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Annex

Appendix 1 Important Events

April	April 2	Convened the "2019 Foreign Pharmaceutical Factory GMP Management and Communication Meeting" and invited 5 public associations related to pharmaceutical imports to join the meeting to continuously improve and implement the management of foreign pharmaceutical factories.
	April 25	Attended the forum "Promoting the Development of Taiwan to Become the R&D Biotechnology Center in Asia Pacific" and served as the representative speaker to report the registration mechanism for new drugs; we focused on the simplified review, priority review, accelerated approval and breakthrough therapy mechanism, as well as the description of multi-regional clinical trials review procedures.
May	May 2	We were invited to the "Practices on Foreign Pharmaceutical Factory Management and Inspection Seminar" to explain the current GMP management status and management system of foreign pharmaceutical factories.
	May 8	The "Regulations for the Management of Regenerative Medicine Preparations" were reviewed by the Sanitation and Environment Committee of the Legislative Yuan (at the 7th meeting in the 9th session).
June	June 1 to June 6	TFDA attended the 1st meeting in 2019 held by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and its work group in Amsterdam, Netherlands, as well as the meeting held by the International Pharmaceutical Regulators Program (IPRP) and the Drug Regulatory Authority (DRA). During the meetings, we communicated and interacted with representatives of pharmaceutical regulators from various countries and continuously enhanced the international visibility and influence of Taiwan regarding pharmaceutical regulations.
	June 5	In response to the first year of "World Food Safety Day," the Ministry of Economic Affairs, the "Cross-Ministry Press Conference for the World Food Safety Day" was jointly organized by the Ministry of Education, the Council of Agriculture of the Executive Yuan and the Environmental Protection Administration, to reinforce our determination for the protection of food safety from farm to table.
	June 11 to June 12	TFDA conducted the "2019 APEC International Workshop on Food Safety and Threat from New Psychoactive Substances" to share and exchange information about the testing technology for NPS and illegal drug with experts from various countries to enhance the domestic testing technology to protect the health and drug safety of the citizens in Taiwan.
	June 19	Conducted the "Excellent Food Suppliers Award Ceremony on the World Food Safety Day" to publicly present awards to 16 excellent food suppliers. With the award and recognition, it is expected to encourage more businesses to voluntarily apply for verification to enhance the overall safety and hygienic quality of the food industry in the nation.
	June 19 to June 21	TFDA hosted the "1st PIC/S Expert Circle Meeting on Control of Cross Contamination" in Taipei in 2019, to learn and discuss the inspection skills of the risk management of cross-contamination in shared facilities with inspectors and experts from various countries.

Angle

	June 23 to June 27	TFDA attended the 55th "Drug Information Association Annual Meetin g (DIA Annual Meeting)" held in San Diego, USA; on June 24, we held the "TFDA Town Hall" with the topic of Regenerative Medicine, to share the new policy of management system for regenerative medicine, views on the regenerative medicine preparation management and inspection experience from Taiwan's competent authorities.
July	July 10 to July 11	Organizing the "International Conference on New Psychoactive Substances(NPS)," we invited international scholars and experts from Malaysia, the United States, Japan, South Korea, etc., as well as specialists and government representatives in Taiwan, to share their experiences and exchange information on three major topics, such as the current global situation of NPS, toxicological assessment and epidemiology.
	July 25	TFDA hosted the "Conference on Analytical Techniques for Cosmetics" to promote global collaboration in cosmetic analytical technology. Forgien experts and sholars from Japan, Italy, Malaysia and India were invited to Taiwan to share the experiences and information on the latest development of cosmetic analytical technology from their countries.
	July 26	Held the "2019 FDA Outstanding and Novice Chefs Award Presentation Ceremony – the Golden Chef Award" to commend the award-winning chefs for their devotion to sanitation management and enhance the image of chefs as well as inspire more chefs to work together to improve the hygiene and quality in the food service industry.
August	July 30 to August 2	Participated in the "APEC Pilot CoE in Advanced Therapy" and the "Asia-US Roundtable on Advanced Therapies" held in South Korea by the Northeastern University and the US Food and Drug Administration. Information and experience were exchanged among representatives of regulatory agencies and international scholars, TFDA had also demonstrated efforts on promoting regenerative medicine development and on improving the regulatory environment.
	August 12	Conducted the "Conference on International Medical Device Regulations in South East Asia and Brazil" to enhance the industry understanding on the New Southbound Policy and the medical device regulations in Brazil.
	August 14 to August 18	We attended the LSIF-RHSC meeting and the Planning Group meeting and we reported the good registration management roadmap as well as the progress of the Regulatory Science Center of Excellence. We were invited to attend the Policy Dialogue on Regulatory Convergence meeting and shared the results of TFDA's active participation in international organizations and the process of speeding up the medical device regulatory convergence for the past few years.
	August 21 to August 22	Conducted the "2019 Annual Food Safety and Analytical Techniques Symposium" to improve the testing quality and promote international exchange and interaction on testing technology.

September

September 4	Conducted the "2019 International Conference on Narcotics: Safe Use and Management." We invited official representatives and experts from EU, the United States, Japan, and Thailand to Taiwan to share the current situation in the management of addictive narcotics from various countries and the strategies for the prevention of addictive narcotics with the medical professionals and public health policy management personnel.
September 17 to September 18	Conducted the "Training for International Food Safety Inspection and Management." We invited officials form New Zealand and Australia with practical experience to Taiwan to share their inspection management for the food industry, border management measures as well as the system and practice for the duty training of inspectors from their country.
September 17 to September 19	TFDA conducted the "2019 APEC Good Registration Management Regulatory Science Center of Excellence Workshop" and invited 21 representatives from the domestic and international pharmaceutical regulatory authorities and experts in the industry to train 67 seed instructors from the industry, government and academe of 12 APEC member economies.
September 21	Held the "Safety of drugs and care of pharmacists" carnival at the Calligraphy Greenway in Taichung.
September 25	Conducted the "Workshop We Symposium on Opportunities and Challenges of the Intelligent Medical Equipment Development in Taiwan."
September 25	Conducted the "International Food Cold Chain Logistics Management Regulations Symposium" we invited experts and scholars to share the development trends of the cold food chain and management in the food industry and the Japanese Yamato International Logistics shared the related specifications of Japanese low-temperature delivery service and the requirements of Publicly Available Specifications (PAS) 1018.
September 25 to September 27	Participated the "6th Bio Investment Asia - Radical Transformation of Life Sciences in Asia" organized by the Thailand Life Science Center of Excellence. This meeting aims to promote the development of biotechnology in Asia and facilitate biotechnology-related commercial investments. In the meeting, TFDA introduced the regenerative medicine related management in Taiwan and our active promotion in related industries.
September 27	Conducted the "Workshop on the Pre-market Review System of Smart Medical Devices from Different Countries."

October

October 1 to October 2	Conducted the "7th Joint Conference of Taiwan and Japan on Medical Products Regulation in 2019". The representatives from both parties shared the progress and trends of pharmaceutical regulations, regulations for precision medicine and in vitro diagnostic reagents, the International Council for Harmonization (ICH), Guidelines E17 of Multi-Regional Clinical Trials (MRCT), electronic package insert, promotion policies for instructed drug and priority review mechanism for medical devices, to strengthen the information exchange between the officials and business operators from the two parties as well as facilitate the business operators' deployment in the international market.
October 19	Conducted the "Sports Day for Medical device and PK with Partners" event to promote the safe use of medical device.

October

October 21	Organized the "International Medical device Regulations Workshop" to help the domestic business operators to better understand the latest international medical equipment regulations.
October 22 to October 24	Held the "2019 APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop" to train the seed instructors of medical devices and regulatory science for APEC member economies.
October 22 to November 1	Directorate General for Health and Food Safety, (DG SANTE) had conducted the on-site inspection in Taiwan regarding to the application of exporting animal origin food products to the EU.
October 24	Conducted the "Risk and Crisis Management Workshop" to enhance our staff's overall concept of risk identification and crisis prevention as well as establish the risk management culture of the organization.
October 28 to October 30	TFDA participated in the "2019 APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop" held in Thailand and was invited to deliver welcome remarks and lectures at the meeting.

November

November 13 to November 14	TFDA held the "2019 Taiwan-ASEAN Regulatory Symposium". We invited the governmental officials from the health authorities of Thailand, Malaysia, and the Philippines to Taiwan to exchange views on the review systems of generic drugs in participating countries. The program included a closed-door workshop for regulators and an open seminar for industry. We invited the ASEAN officials to share the latest status of its their generic drug regulatory system.
November 14 to November 21	Attended the 2nd meeting in 2019 held by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and its working group in Singapore, as well as the meeting held by the International Pharmaceutical Regulators Programme (IPRP) and the Drug Regulatory Authority (DRA); and participated in the discussion on the stipulation of ICH regulations and guidelines.
November 21	TFDA organized the "Food Safety Management Workshop" and invited the governmental representatives from Federal agency for the Safety of the Food Chain (FASFC) to give speeches on the topics: "Food Safety Barometer," "Traceability Exercise of Food Incident," and "Imported and Exported Food Management". In order to enhance the bilateral food safety cooperation between Belgium and Taiwan, we also invited people in the Office of Food Safety, Council of Agriculture and Environmental Protection Administration, Executive Yuan, and food associations and groups, etc.
November 26	Held the "2019 Annual Press Conference for the Chinese New Year Dishes and the Promotional Award Ceremony for the Effective Use of Food Ingredients in Food Service Businesses" and we invited chef representatives who won the 2019 "FDA Excellent Chef" Golden chef Award to teach the general public to use the leftover food materials to make hygienic and delicious New Year dishes. At the same time, we also awarded the food service businesses who actively devote in the reduction of food waste to commend their contribution on food waste reduction.
November 27	Conducted the "Symposium on the Food Management System of Japanese Foods with Function Claims." Mr. Masashi Hashimoto was invited, the chairman of the Health Food Industry Association of Japan, to share views on the subject of Foods with Function Claims (FFC).

