

Section 1 Administrative Goals

TFDA sets the administrative goals and focuses based on the administrative policies of Executive Yuan and administrative programs of MOHW along with the budget plans, current development highlights and social needs on food, medicinal products and cosmetics management in 2017.

1. Promote total product life cycle quality management of food, medicinal products and cosmetics.
Under the premises of quality and safety of food, TFDA established a modern policy and legal environment aligned with international standards to restore the reputation of Made-in- Taiwan (MIT) food and drug products.
2. Promote inter-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. Recognize real-time public opinions, facilitate information transparency, and construct a safe protection network for food and medicinal products.

Section 2 Organization Framework

Director-General is the recommending officer of all TFDA-related businesses, and 2 Deputy Director-General and 1 Chief Secretary directly respond to Director-General's commands. TFDA consists of 7 Business Units, including Division of Planning and Research Development, which is responsible for planning, technology program management, regulatory and international collaboration; Division of Food Safety, Division of Medicinal Products, Division of Medical Devices & Cosmetics, as well as Division of Controlled Drugs are responsible for corresponding products management and the stipulation/amendments of relevant policies and laws; Division of Risk Management is responsible for risk analysis, laboratory management/ certification, and factory management/ inspections; Division of Research and Analysis is responsible for the development and assessment of tests and methods. TFDA also sets 3 District Centers (North, Central, and South) for laboratory testing of imported products, distribution examinations and inspections. In addition, TFDA also composed of 5 Administrative Units (Office of Secretariat, Office of Personnel, Office of Accounting, and Office of Information management) to support administrative/management matters. (Figure 7-2)

TFDA has two Task Forces (*i.e.* Manufacturing facility for controlled drug and Decision Support Center). The Manufacturing facility for controlled drug is responsible for the import, export, manufacturing, and sales of tier 1 & 2 controlled drugs to sufficiently supply the needs for

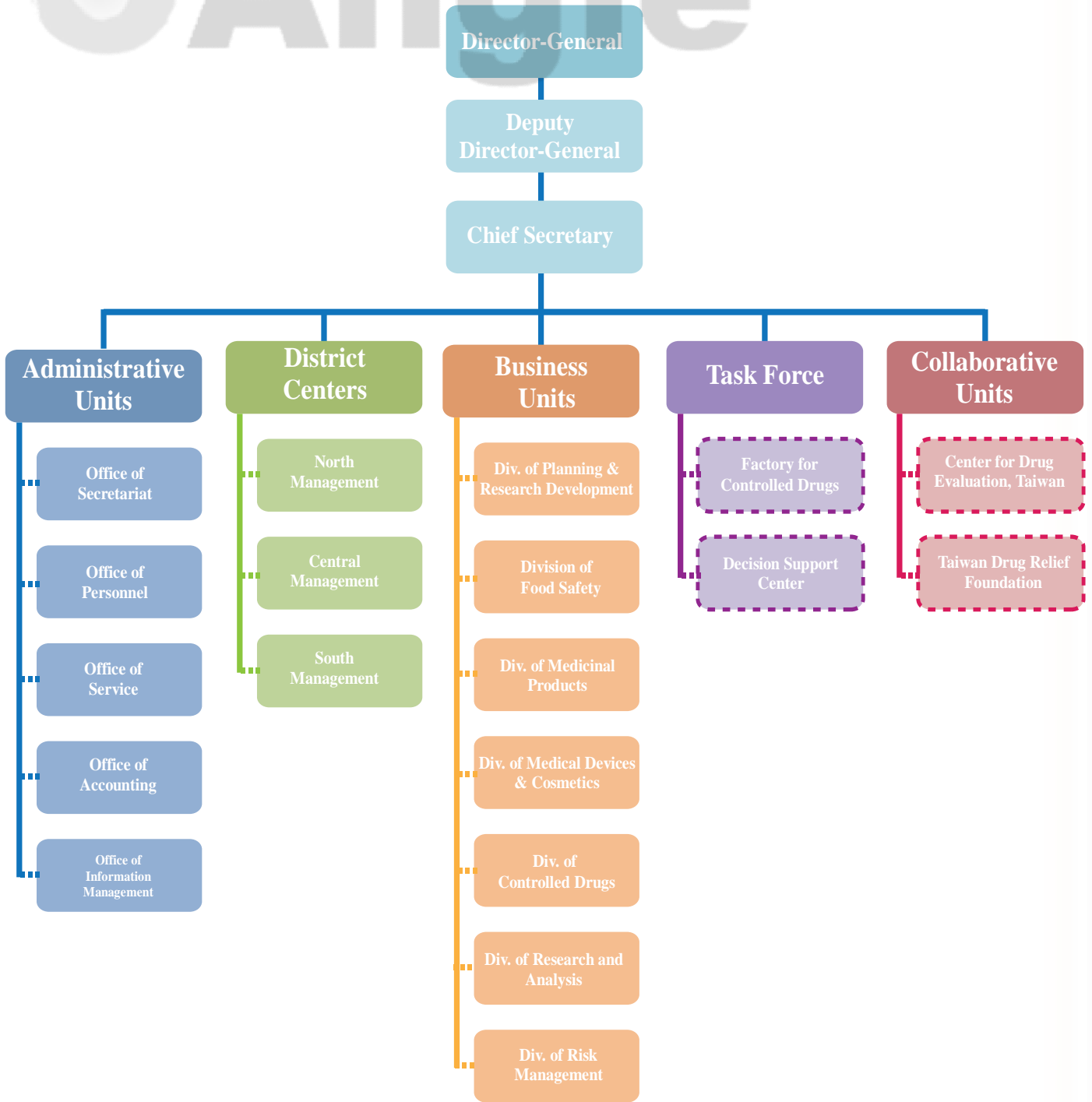


Figure 7-2 Organization framework

domestic medical needs. In addition, to control complete food and medicinal product information, the Decision Support 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. Moreover, product management requires highly professional information to effectively promote relevant businesses and become the fundamental basis of policies. To achieve proper product management, TFDA actively establishes a close partnership with professional consultation units such as Center for Drug Evaluation, Taiwan and Taiwan Drug Relief Foundation.

Section 3 Future Perspectives

With the trends of global trade and the development of technology, the discovery of novel substances and the impact of emerging technologies and new chemicals, the safety and sanitary issues of food and medicinal products gradually become critical. In view of the importance of food and drug safety and the expectations from the public, TFDA integrates different departments and businesses, and expand the participation of the public to construct a safe protection network for agriculture and food industry. Future important administrative plans include:

1. Adopt perspective ideas (Food safety establishment plan) to respond to future challenges, and execute 4 sub-programs, *i.e.* “The construction plan of modern national food and drug laboratory and educational training buildings,” “Efficiency improvement program to expedite border inspection system,” “Program to strengthen health department’s food safety audition and inspection capacity” and “Program to strengthen central competent authority’s food safety, safe drug use and illegal drug inspection capacity.”
2. Improve food safety and management, implement five-point food safety policy, and explore food safety management resources through integrating inter-departmental resources, combining the power of business self-discipline and public participation to maximize the benefits of applicable resources. These perspective plans will eventually carry out three-level quality control, expand market inspection by 10 times, and enhance the management competence and inspection capacity on food safety.
3. Establish a traceability and follow-up system for medicinal products to prevent counterfeits from entering the legal supply chain, as well as to detect and recycle suspicious drugs rapidly and effectively.
4. Expedite the stipulation of medical device exclusive laws and the addendum/amendments on sanitary management regulations for cosmetics to strengthen consumer protection and be in line with international trends.