Appendix 2 Important Achievements and Statistics in 2019

Table 1 Addendum/amendment to the regulations and standards related to food safety and health management in 2019

Date of announcement	Name	Important content
January 17	Amended Articles 11 and 12 of the "Enforcement Rules of Health Food Control Act"	In line with the additional clauses and amendment to the labeling regulations in Article 13 of the Health Food Control Act by the Presidential Decree on January 24, 2018, as its subparagraph 2 in paragraph 1 have been added and the number of subparagraphs has been shifted accordingly, thereby the authorization foundation and quoted clauses were revised and the substantive content is in accordance with the original regulations without any changes.
	Stipulate the "Regulations Governing the Labeling of Health Food"	In line with the additional clauses and amendment to the labeling regulations in Article 13 of the Health Food Control Act by the Presidential Decree on January 24, 2018, as its subparagraph 2 in paragraph 1 have been added and the number of subparagraphs has been shifted accordingly, thereby the authorization foundation and quoted clauses were revised and the substantive content is in accordance with the original regulations without any changes; and the original regulations were announced to be abolished on the same day.
	Abolished the "Regulations Governing the Labeling of Health Food" with the announcement Wei-Shou-Shi-Zi No. 1061303745 on December 29, 2017	
	Stipulated the "Health Food Shall Be Clearly Indicated the Content of Ingredients with Health Care Effects in the Product Container or Packaging"	In line with the additional clauses and amendment to the labeling regulations in Article 13 of the Health Food Control Act by the Presidential Decree on January 24, 2018, as its subparagraph 2 in paragraph 1 have been added and the number of subparagraphs has been shifted accordingly, thereby the authorization foundation and quoted clauses were revised and the substantive content is in accordance with the original regulations without any changes; and the original regulations were announced to be abolished on the same day.
	Abolished the "Health Food Shall Be Clearly Indicated the Content of Ingredients with Health Care Effects in the Product Container or Packaging" with the Announcement Bu-Shou-Shi-Zi No. 1041301610 on June 9, 2015	
January 28	Amended Table 1 of Article 3 and Table 4 of Article 5 in the "Standards for Pesticide Residue Limits in Foods" and Article 3 in the "Standards for Pesticide Residue Limits in Animal products"	1.Added and revised 168 residue limits for 27 pesticides. 2.Added 3 pesticides' and deleted 1 pesticide's residue limits in poultry and livestock products.
March 19	Stipulated "The Use Restrictions and Labeling Requirements of the Food Ingredient Chitosan Produced from Shrimp, Crab Shells or the Mycelium of *Aspergillus Niger*"	The regulation specifies the use restrictions and labeling requirements for the chitosan produced from shrimp shells, crab shells or the mycelium of *Aspergillus niger* for food purposes.
March 27	Stipulated "The Use Restrictions and Labeling Requirements of the Food Ingredient Olive (*Olea europaea*) Pomace Extract Containing Hydroxytyrosol"	Stipulated the regulation of olive (*Olea europaea*) pomace extract containing hydroxytyrosol for food purposes, including the manufacturing method, the content of hydroxytyrosol, the daily intake and the warning statement.

Date of announcement	Name	Important content
March 28	Revised the "The Efficacy Assessment Method Of Health Food to Enhance Iron Bioavailability"	1.Revised the name of the assessment method. 2.Deleted *in vitro* measurement method, *in vitro* digestion and dialysis method and *in vitro* digestion Caco 2 cell iron absorption method. 3.Revised the regulations for trial institution and principal investigator. 4.Revised the inclusion and exclusion of trial subjects and experimental measurement as well as added the safety assessment. 5.Revised the evaluation criteria for results. 6.Added the description for the health care effect.
April 3	Revised Article 4 of the "Act Governing Food Safety and Sanitation"	Revised the regulations concerning the formation, proceedings, procedures and other matters to be complied with council advisory committee.
April 9	Amendment to the" Regulations Governing the Establishment of the Sanitation Control Personnel of Food Manufacturing Factory"	Added: the sanitation control personnel for the food manufacturing plants with a capital of less than NTD30 million is eligible by senior staff with vocational education from relevant departments after receiving relevant education and training.
	Amendment to "Categories and Scale of Food Manufacturing Factory Shall Have Sanitation Control Personnel"	The expansion of regulations for other food manufacturing industries shall have sanitation control personnel.
April 10	Amendment to "Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products"	The original regulations regarding the scope of application for registration of special dietary food the required documents the operational methods precautions, etc., are included in the "Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products."
	Abolished the "Regulations for Special Dietary Food Registration"	
April 16	Stipulated the "Requirements for Exemption from Inspection Application for Import of Food and Related Products and Their Applicable Custom Codes"	1.The self-use import amount and quantity restrictions are applied for foreign embassies and consulates in Taiwan or personnel with diplomatic immunity. 2.Imported plastic containers are not included in the scope. 3.The definition of a single item is clearly stipulated in the new announcement as in the advance notice. 4.Deleted the first and second Table in point 5-2 of the original announcement "meats, tissues, organs, derivatives of bovine or those containing the preceding products from the countries with mad cow disease (bovine spongiform encephalopathy) (BSE)."
	Abolished the "Requirements for Exemption from Inspection Application for Import of Food and Related Products and Their Applicable Custom Codes" with the Announcement Bu-Shou-Shi-Zi No. 1041303340 on November 5, 2015	
April 17	Added Article 18-1 and amended Article 3, Article 47 and Article 51 of the "Act Governing Food Safety and Sanitation"	Revised the definition and usage regulations for the processing aids; it was raised to the Act level to specifically manage products with this ingredient.

Date of announcement	Name	Important content
April 22	Amended Article 3 of the "Standards for Veterinary Drug Residue Limits in Foods"	In coordination with the Guidelines on veterinary drugs of aquatic animals amended by the Council of Agriculture, Executive Yuan, we added the maximum residue limits of Florfenicol for Testudines.
April 26	Amendment to the "Categories, Scale, and Implementation Date of Food Business Operators Required Registration Prior to Business Operations"	Specified the scale and implementation date of logistics businesses that are required for registration as follows: the implementation date is from the announcement date for new factory registration, commercial registration or company registration; for those companies that already have a factory registration, commercial registration or company registration, the implementation starts from July 1, 2019.
May 2	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China"	1.The products with schedule number of 2106.90.96.00-5 are changed to be listed in the "Complex import regulation for commodities containing F01 category list." 2.In line with the Bureau of Foreign Trade of the Ministry of Economic Affairs to amend the Chinese and English product name for products with commodity classification number of 2103.90.90.30-8. 3.Added the import regulations F02 for products with commodity classification number of 6912.00.10.00-3.
	Amendment to the "Import Regulation of 508 in Import Commodity Classification of Republic of China".	Added 4 item numbers to the import regulations 508.
	Amendment to the "Complex Import Regulation Containing F01 in Import Commodity Classification of Republic of China"	1.The product commodity classification number 2106.90.96.00-5 is changed to be listed in the "Complex Import Regulation Containing F01 in Import Commodity Classification of Republic of China." 2.In accordance with the announcement of the Bureau of Foreign Trade of the Ministry of Economic Affairs to amend the import regulations for product commodity classification number of 2811.29.90.10-1 to 838.
May 20	Stipulated the "Import Eggs and Egg Products for Food Purpose Shall Be Accompanied with Official Certificates Issued by the Competent Authority of the Exporting Country"	Imported eggs and egg products for food purpose shall be accompanied with official certificates issued by the competent authority of the exporting country that shall be attested the products are "for human consumption", or "in compliance with relevant food safety and sanitary regulations."
May 23	Stipulated the "Import Gelatin and Its Derivatives, Other Glues of Animal Origin and Peptones and Their Derivatives for Food Purpose Shall Be Accompanied with Official Certificates Issued by the Competent Authority of the Exporting Country"	Imported gelatin and its derivatives, other glues of animal origin and peptones and their derivatives for food purpose shall be accompanied with official certificates issued by the competent authority of the exporting country that shall be attested the products are "for human consumption", or "in compliance with relevant food safety and sanitary regulations."
June 12	Amendment to the "Import Regulation of 508 in Import Commodity Classification of Republic of China"	In line with the Bureau of Foreign Trade of the Ministry of Economic Affairs to announce and revise in accordance with the amendment to the toxic chemical substance management number by the Environmental Protection Administration of the Executive Yuan.

Date of announcement	Name	Important content
June 18	Amendment to Table 1 of Article 3, Table 3 of Article 4, Table 4 of Article 5 and Table 5 of Article 6 in the "Standards for Pesticide Residue Limits in Foods"	1.Added and amended 129 residues limits in 34 pesticides for agricultural products. 2.Added *Beauveria bassiana* A1 and *Bacillus. amyloliquefaciens* YCMA1 as MRL omitted pesticides. 3.Added Propaphos (50 % EC) as pesticide prohibited for use. 4.Added the regulations: dried peas are classified in the dried beans and mitsuba is classified as small leafy vegetables.
June 26	Amended the "Import Gelatin and Its Derivatives, Other Glues of Animal Origin and Peptones and Their Derivatives for Food Purpose Shall Be Accompanied with Official Certificates Issued by the Competent Authority of the Exporting Country"	The name and scope of product implementation were changed.
July 12	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China"	1.Added 4 item numbers to the import regulations F01". 2.Deleted the number "1212.99.40.00-6, Pumpkin or squash seed" in accordance with the management requirement by the Council of Agriculture and added the import regulation F01 for 3 item numbers. 3.Deleted "0805.29.00.00-4, Wilkings and similar citrus hybrids, fresh or dried" in accordance with the management requirement by the Council of Agriculture and added 2 item numbers to the import regulations F01.
July 25	Stipulated "The Use Restrictions and Labeling Requirements of Green Coffee Bean Extract as a Food Ingredient"	Stipulated the regulations of green coffee bean extract for food purposes, including the source of green coffee beans, used parts, types, manufacturing method, daily intake and the warning statement.
August 2	Amendment to Table 1 of Article 3 and Table 5 of Article 6 in the "Standards for Pesticide Residue Limits in Foods."	1.Added and revised 238 residue limits for 34 pesticides. 2.Added the regulations: durum wheat is classified as wheat and buckwheat is classified as miscellaneous grains.
August 15	Amended 7 sanitation standards including the "General Food Sanitation Standards" Abolished 12 sanitation standards including the "Sanitation Standards for Eggs," etc.	1.A total of 7 standards were revised. Due to the setting of "Sanitation standard for contaminants and toxins in food", the duplicate clauses in these 7 standards are deleted and only the requirement for microorganisms are retained. 2.Due to the setting of "Sanitation Standard for Contaminants and Toxins in food," 12 sanitation standards such as the "Sanitation Standards for Eggs" thereby the relevant provisions are abolished.
August 29	Amended Article 3 of the "Standards for Veterinary Drug Residue Limits in Foods"	In coordination with the use of Fluralaner in chickens approved by council of Agriculture, Executive Yuan, therefore we added the maximum residue limit in muscle, liver, kidney, fat (including the skin) and eggs for Fluralaner in chickens.
September 26	Revised on Article 4 and 6 and the appendix of Article 3 of "Regulations for Systematic Inspection of Imported Food"	Revised the scope of "meat products" and "dairy products" added "other deer-derived products" and deleted "other bovine-derived products."

Date of announcement	Name	Important content
October 18	Stipulated 19 regulations such as "The Use Restrictions and Labeling Requirements of Coenzyme Q10 as a Food Ingredient"	To update the legal authorization basis, the title and terms for the regulations of 19 food ingredients. The original regulations were abolished while the relevant regulations were stipulated simultaneously for completing the legal procedures. The substantial content of new regulations is in accordance with the original regulations.
	Abolished 19 regulations such as "Permit and Warning Label Requirement of Coenzyme Q10 Used as a Food Ingredient"	
November 6	Amendment to Table 1 of Article 3 in the "Standards for Pesticide Residue Limits in Foods" and Article 3 in the "Standards for Pesticide Residue Limits in Animal products"	1.Table 1 of Article 3 in the "Standards for Pesticide Residue Limits in Foods:" Added 16 residue limits for 10 pesticides. 2.Article 3 in the "Standards for Pesticide Residue Limits in Animal products:" Addition of 9 pesticide residue limits in bee pollen.
November 7	Amendment to "Regulations of Nutrition Label for Packaged Vitamins and Minerals in the Form of Tablets and Capsule"	1.Revision of nutrition labeling form, If the vertical form can't be fully presented, it can be labeled in horizontal continuous form. 2.Revision of the ways of labeling in terms of the contents of nutrients and units about g, mg and μg. 3.Revision of the principles of data formatting, and added the method of rounding half up.
	Amendment to Article 1 and Article 4, Appendix 1 of Appendix 2 and Table 2 of Article 3 in the "Standards for Specification, Scope, Application and Limitation of Food Additives"	The nitrous oxide is changed to the food additive management and the scope, limits, restrictions, specifications and standards for food usage are stipulated.
	Stipulated the "Sanitation Standard for Liquid Eggs" and "Regulations Governing the Labeling of Liquid Egg Products"	1.Strictly regulate the types of shell eggs can be used for making liquid eggs and standard for microorganisms in liquid eggs. 2.The liquid egg products should be clearly labeled with the wording "pasteurized" or "unpasteurized" on their product names and the expiry date and storage conditions should be labeled. For unpasteurized liquid egg products, in addition to the aforementioned requirements, it should be clearly labeled in Chinese at an obvious location on the outer packaging of the product with the following or similar warning message: "The product must be used in the production of foods that will be sufficiently heated or other processing methods sufficient for effective pasteurization" or other synonymous terms.
December 10	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China"	Deleted "0304.49.90.90-8, Other fish fillets, fresh or chilled" in accordance with the management requirement by the Council of Agriculture and added 18 item numbers to the import regulations F01.

Remarks:
Commodity classification number list: According to Article 30 of the Act Governing Food Safety and Sanitation, the import of food and other related products announced by the central competent authority shall be in accordance with the commodity classification number list. As of the end of 2019, there are 2,640 announced commodity classification numbers for the inspection of imported foods, of which 2,063 are in the import regulation F01, 122 are in the import regulation F02 and 371 are in the import regulation 508, the 84 are in the complex import regulation.

Table 2 The guidance of food hygiene management and operations was announced in 2019

Numbering	Announcement date	Announcement name	Description
1	March 14	"GHP Guidelines for Manufacturers of Liquid Egg Products"	It happened in the past that domestic egg manufacturers used the problematic raw materials of eggs to make liquid egg products. These guidelines were stipulated for the liquid egg manufacturers to follow, so that the sanitation and safety in the production process of liquid egg products can be ensured.
2	July 22	Revised the "Good Hygienic Practice Guidelines for Food Manufacturers of Soy Sauce Products"	To avoid cross-contamination in different types of soy sauce during the production process of soy sauce, such as the content of levulinic acid should meet the limit of 0.1% for label processing method as "fermentation", thereby these guidelines were revised for the soy sauce manufacturers to follow.
3	September 19	Guidelines of Hygiene Self-Management for Online Food Delivery Platform Business Operators	The "food delivery platform" business type has emerged in Taiwan in recent years. These guidelines have been stipulated for platform operators in order to ensure the hygiene, safety, quality and information disclosure of the food provided by the food delivery platform business operators.

Table 3 Registration of specific food and food additive in 2019

The food category should be registered		Number of permit documents
Imported food in tablet or capsule form		6,982
Health Food		388
Food Additives		6,033
Genetically modified food		149
Special dietary food	Formula for certain disease	230
	Infant and follow-up formula	118
Domestic capsule and tablet vitamin products		1,239
Vacuum-packed ready-to-eat soybean food		72
Total		15,211

Table 4 2019 Food Random Inspection Project

Numbering	Project name	Result
1	HACCP Inspection Project for Processed Meat Industry	I. Inspected: 155 companies (I) GHP: 86 companies were required to make improvements within a deadline, of which 85 passed the re-inspection and 1 did not pass the re-inspection. (II) HACCP: 105 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Tracing and tracking: 26 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Mandatory inspection: 17 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Others: 1.3 companies stored expired food and food additives. 2.5 companies did not hire professional staff or technical personnel. 3.4 companies did not have hygiene inspector. II.Random inspection: 320 cases, all comply with the regulations.
2	HACCP Inspection Project for Dairy Processing Industry	I. Inspected: 12 companies (I) GHP: 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 1 company was required to make improvements within a deadline and it passed the re-inspection. (IV) Mandatory inspection: 7 companies passed the inspection and 5 companies are not applicable. (V) Food safety monitoring plan: 5 companies passed the inspection and 7 companies are not applicable. (VI) Tracing and tracking: All are in compliance with the regulations. (VII) Electronic declaration required to be traced: 1 company was required to make improvements within a deadline and it passed the re-inspection. II.Labeling: 29 cases, of which 1 case does not meet the regulations. III.Random inspection: 19 cases, all are in compliance with the regulations.
3	HACCP Audit Project for Aquatic Food Industry	I. Inspected: 104 companies (I) GHP: 48 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 77 companies were required to make improvements within a deadline, of which 76 had passed the re-inspection and 1 did not pass the re-inspection. (III) Registration: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Mandatory inspection: 27 are not applicable, 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Food safety monitoring plan: 72 are not applicable, 1 company was required to make improvements within a deadline and all of them passed the re-inspection. (VI) Tracing and tracking: 20 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Others: 1.1 company stored expired products. 2.1 company did not hire professional staff or technical personnel. 3.3 companies did not have a hygiene inspector. II.Labeling: 225 cases, of which 3 cases do not meet the regulations. III.Random inspection: 97 cases, all are in compliance with the regulations.
4	HACCP Inspection Project for Meal Box Factory	I. Inspected: 86 companies (I) GHP: 45 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 67 companies were required to make improvements within a deadline and 1 of them did not pass the re-inspection. (III) Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Must trace: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Waste flow: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Others: 1.2 companies used expired ingredients. 2.2 companies did not hire professional staff or technical personnel. 3.1 company did not have a hygiene inspector. 4.The outer package label of 1 company does not meet the regulations.

Numbering	Project name	Result
4	HACCP Inspection Project for Meal Box Factory	II.Random inspection: 205 cases (I) 86 finished products and all are in compliance with the regulations. (II) 100 semi-finished products and 1 product is not in compliance with the regulations. (III) All of the 19 tableware cases are in compliance with the regulations.
5	Hotel Food Service HACCP Inspection Project	I. Inspected: 60 companies (I) GHP: 40 companies were required to make improvements within a deadline and 1 of them did not pass the re-inspection. (II) HACCP: 51 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: All are in compliance with the regulations. (IV) Standard form contract: 2 companies do not meet the regulations. (V) Others: 1.6 companies stored expired ingredients. 2.1 company did not hire professional staff or technical personnel. 3.1 hotel uses the ‘‘non-food grade baking soda’’ for soaking food ingredients. 4.1 company’s menu label does not match with the actual food ingredients. II.Random inspection: 121 cases, of which 3 cases do not meet the regulations.
6	HACCP Inspection Project for an Edible Oil Factory	【First stage】 I. Inspected: 33 companies (I) GHP: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Tracing and tracking: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Login, mandatory inspection and food safety monitoring plan are in compliance with the regulations. II.Random inspection: 35 cases, all are in compliance with the regulations. III.Labeling: 48 cases, all are in compliance with the regulations. 【Second stage】 I. Inspected: 7 companies (I) GHP: 1 company was required to make improvements within a deadline and it passed the re-inspection. (II) HACCP: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 1 company was required to make improvements within a deadline and it passed the re-inspection. (IV) Tracing and tracking: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Mandatory inspection: all comply with the regulations. (VI) Food safety monitoring plan: 1 company was required to make improvements within a deadline and it passed the re-inspection. II.Random inspection: 9 cases, of which 1 case did not meet the regulations. III.Labeling: 12 cases, all are in compliance with the regulations.

Numbering	Project name	Result
7	HACCP Inspection Project for Canned Food Factory	【First stage】 I. Inspected: 46 companies (I) GHP: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 22 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Electronic declaration: 19 are not applicable, 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Tracing and tracking: All are in compliance with the regulations. (VI) Food safety monitoring plan: 1 company was required to make improvements within a deadline and it passed the re-inspection. (VII) Others: 1 company did not hire professional staff or technical personnel. II.Random inspection: 73 cases, of which all are in compliance with the regulations. III.Labeling: 124 cases, of which 1 did not meet the regulations. 【Second stage】 I. Inspected: 31 companies (I) GHP: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Tracing and tracking: 1 company was required to make improvements within a deadline and it had passed the re-inspection. (V) Electronic declaration: 16 are not applicable and all the others are in compliance with the regulations. (VI) Mandatory inspection: 1 company is not applicable, 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Food safety monitoring plan: 5 are not applicable, 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Random inspection: 40 cases, of which all are in compliance with the regulations. III.Labeling: 73 cases, all are in compliance
8	Inspection Project for *Antrodia Cinnamomea* Food Manufacturers	I. Inspected: 42 companies (I) GHP: 11 companies are not applicable, 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Source of ingredients: 6 are not applicable, 36 are in compliance with the regulations. II.Labeling: 37 cases, of which 3 cases (2 companies) do not meet the regulations.
9	Inspection Project for Health Food Factory	I. Inspected: 65 companies (I) Good operating practice for health food factories: 15 are not applicable and 1 did not meet the regulations. (II) Registration: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Tracing and tracking: 22 are not applicable and all the others are in compliance with the regulations. (IV) Mandatory inspection: 22 companies are not applicable and all the others are in compliance with the regulations. (V) Compliance of the registration permit: 74 cases, of which 1 did not meet the regulations. (VI) Others: 1 company stored expired products. II.Labeling: 74 cases, of which 1 did not meet the regulations.
10	Domestically Produced Vitamin Tablet and Capsule Food Factory Inspection Project	I. Inspected: 40 companies (I) GHP: 4 companies are not applicable, 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Tracing and tracking: 16 are not applicable and all the others are in compliance with the regulations. (IV) Food safety monitoring plan: 16 are not applicable, 1 company was required to make improvements within a deadline and all of them passed the re-inspection. (V) Mandatory inspection: 16 companies are not applicable, 1 company was required to make improvements within a deadline and all of them passed the re-inspection. (VI) Product recall and the processing workflow: 4 companies are not applicable, 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Compliance of the registration permit: 90 cases, of which 9 cases do not meet the regulations. (VIII)Others: 1 company stored expired ingredients. II.Labeling: 79 cases, of which 11 cases did not meet the regulations.

Numbering	Project name	Result
11	Inspection Project for Special Nutritional Food Manufacturers and Importers	I. Inspected: 29 companies (I) GHP: 1 company is not applicable, 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 1 company was required to make improvements within a deadline and it passed the re-inspection. (III) Compliance of the content and registration permit: 63 cases, of which 1 did not meet the regulations. (IV) Tracing and tracking: 6 companies are not applicable and all the others are in compliance with the regulations. (V) Electronic declaration: 16 are not applicable, 1 company was required to make improvements within a deadline and it passed the re-inspection. (VI) Food safety monitoring program: 7 companies are not applicable and the remainders are in compliance with regulations. (VII) Mandatory inspection:3 are not applicable and all the others are in compliance with the regulations. II.Labeling: 62 cases, all are in compliance with the regulations. III.Random inspection: 63 cases, of which 1 case did not meet the regulations.
12	Inspection Project for Food Additive Manufacturers and Import Businesses	I. Inspected: 51 companies (I) GHP: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Mandatory Inspection: 4 companies were required to make improvements within a deadline, of which 3 passed the re-inspection and 1 did not pass the re-inspection. (IV) Electronic declaration: 1 is not applicable; 9 companies were required to make improvements within a deadline, of which 8 passed the re-inspection and 1 did not pass the re-inspection. (V) Tracing and tracking: 2 are not applicable, 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Food safety monitoring plan: 9 are not applicable, 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Labeling: 72 cases, all are in compliance with the regulations. III.Random inspection: 49 cases, all are in compliance with the regulations.
13	Inspection Project for Bean Products Manufacturers	I. Inspected: 104 companies (I) GHP: 48 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 15 companies were required to make improvements within a deadline and all of them had passed the re-inspection. II.Random inspection: 185 cases, of which 7 cases do not meet the regulations; additional Random inspections on 28 sampling cases of hard tofu, dried tofu products, tofu skin and processed products meet the requirements. III.Labeling: 78 cases, of which 2 cases do meet the regulations; additional Random inspection on 28 cases of vegetarian food with full packaged products: all are in compliance with the regulations.
14	Inspection Project for Pickled Vegetables	【First stage】470 inspection cases, of which 46 cases do not meet the regulations. 【Second stage】 I. Inspected: 96 companies (I) Registration: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) GHP: 50 companies were required to make improvements within a deadline and all of them had passed the re-inspection. (III) Others: 1 company stored expired ingredients. II.Random inspection: 88 finished products, of which 86 cases passed the inspection and 2 cases did not meet the regulations. III.Labeling: 111 cases meet the requirements and 3 cases do not meet the regulations.
15	Inspection Project for Liquid Egg Manufacturers	I. Inspected: 53 (I) GHP: 22 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: All are in compliance with the regulations. (III) Product liability insurance: All are in compliance with the regulations. (IV) Others: 1 company was under work suspension but did not follow. II.Random inspection: (I) Fresh raw eggs: 44 cases, of which 1 did not meet the regulations. (II) Sterilized liquid egg: 12 cases, of which 1 did not meet the regulations.

Numbering	Project name	Result
16	Inspection Project for Preserved Eggs and Salted Eggs Manufacturers	I. Inspected: 48 companies (I) GHP: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 5 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: All are in compliance with the regulations. (IV) The waste store area with disposal and transportation record: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Others: the labeling of 2 companies do not meet the regulations. II.Random inspection: (I) Fresh raw eggs (residues of veterinary drugs): 46 cases, all are in compliance with regulations. (II) Preserved eggs (lead, copper): 48 cases, all are in compliance with the regulations. (III) Salted eggs (preservatives and Sudan pigments): 38 cases, all are in compliance with the regulations.
17	Compliance of Labeling on Friendly Production System of Egg Labeling and Eggs on the Market	Labeling: 256 cases, all are in compliance with the regulations.
18	Random Inspection Project for Dried Lily Mushroom Products	I. Inspected: 402 companies were registered for inspection, of which 30 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Random inspection: 504 cases, of which 7 cases did not meet the regulations. III.Labeling: 274 cases, of which 1 did not meet the regulations.
19	Inspection Project for Edible Ice Manufacturers	I. Inspected: 100 companies (I) GHP: 45 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 6 companies are not applicable and 1 company is not in compliance with the regulations. II.Random inspection: 98 cases, of which 13 cases do not meet the regulations.
20	Inspection Project for Soy Sauce Manufacturers	I. Inspected: 75 companies (I) GHP: 45 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: All are in compliance with the regulations. II.Labeling: 201 cases, of which 3 cases did not meet the regulations. III.Random inspection: (I) Finished products of soy sauce: 76 cases, all are in compliance with the regulations. (II) Claim or labeled as brewed soy sauce: 59 cases, of which 2 cases do not meet the regulations. (III) Non-brewed soy sauce: 23 cases, all are in compliance with the regulations. (IV) Caramel pigment: 19 cases, all are in compliance with the regulations.
21	Random Inspection Project for Drinks Made on Site	I. Inspected: 291 companies (I) GHP: 115 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 19 companies are not applicable, 34 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Others: 1 stored expired ingredients. II.Labeling: (I) On-site labeling: 170 franchised beverage companies, of which 15 companies do not meet the regulations. (II) Packaged food labeling: 1 does not meet the regulations. III.Random inspection: 447 cases (I) Raw material of tea: 80 cases, of which 4 cases do not meet the regulations. (II) Coffee drinks: 47 cases, of which 10 cases do not meet the regulations. (III) Edible ice: 65 cases, of which 9 cases do not meet the regulations. (IV) Tea drinks and ingredients: 255 cases, of which 18 cases do not meet the regulations.
22	Random Inspection Project for Ice Products Made on Site	I. Inspected: 91 companies (I) GHP: 47 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 7 companies are not applicable, 14 companies were required to make improvements within a deadline and all of them had passed the re-inspection. II.Random inspection: 178 cases (I) Edible ice or ice products: 110 cases, of which 19 cases do not meet the regulations. (II) Ingredients: 68 cases, all are in compliance with the regulations.

Numbering	Project name	Result
23	Random Inspection Project for Breakfast and Popular Brunch Business Operators	I. Inspected: 212 companies (I) GHP: 99 companies were required to make improvements within a deadline, of which 98 companies passed the re-inspection and 1 company is no longer in business. (II) Registration: 57 companies are not applicable, 32 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 99 companies are not applicable and 113 companies are in compliance with the regulations. (IV) Others: 1 company stored expired ingredients. II.Indication on the site: (I) Origin of raw beef: 103 are not applicable and 109 are in compliance with the regulations. (II) Restructured meat products: 104 companies are not applicable and 108 companies are in compliance with regulations. (III) Genetically modified foods: 70 companies are not applicable and 2 companies do not meet the regulations. III.Random inspection: (I) Soymilk: 25 cases, of which 2 cases do not meet the regulations. (II) Eggs: 47 cases, of which 2 cases do not meet the regulations. (III) Lettuce salad: 25 cases, of which 5 cases do not meet the regulations. (IV) Ready-to-eat cooked foods: 57 cases, of which 1 case does not meet the regulations. (V) Beverage: 52 cases, of which 3 cases do not meet the regulations.
24	Inspection Project for Food Package and Lunch Box Food Service	I. Inspected: 218 companies (I) GHP: 106 companies were required to make improvements within a deadline, of which 104 companies passed the re-inspection and 2 companies are no longer in business. (II) Registration: 31 companies were required to make improvements within a deadline, of which 30 companies passed the re-inspection and 1 company is no longer in business. (III) Product liability insurance: 25 companies are not applicable and 193 companies are in compliance with the regulations. (IV) On-site labeling: 1 company did not meet the regulations. II.Random inspection: (I) Combo food products: 66 cases and 4 of them did not meet the regulations. (II) Free drinks offered with the meals: 52 cases, of which 17 cases do not meet the regulations. (III) Fresh meat: 36 cases, all are in compliance with the regulations. (IV) Fresh vegetables: 51 cases, of which 6 cases do not meet the regulations. (V) Processed products: 31 cases, all are in compliance with the regulations.
25	Inspection Project for Banquet Restaurants	I.Inspected: 303 companies (I) GHP: 130 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 41 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: All are in compliance with the regulations. (IV) Others: 18 companies stored expired ingredients. II.Random inspection: 160 cases, all are in compliance with the regulations.
26	Inspection Project for Popular Restaurants	I.Inspected: 173 companies (I) GHP: 69 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 1 company did not comply with the regulations. (IV) Labeling: 1 company did not meet the regulations. (V) Others: 5 companies stored and used expired ingredients. II.Random inspection: 343 cases, of which 15 cases do not meet the regulations.
27	Inspection Project for the Cultural and Creative Park and the Old-Street Food Service	I.Inspected: 239 companies (I) GHP: 100 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 24 companies are not applicable, 26 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 4 companies did not comply with the regulations. (IV) Others: 3 companies stored expired products. II.Random inspection: 292 cases, of which 3 cases do not meet the regulations.

Numbering	Project name	Result
28	Inspections Project for Food Businesses in the Food Court	I.Inspected: 280 companies (I) GHP: 87 companies were required to make improvements within a deadline, of which 86 companies passed the re-inspection and 1 company is no longer in business. (II) Registration: 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 7 companies are not applicable and all the others are in compliance with the regulations. (IV) Labeling at food and drink places: 1 company did not meet the regulations. (V) Others: 3 companies stored expired products. II.Random inspection: 108 cases, of which all are in compliance with the regulations.
29	Inspection Project for Food Utensils, Food Containers or Package Containing Plastic and in Contact with Food	Inspected: I. Manufacturer: 26 manufacturers (I) GHP: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: All are in compliance with the regulations. (III) Random inspection: 52 cases, of which all are in compliance with the regulations. II.Retail business: (I) Labeling: 211 cases, of which 8 cases did not meet the regulations. (II) Random inspection: 53 cases, of which 1 case did not meet the regulations.
30	Inspection Project for the Food Logistics and Storage Industry	Inspected: 143 companies I. GHP: 28 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Registration: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. III.Others: 3 companies stored expired products.
31	Inspection Project for Chinese New Year	Inspection on online order food manufacturers for Chinese New Year I. Inspected: 57 companies (I) GHP: 37 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Standard form contract: 13 companies are not applicable, 22 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Product liability insurance: 2 companies are not applicable and 4 companies are not in compliance with the regulations. (V) Use and management of food additives: 25 are not applicable, 16 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Waste management: 3 companies are not applicable, 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Others: 2 companies stored expired products. II.Random inspection: 166 cases, of which 2 cases do not meet the regulations. III.Labeling: 145 cases, of which 6 cases did not meet the regulations.
		Random inspection for food sold during the Chinese New Year holidays I. Inspected: 505 companies (I) GHP: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Random inspection: 1,894 cases, of which 31 cases do not meet the regulations. III.Labeling: 1,743 cases, of which 4 cases do not meet the regulations.
		Random inspection for food served in the restaurants during the Chinese New Year holidays I. Inspected: 54 companies (I) GHP: 25 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: all of them are in compliance with the regulations. (IV) Standard form contract: 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Others: 1.3 companies used expired ingredients. 2.1 company did not hire professional staff or technical personnel. II.On-site labeling: 2 companies do not meet the regulations. III.Random inspection: 61 cases, all are in compliance with the regulations.

Numbering	Project name	Result
32	Inspection Project for Dragon Boat Festival	Inspection project for source manufacturers of the rice dumplings I. Inspected: 27 companies (I) GHP: 13 companies were required to make improvements within a deadline, of which 12 passed the re-inspection and 1 did not pass the re-inspection. (II) Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Use and management of food additives: 7 companies were required to make improvements within a deadline and all of them had passed the re-inspection. (IV) Waste management: 8 companies were required to make improvements within a deadline and all of them had passed the re-inspection. (V) Others: 1 company stored expired ingredients. II.Labeling: 9 cases, all are in compliance with the regulations. III.Random inspection: 74 cases, of which 2 cases do not meet the regulations.
		Inspection on Dragon Boat Festival products Random inspection: I. Other seasonal foods for Dragon Boat Festival: 581 cases, of which 2 cases do not meet the regulations. II.Livestock products: 136 cases, all are in compliance with the regulations. III.Salted egg yolk: 88 cases, all are in compliance with the regulations. IV.Fresh eggs: 57 cases, all are in compliance with the regulations.
		Inspection on online order the rice dumplings manufacturers I. Inspected: 25 companies (I) GHP: 16 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Use and management of food additives: 10 companies are not in compliance with the regulations. (IV) Standard form contract: 2 companies are not applicable, 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Labeling: 19 cases, all are in compliance with the regulations. III.Random inspection: 46 cases, of which 1 case did not meet the regulations.
33	Inspection Project for Mid-Autumn Festival	Inspection on the moon cake and stuffing manufacturers I. Inspected: 193 companies (I) GHP: 85 companies were required to make improvements within a deadline and 1 of them did not pass the re-inspection. (II) Registration: 25 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 1 company does not comply with the regulations. (IV) Standard form contract: 30 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Others: 6 companies stored expired foods. II.Labeling: 188 cases, of which 1 case did not meet the regulations. III.Random inspection: 382 cases, all are in compliance with the regulations.
		Inspection on food served during Mid-Autumn Festival I. Inspected: 174 restaurants (I) GHP: 48 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 8 companies are not applicable and all the others are in compliance with the regulations. II.Random inspection: 185 cases, all are in compliance with the regulations.
		Mid-Autumn Festival food inspection:1,446 cases I. Livestock and aquatic products and their processed products: 433 cases, all are in compliance with the regulations. II.Fresh vegetables and the processed products: 297 cases, of which 8 did not meet the regulations. III.Others: 716 cases, of which 5 cases do not meet the regulations.

Numbering	Project name	Result
34	Random Inspection Project for Lantern Festival	I. Inspected 242 companies (I) GHP: 45 companies were required to make improvements within a deadline, of which 44 companies passed the re-inspection and 1 company is no longer in business. (II) Registration: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 4 companies did not comply with the regulations. II.Random inspection: 433 cases, of which 4 cases do not meet the regulations.
35	Random Inspection Project for Tomb Sweeping Day	Random inspection: 764 cases, of which 14 cases do not meet the regulations.
36	Random Inspection Project for Ghost Festival	Random inspection: 912 cases, of which 7 cases do not meet the regulations.
37	Random Inspection Project for Frozen Treats and Drinks in the Summer	Random inspection: 1,017 cases, of which 105 cases do not meet the regulations.
38	Random Inspection Project for Foods in the Winter	Random inspection: 539 cases, of which 3 cases do not meet the regulations.
39	Random Inspection Project for Lunch on Campuses	I. Inspected: 2,138 companies GHP: 66 companies were required to make improvements within a deadline and all of them had passed the re-inspection. II.Random inspection: (I) Labeling: 2,128 cases, of which 1 case did not meet the regulations. (II) Semi-finished products: 132 cases, all are in compliance with the regulations.
40	Inspection Project of Catering Businesses for Providing Lunch to Schools	I. Inspected: 504 companies GHP: 97 companies were required to make improvements within a deadline and 1 of them did not pass the re-inspection. II.Random inspection: 669 cases, of which 32 cases do not meet the regulations.
41	New Sales Model - Inspection Project for Food, Drugs and Cosmetics in the Claw Machine	【First stage】 Investigation: A total of 79 claw machine shops (with 2,006 claw machines) in the nearby area of 36 elementary schools, junior high schools and senior high schools in the non-municipal cities, of which 2.7% of the machines contain food, 1.3% of them contained cosmetics and 0.1% of them contained medicine. 【Second stage】 Inspection: 288 shops (7,994 machines), of which 100 shops (226 machines) contain food, medical equipment and cosmetics. I. Food on display: 163 machines, of which 16 machines are not in compliance with regulations. II.Medicines on display: 0 machines. III.Medical equipment on display: 1 machine, of which 1 machine did not comply with the regulations. IV.Cosmetics on display: 62 machines, of which 35 machines did not comply with the regulations.
42	Inspection Project for Multi-Schedule Marketing Businesse	Labeling inspection: 5 companies, with a total of 23 cases I. Food products: 13 cases, of which 1 does not meet the regulations. II.Cosmetics: 10 cases, all are in compliance with the regulations.
43	Inspection Project for Food Ingredient in the Baking Industry	I. Inspected: 64 companies (I) GHP: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Labeling: 2 companies do not meet the regulations. II.Random inspection: 44 cases, all are in compliance with the regulations.

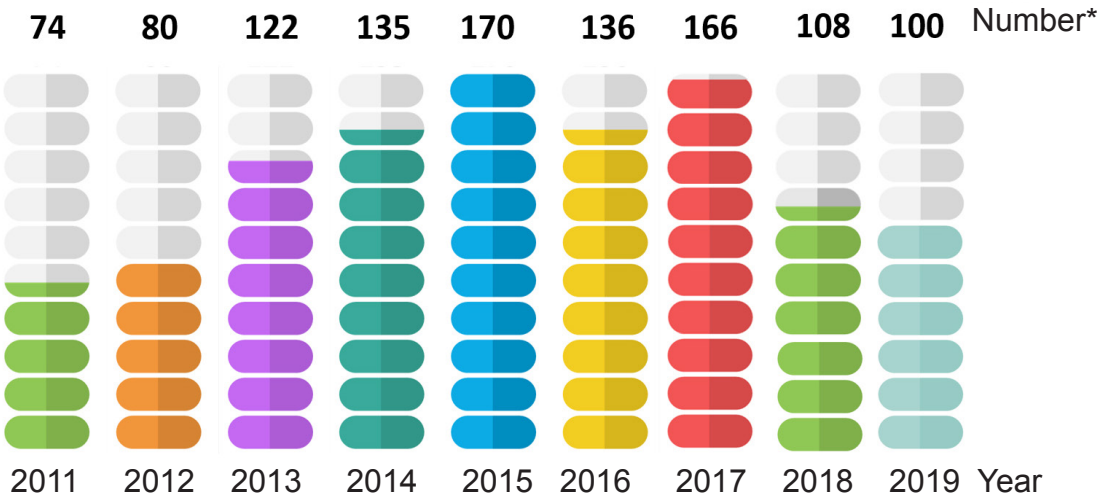
Numbering	Project name	Result
44	Inspection Project for Bakery and Food Service	I. Inspected: 136 companies (I) GHP: 59 companies were required to make improvements within a deadline, of which 58 passed the re-inspection and 1 did not pass the re-inspection. (II) Registration: 1 company is not applicable and 13 companies do not meet the regulations. (III) Tracing and management for the source of ingredients: 30 are not applicable, 6 are not in compliance with the regulations. (IV) Use and management of food additives: 29 companies are not applicable and 29 companies did not meet the regulations. (V) Waste treatment: 1 company is not applicable and 9 companies are not in compliance with the regulations. (VI) Others: 6 companies stored expired products. II.Random inspection: 243 cases, of which 17 cases do not meet the regulations.
45	Inspection on the Manufacturers of Sennosides Products in the Market	【First stage】 I. Inspected: 20 companies (I) GHP: 2 companies are not applicable, 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: All are in compliance with the regulations. (III) Inspection on the use of senna products: 9 cases, of which 5 cases are not applicable and 4 cases are in compliance with the regulations. II.Labeling: 8 cases, all are in compliance with the regulations. III.Random inspection: 2 cases, all are in compliance with the regulations. 【Second stage】 I. Inspected: 29 companies (I) GHP: 5 companies are not applicable, 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Inspection on the use of senna products: 7 cases, of which 3 cases are not in compliance with the regulations. II.Labeling: 23 cases, of which 4 cases did not meet the regulations. III.Random inspection: 12 cases, all are in compliance with the regulations.
46	Inspection Project for Nuclear Radiation in Japanese Food on the Market and Labeling Check	I. Inspection on radiation (iodine-131, cesium-134, cesium-137): 530 cases, all are in compliance with the regulations. II.Labeling: 530 cases, all are in compliance with the regulations.

Table 5 Addendum/amendment to the regulations and standards related to pharmaceutical administration in 2019

Date of announcement	Name	Important content
January 19	Updating the list of drugs for The Rare Disease and Orphan Drug Act	Adding "Patisiran (Solution for infusion, 2mg/mL)" and "Icatibant (Injection, 10mg/mL)."
February 14	Revised part of the articles of "Regulations for Registration of Medicinal Products"	Amended the some of the clauses in the "Regulations for Registration of Medicinal Products" in order to keep up with the trend of international drug management, in line with online E-submission, simplify the review process, enhance international competitiveness and enable consumers to easily see the labeling of the manufacturing date and shelf life.
March 6	Stipulated the "Regulations for the Notification of Drug Patent Linkage Agreements"	On the basis of paragraph 2, Article 48-19 in the Pharmaceutical Affairs Act, we stipulated the "Regulations for the Notification of Drug Patent Linkage Agreements" in order to prevent unfair agreements or agreements with restrictive competition that hinder other generic drugs to be on the market and improperly affect patient's access of medicine, public health and transaction order on the market.
April 2	Announcement of the stipulation of "Guidelines for Good Preparation Operations of Positron Emission Tomography"	The "Guidelines for Good Preparation Operations of Positron Emission Tomography" was announced to effectively enhance the quality of self-prepared positron medicines of medical institutions and ensure the safety of the people's use of the medicine.
April 11	Amendment to Article 4 of the "Regulations on Management of Medicament Samples and Gifts"	In line with the government to facilitate the development of biomedical industry and enhance Taiwan's competitiveness in clinical trials in the world, we manage the materials and equipment required for clinical trials based on the level of risk; For the low-risk of consumable sample collecting sets in clinical trials are simplified their application procedures , therefore a proviso was added in the first paragraph. In line with the residency policy of the Ministry of the Interior, the Alien Resident Certificate (ARC) and Alien Permanent Resident Certificate (APRC) are deemed as an identity document with the same effect as a passport. Therefore, paragraph 2 was amended and the documents required for foreigners to apply to import self-use drugs were relaxed.
May 10	Announcement of the "Implementation Details and Transition Periods of the Western Pharmaceuticals Good Distribution Practice (GDP) Regulations for Pharmacy Operators	The business undertakings of western pharmaceutical preparations that require cold-chain storage and transportation for wholesaling, importing and exporting processes should apply to TFDA for inspection of the "Western Pharmaceuticals Good Distribution Practice Regulations," and they shall fulfill the requirements of the regulations before December 31, 2021.
May 20	Reassessed the risk factors of medicinal products containing Benzocaine used in children	When the drug products containing benzocaine are used in children, it may occasionally cause rare but potentially fatal blood disorder, "methemoglobinemia." Therefore, TFDA re-assess the risk factors of these drugs used in children according to Article 48 of the Pharmaceutical Affairs Act.
	Abolished the "Announcement of Required Remarks in Package Insert for Drugs Containing Benzocaine"	The principle for the use of drugs containing benzocaine was announced and hence the former Shu-Shou-Shi-Zi No. 1011406106 "Announcement of required remarks in package insert for drugs containing benzocaine" announced by the Department of Health, Executive Yuan on September 13, 2012 was abolished.
May 30	Updating the list of drugs in The Rare Disease and Orphan Drug Act	Adding "Migalastat(capsule, 123mg)," indication for the treatment of ≧16 year-old patients with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

Date of announcement	Name	Important content
July 1	Stipulated the "Regulations for the Patent Linkage of Drugs"	The Pharmaceutical Affairs Act was amended on January 31, 2018 in accordance with the patent linkage system of medicines and the "Regulations for the Patent Linkage of Drugs" were stipulated with regards to related matters to facilitate the implementation of the patent linkage system of medicines.
July 18	Updating the list of drugs in The Rare Disease and Orphan Drug Act	Adding "Tafamidis" (soft capsule, 20mg) and "Stiripentol" (capsule, 250, 500mg; powder, 250, 500mg).
July 19	Amended the "Administration and Technical Data Table for Inspection and Registration of Generic Drugs" and the name was changed to "Table of Refuse to File (RTF) for Generic Drugs"	The name was changed to "Table of Refuse to File (RTF) for Generic Drugs."
July 31	Amendments to Article 6-1 of the "Pharmaceutical Affairs Act" that a drug category of trace or track system shall be established	Revised 38 items in the high concern category and added preparations containing ephedrine or pseudoephedrine (not including the controlled drugs) to the declaration of drug trace and track.
August 5	Revised the "Review Standards for Indicators"	Added the standards for "external hemorrhoid preparations" and "touch on (spray) nasal preparations."
September 24	Updating the list of drugs in The Rare Disease and Orphan Drug Act	Adding "Lanadelumab (injection, 150mg/ml)," with indication for prophylaxis to prevent attacks of hereditary angioedema (HAE). Explanation: 1. Patients who experienced at least 3 HAE attacks per month or 5 attacks per 6 months. 2. Patients who experienced life-threatening circumstances.
November 18	Announced the "Points To Consider on Drugs for Pediatric or Rare Disease Designation"	In order to encourage pharmaceutical industries to develop medicines for pediatrics or rare diseases, TFDA has stipulated the designation criteria and designed review mechanisms to simplify and speed up the drug review process so that the medicines can be available on the market sooner to benefit the patients.
	Revision of the "Abbreviated Review Mechanism for New Drug Applications," "Priority Review Mechanism for New Drug Applications," "Accelerated Approval Mechanism for New Drug Applications," and "Points to Consider for Breakthrough Therapy Designation"	1.For the new drugs with new chemical entities that have obtained marketing authorization from the US Food and Drug Administration (FDA), European Union European Medicines Agency (EMA) and/or the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), we take regulatory reliance approach for our good communication and cooperation experience with these stringent regulatory authorities. Therefore the Abbreviated Review procedure was stipulated. 2.The Priority Review procedures was stipulated for new drugs with urgent needs for public health in Taiwan. 3.To fulfill the unmet medical needs for the citizens in Taiwan, the Accelerated Approval Mechanism for New Drug Application was stipulated for increase drug accessibility for unmet medical needs by accepting method of surrogate endpoint clinical trial design based on scientific evidence. 4.The Points to Consider for Breakthrough Therapy Designation was stipulated for the designation on drugs that have significant improvement with clinical evidence in treating serious diseases or rare diseases in Taiwan. To support and facilitate the development and approval of these drugs, we provided a two-way communication channel through consultation for clinical trial and registration related issues.

Table 6 Number of new drugs approved in 2019



*The number of cases is based on the number of permits

Remarks: Among the 100 new drugs, 37 are new drugs with new chemical entities and 22 are biological products. Main indications of the approved new drugs includes cancer, nervous system, infection (bacteria or virus, such as HIV) and rare diseases. The approval of these new drugs provide new treatment options and are beneficial to the patients.

Table 7 **Addendum/ amendment to the schedule of Controlled Drugs in 2019**

Date of amendment	Schedule	Promulgate the names of the controlled drugs	Description
January 2	Schedule 3	Methyl (1-(4-Fluorobenzyl)-1H-indazol-3-carbonyl) valinate, AMB-FUBINACA, FUB-AMB, MMB-FUBINACA	A central nervous stimulant. No therapeutic effects which is a synthetic cannabin.
		1-(Chlorophenyl)-2-(1-pyrrolidinyl)-1-pentanone, Cl-Alpha-PVP, Cl-PVP, C-PVP, including three isomers (i.e. 2-Cl-Alpha-PVP, 3-Cl-Alpha-PVP and 4-Cl-Alpha-PVP).	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Kratom, Ketum, Mitragyna speciosa	Its leaves contain Kratom. It is an opioid substance which is a central nervous stimulant.
		N-Ethylhexedrone, N-Ethylnorhexedrone, α-Ethylaminocaprophenone, Hexen, NEH	It is a stimulant of central nervous and is a chemical compound of cathinone.
	Schedule 4	Chlorodimethylcathinone and CDMC, including three isomers such as 2-CDMC, 3-CDMC and 4-CDMC.	It is a stimulant of central nervous and is a chemical compound of cathinone.
April 11	Schedule 2	Khat, Qat, Kat, Chat, Abyssinian Tea, Arabian Tea, Catha Edulis Forsk	Its leaves contain Cathinones, which is a central nervous system stimulant.
	Schedule 3	4-ethyl-2,5-dimethoxyphenethylamine, 2,5-dimethoxy-4-ethylphenethylamine, 2-(4-ethyl-2,5-dimethoxyphenyl) ethanamine, 2,5-dimethoxyphenethylamine, 2C-E	It is a stimulant of the central nervous system and is a chemical compound of amphetamines.
		N-[(2S)-1-amino -3-methyl-1-oxobutan-2-yl]-1-pentylindazole-3-carboxamide, AB-PINACA	A central nervous stimulant. No therapeutic effects which is a synthetic cannabin.
		Ethylmethcathinone and EMC, including three isomers such as 2-EMC, 3-EMC and 4-EMC.	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Mitragynine, 9-Methoxycorynantheidine	It is an opioid substance which is a central nervous system stimulant.

Date of amendment	Schedule	Promulgate the names of the controlled drugs	Description
December 5	Schedule 3	1-(Chlorophenyl)-2-(1-pyrrolidinyl)-1-propanone, Chloro-α-pyrrolidinopropiophenone, Chloro-α-PPP , Including three isomers such as 2-Chloro-α-PPP, 3-Chloro-α-PPP and 4-Chloro-α-PPP.	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Deschloro-N-ethyl-Ketamine, 2-(ethylamino)-2-phenylcyclohexan-1-one, 2-DCNEK	An inhibitor of central nervous which is a chemical compound of Ketamine.
		Ethylethcathinone, EEC, including three isomers such as 2-EEC, 3-EEC and 4-EEC.	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Fluoro-α-pyrrolidinohexanophenone, 1-(Chlorophenyl)-2-(1-pyrrolidinyl)-1-pentanone, Fluoro-α-PHP), including three isomers such as 2-Fluoro-α-PHP, 3-Fluoro-α -PHP and 4-Fluoro-α -PHP.	It is a stimulant of central nervous and is a chemical compound of cathinone.
		2-Fluorodeschloroketamine, 2-(2-Fluorophenyl)-2-methylamino-cyclohexanone, Fluoroketamine, 2-FDCK	An inhibitor of central nervous which is a chemical compound of Ketamine.
		3,4-Methylenedioxy-α-pyrrolidinohexiophenone, MDPHP	It is a stimulant of central nervous and is a chemical compound of cathinone.
		(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone, UR- 144	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Etizolam	An inhibitor of the central nervous system which is a chemical compound of Benzodiazepine.
		Methyl-N,N-Dimethylcathinone, Methyl-N,N-DMC, including three isomers such as 2-Methyl-N,N-DMC, 3-Methyl-N,N- DMC and 4-Methyl-N, N-DMC.	It is a stimulant of central nervous and is a chemical compound of cathinone.

Date of amendment	Schedule	Promulgate the names of the controlled drugs	Description
December 5	Schedule 4	Chlorodiazepam, including three isomers such as 2-Chlorodiazepam (also known as Diclazepam), 3-Chlorodiazepam and 4-Chlorodiazepam.	An inhibitor of the central nervous system which is a chemical compound of Benzodiazepine.
	Schedule 4 Active Pharmaceutical Ingredients of Controlled Drugs	Hydroxylimine HCl	Precursors of ketamine
		o-Chlorphenyl cyclopentylketone, 2-Chlorophenylcyclopentylketone, o-Chlorobenzoylcyclopentane	Precursors of ketamine.
		Alpha-Acetylphenylacetonitrile, APAAN	Precursors of amphetamines
		Phenyl-2-propanone, P2P	Precursors of amphetamines
		Chloroephedrine (alkaloid)	Precursors of amphetamine or cathinone.
		Chloropseudoephedrine (alkaloid)	Precursors of amphetamine or cathinone.
		2-Bromo-4-methylpropiophenone	Precursors of cathinone.
		N-Boc-Norketamine	Precursors of ketamine.
		4-anilino-N-phenethylpiperidine, ANPP	Precursors of fentanyl.
		N-phenethyl-4-piperidone, NPP	Precursors of fentanyl.

Table 8 Addendum/amendment to the regulations and standards related to medical devices management in 2019

Date of announcement	Name	Important content
January 17	Announced the "Examples of Proper and Improper Advertisement Wording of Class I Medical Devices" for 11 items	This provide clear and specific basis for businesses to revise or edit their advertisement wording for Class I medical devices and to prevent unintentional violation of laws and regulations.
May 22	Amendment to the "Fee-Charging Standards for Registration and Market Approval and Cosmetic Advertisements of Medical Devices"	Fees related to medical devices are independently specified in the "Fee-Charging Standards for Registration and Market Approval and Cosmetic Advertisements of Medical Devices" This fee-charging standards are effective on July 1, 2019.
June 20	Announced that "for medical devices that require inclusion of specified text in accordance with the provisions of Administrative Regulations on Low Power Radio Waves Radiated Devices, firms shall follow the regulations and do not need to submit application of registration and market approval to TFDA."	For medical devices that require inclusion of specified text in accordance with the provisions of Administrative Regulations on Low Power Radio Waves Radiated Devices, firms shall follow the regulations and do not need to submit application of registration and market approval to TFDA.
July 17	Announced the "Examples of Proper and Improper Advertisement Wording of Class I Medical Devices" for 10 items	This provide clear and specific basis for businesses to revise or edit their advertisement wording for Class I medical devices and to prevent unintentional violation of laws and regulations.
July 29	Revise Annexes for Articles 8 and 3 of Regulations for Governing the Management of Medical Device	Amended medical devices classification, categorization, item names and identification to clarify identification, use and align with international management model for businesses to follow.
August 14	Announced the "2019 List of Medical Devices Recognized Standards"	Announced that 1,051 international medical device standards would be recognized, so medical device manufacturers can choose to follow these standards when they develop and test medical devices to ensure the safety and effectiveness of products in the market.
September 2	Announced the pre-clinical testing guidance for "tooth shade resin material (F.3690)" and "vascular graft prostheses (E.3450)"	Business can use the guidance as a reference for research and development of product and registration and market approval; Inspectors can also use the guidance as a reference to ensure the safety and effectiveness of the products in the market.
September 4	Modified the pre-clinical testing guidance for "infrared lamp (therapy apparatus)," "oximeter," "electronic sphygmomanometers," and "electrocardiograph"	
November 18	Announced the "Guidance for Manufacturers: Cybersecurity for Networked Medical Devices"	For medical device manufacturers, the guidance provides key points related to cybersecurity for product design, research and development, application of registration and market approval and post-market considerations, to ensure that medical devices can meet the cybersecurity requirements.

Table 9 Addendum/amendment to the regulations and standards related to cosmetics management in 2019

Date of announcement	Name	Important content
May 22	Stipulated the "Regulations Governing the Source and the Flow Data of Cosmetic Products"	Stipulated the scope, items, content, establishment and expiration date, methods and other compliance matters for the cosmetics industry to create and maintain the information on direct source of supply and product flow.
	Stipulated the "Regulations for Cosmetics Recall"	Stipulated the classification, disposal methods, implementation methods of recycling, completion timeline, contents of plan and report, record keeping, and other compliance matters for the cosmetics manufacturers or importers.
	Stipulated the "Regulations for Reporting Cosmetics Serious Adverse Effects and Hazards to Hygiene and Safety"	Stipulated the notification target, notification method, notification period and notification content of incidents such as serious adverse reactions in cosmetics.
	Stipulated the "Regulations for Issuance and Management of the Cosmetics Certificates"	Stipulated the application criteria, review procedures and standards, validity term, revocation, return, cancellation, and other compliance matters regarding the issuance of certificates, to specifiy the application criteria and review standards for the issuance of cosmetics certificates.
May 28	Stipulated the "Regulations for Issuance of License of Specific-Purpose Cosmetics"	The issuance, modification, revocation and rescission of license of specific-purpose cosmetics for cosmetic manufacturers or importers, as well as the application procedures and other matters need to be followed for license extension of cosmetics containing medical or poisonous drugs.
	Stipulated the "Regulations for Authorizing the Applications of Import of Non-licensed Specific-Purpose Cosmetics"	The regulations regulated the application qualification and purpose of the specific purpose cosmetics for the application for registration or for use in research and trial, the required documents and information for applicants, and the required quantity. The regulations also stipulated that the competent authority may revoke and rescind the grant for documents that are false or the actual usage is inconsistent with the content of approval. These applications will be refused by the competent authority within 2 years.
	Revised the "Fee Standards for Cosmetics and Cosmetics Dye Registration" and the name was amended to "Standards of Administrative Fees for Cosmetics"	Stipulated the required inspection fees and certificate fees of the notification of cosmetics, the permission of animal testing for the safety assessment of cosmetics or cosmetic ingredients, specific-purpose cosmetics registration, the manufacturing quality inspection and certificate of Cosmetics Good Manufacturing Practice Regulations.

Date of announcement	Name	Important content
	Stipulated the "Particulars of Specific Purpose Cosmetics that May Be Voluntarily Modified"	The label, leaflet or outer packaging for specific purpose cosmetics that meet the announcement content may be voluntarily modified without the approval of the central competent authority.
	Stipulated the "Limited Numbers on Registration of Exemptions from the Inspection of Imported Specific Purpose Cosmetics for Personal Use"	It may exempted from applying for registration if the amount of imported specific-purpose cosmetics for personal use is not over the announced limits by the central competent authority and the supply, sale, public display, consumer trial offer or transfer to other uses of these cosmetics shall be forbidden.
	Revised the "Scope and category list of cosmetics"	In line with the amendment to the definition of cosmetics, MOHW announced to include the non-medicinal toothpaste and mouthwash in cosmetics management as well as the dates for implementation.
May 30	Stipulated the "Regulations Governing Notification of Cosmetic Products"	Stipulated Regulations for the certain scale of cosmetic manufacturers or importers, product items, contents, procedures, changes, validity term, abolitions and cancellations, and other compliance matters.
	Stipulated the "Regulations for Cosmetic Product Information File Management"	Stipulated Regulations for the certain scale of cosmetic manufacturers or importers, product items, contents, procedures, molification, establishment and storage of product information file, validity term, location and qualification of signatory for the safety report, and other compliance matters.
	Stipulated the "Categories of Cosmetics and the Enforcement Date that Business Shall Complete Product Notification"	Stipulated the categories of cosmetics and the enforcement date that manufacturers or importers shall complete product notification.
	Stipulated the "Categories of Cosmetics and the Enforcement Date that Business Shall Establish Product Information File"	Stipulated the Categories of Cosmetics and the Enforcement Date that manufacturers or importers shall establish product information file.
	Stipulated the "Labeling Regulations for Cosmetic Packaging, Containers, Labels or Directions" and abolished the "The Names of All Ingredients Contained in the Cosmetic Product Shall Be Indicated on the Outer Packaging" and "The Indication Requirement for the Label, Leaflet, and Packaging of Cosmetic Products"	According to Paragraph 4 of Article 7 in the Cosmetic Hygiene and Safety Act, the labeling format, method of cosmetic packaging, containers, labels or directions, and other compliance matters were stipulated. The original regulations were abolished.
	Stipulated the "For Imported Cosmetic Products that Are Re-packaged Domestically, the Packaging or Containers Shall Be Labelled "Re-packaged in Taiwan"	For consumers to easily identify the imported cosmetics that are non-originally packaged, it is required for those imported cosmetics that are re-packaged domestically to be clearly labelled the re-package information with the wording "re-packaged in Taiwan."

Date of announcement	Name	Important content
May 30	Stipulated the "List of Specific Purpose Ingredients in Cosmetic Products," "List of Ingredients Prohibited in Cosmetic Products," "List of Ingredients Restricted in Cosmetic Products," "List of Preservatives in Cosmetic Products," "List of Colorants in Cosmetic Products," and "List of Microorganisms Limits in Cosmetic Products"	For importing or manufacturing of specific purpose cosmetics designed by the public announcement of the central competent authority, an application for registration shall be filed with the central competent authority. No manufacturing or import shall be allowed until a license is approved and issued. Cosmetics shall not contain mercury, lead or other ingredients banned for use as per announcement of the central competent authority; the central competent authority may restrict the use of cosmetic ingredients to prevent and avoid causing allergies, irritation, depigmentation, conditions that pose a hazard to human health. Hence the relevant regulations are announced.
June 4	Stipulated the "Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical Efficacy of Cosmetic Products"	The "Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical Efficacy of Cosmetic Products" have been stipulated as the identification standards in order to protect the health of Taiwanese citizens and the rights and interests of consumers, as well as maintain the stability of the laws.
June 25	Stipulated the "Types of cosmetics that are required to meet the Cosmetics Good Manufacturing Practice Regulations"	According to Paragraph 2 of Article 8 in the Cosmetic Hygiene and Safety Act, the types of cosmetics that are required to meet the Cosmetics Good Manufacturing Practice (GMP) Regulations are stipulated.
June 27	Stipulated the "Enforcement Rules of Cosmetic Hygiene and Safety Act"	In accordance with the amendment of the Cosmetic Hygiene and Safety Act, to add the specifications on the person who is responsible for product notification and product information file, the definition of country of origin of the cosmetics, the definition of manufacturing facilities, the exception for hiring and stationing licensed pharmacists or personnel with professional skills in the field of cosmetics at the factory to supervise the dispensation and manufacturing of cosmetics, the storage procedures and the storage obligations of the business operators, and the definition of severe violation in cosmetics promotion or advertisements.
	Stipulated the "Regulations for Qualifications and Training of Cosmetics Professional Technicians"	Stipulated the qualifications, training, responsibilities, and other compliance matters for the cosmetics professional technicians.
	Stipulated the "Regulations for the Inspection and Examination of Imported Cosmetics"	Announced certain cosmetics categories or items that could possibly pose a hazard to hygiene and safety and stipulated the methods, techniques, items, scopes of sampling checks and sampling tests, and other compliance matters. Above cosmetics may only be imported after sampling checks and sampling tests show compliance.

Date of announcement	Name	Important content
June 27	Stipulated the "Cosmetic Manufacturing Facilities Exempted From Factory Registration"	Announced that if the scale of manufacturing facilities for solid handmade soaps that is smaller than the factory standards for product manufacturing and processing scope, area, power capacity and thermal energy and the manufacturing sites is only for the operations of cosmetic packaging, it can be exempted from factory registration.
	Stipulated the "Words and Phrases That Should Be Additionally Labelled on the Outer Packaging or Containers of Imported Cosmetics Which Are Labelled With Words Like 'Medicinal', 'Medicine', 'Medicinal drug', 'Medicate', etc."	With the developing international trade, some foreign products that are regulated as quasi-drugs or OTC drugs, but regulated as cosmetics after importing to Taiwan, such as sunscreens and whitening agents; the outer packaging of these imported cosmetics is labelled with words like "medicine", "medicinal", "medical drug", "medicate", ect. When imported into Taiwan, so we announced that an additional words and pharses is required to be labelled on the outer packaging of these imported cosmetics, to reduce the impact of Cosmetic Hygiene and Safety Act on the imported products and remind Taiwanese citizens not to get confused.
	Stipulated the "Regulations on Cosmetic Hygiene and Safety Violation Report and Reward"	We stipulated the "Regulations on Cosmetic Hygiene and Safety Violation Report and Reward" in order to encourage the public to report unlawful matters, protect the health of the citizens and the rights and interests of consumers, as well as to clarify the relevant regulations for rewarding whistleblowers and issuance of rewards.
June 28	Revised "Regulations Governing the Applications for Animal Testing for the Safety Assessment of Cosmetics or Cosmetic Ingredient"	Specified and amended the regulations in accordance with Cosmetic Hygiene and Safety Act.
August 5	Stipulated the "Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions"	In line with the additional Paragraph 3 of Article 28 in the Cosmetic Hygiene and Safety Act, we stipulated the Regulations for the Management of Certification and Entrusted Certification of the Cosmetic Inspection Agency, including application conditions, certification procedures, validity period, abolishment and matters to be followed.
August 13	Stipulated the "Cosmetics Good Manufacturing Practice Regulations"	On the basis of the requirements of ISO22716, we stipulated the Cosmetics Good Manufacturing Practice Regulations to promote quality management of cosmetic manufacturers and ensure quality, hygiene and safety of the produced cosmetics.

Date of announcement	Name	Important content
August 29	Stipulated the "Establishment Standards for Cosmetics Manufactory"	Revised the relevant requirements for facilities and equipment in the factory according to the operations of the cosmetics manufacturing sites and requirements of dosage form.
October 23	Stipulated the "Usage Precautions for Hair Dyes on the Labels or in the Package and Leaflet," "Usage Precautions for Permanent Wave Agents on the Labels or in the Package and Leaflet," "Usage Precautions for Hair Colour Remover on the Labels or in the Package and Leaflet;" abolished "Usage Precautions for Hair Dyes on the Label or in the Package and Leaflet," "Precautions for Permanent Wave Agents on the Labels or in the Package and Leaflet for Manufacturing or Import," "Usage Precautions for Hair Colour Remover on the Labels or in the Package and Leaflet"	On the basis of Article 7, Paragraph 1, Sub-paragraph 10 of the Cosmetic Hygiene and Safety Act, It is authorized to stipulate that outer packaging or container of cosmetics shall clearly label the matters required by the central competent authority and abolish the former regulation.
December 2	Stipulated the "Technical Guidelines for Water Resistance Test (Test on Human) of Cosmetics with Sunscreen," "Technical Guidelines for Human Skin Patch Test of Cosmetics" and "Technical Guidelines for Human Skin Test of Cosmetics"	To enhance the industrial development of the domestic cosmetics industry as well as strengthen the cosmetic management and protect the safety of the testing subjects, TFDA stipulated the "Technical Guidelines for Water Resistance Test (Test on Human) of Cosmetics with Sunscreen," "Technical Guidelines for Human Skin Patch Test of Cosmetics," and "Technical Guidelines for Human Skin Test of Cosmetics."
December 5	Revised the "List of Preservatives in Cosmetic Products"	In response to non-medicinal toothpaste and mouthwash to be included in the cosmetics management in the future, the regulations for the ingredients of non-medicinal toothpaste and mouthwash are also added and it will take effect on July 1, 2020.

Table 10 Collaborative Inspection of Food, Drugs and Cosmetics in 2019

Inspection type	Numbering	Project name (Implementation time)	Results
Food safety	1	Random inspection plan for honey products (March to May)	Inspected: 29 companies I.Registration: 2 companies are not applicable, 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Labeling: 6 cases do not meet the regulations.
	2	The collaborative inspection project for egg products (July to November)	Inspected: 18 companies I.GHP: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.HACCP: 4 companies are required for the establishment; 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. III.Registration: 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. IV.Random inspection: 8 liquid egg products, of which 1 case did not meet the regulations.
Medical devices	1	Inspection project for online sales of medical equipment (January to June)	We inspected a total of 162 medical equipment sold on 10 online platforms, of which 61 cases were in violation of the relevant regulations of the Pharmaceutical Affairs Act. The violations included not having a pharmaceutical license, not registered in accordance with the "Medical devices that pharmaceutical companies (drugstores) may sell through the communication-based transaction channels and registration requirement," selling of medical equipment that is approved to be sold through the communication-based transaction channels, not disclosing the information (including incorrect license number, the license number and product name of medical device are not completely revealed, etc.) that should be disclosed at an obvious location for consumers through the communication-based transaction channels and do not match with the approved document.
	2	The collaborative inspection project for medical equipment (January to April)	We inspected a total of 63 cases in 57 clinics and medical institutions, including 45 cases of medical equipment. A total of 4 cases were suspected of violating the regulations of Pharmaceutical Affairs Act and the violations include the labeling and product name not match with the original approved document, etc.
	3	The collaborative inspection project for medical equipment (April to June)	We inspected a total of 70 medical equipment shops and other shops with pharmaceutical licenses and pharmaceutical companies with licenses. We inspected 10 non-powered therapeutic mattresses, including 8 medical equipment license numbers, all of their product packaging, labeling, description, package insert and medical license numbers match with the original approved document and their declared uses are also in compliance with the regulations of Pharmaceutical Affairs Act.
Drugs	1	The collaborative inspection project for drugs (July to August)	Inspected 266 companies and 45 pharmacies and 6 cosmetic and drugstores were found in violation of regulations, including sales of prescription drugs without a prescription, pharmaceutical practices not by pharmaceutical personnel and provision and sale of expired drugs.
Controlled drugs	1	Inspection Project for Controlled Drugs (March to September)	We inspected a total of 376 companies, of which 134 companies had violations, including the fact that the books for keeping accounts did not record the daily income, expenditure and balance in accordance with the regulations and the books for keeping accounts did not record the correct information and improper use of medical devices.
Cosmetics	1	The collaborative inspection project for teeth whitening cosmetics (January to April)	We inspected a total of 40 tooth whitening cosmetic companies with medicated cosmetics licenses, of which 23 companies are not applicable; thus we inspected 17 companies with a total of 28 tooth whitening cosmetic products of which 18 products were brought back for quality inspection (the other 10 products cannot be inspected due to insufficient number of sampling). 5 products were found to have inconsistent labeling, of which the inspection results of 3 products did not meet the requirements (1 inspection sample was not labeled in Chinese and thence the test results could not be verified; and the amount of the main ingredient for the other 2 test results did not match with the originally registered document).
	2	The collaborative inspection project for spices cosmetics (May to June)	We inspected 49 cosmetics and drugstores and there is no violation found in the 87 inspected face powder cosmetic products containing talc. In addition, 30 of the face powder cosmetic products containing talc were brought back for inspection (test for asbestos ingredient) and all the 30 products passed the inspection.
	3	Inspection project for cosmetics manufacturers in violation of advertising rules (September to October)	We inspected 10 companies and 44 cosmetic products, of which 1 product label did not meet the regulations.

Table 11 **Amendments for the Chinese Pharmacopoeia and the publication of the "Chinese Pharmacopoeia edition VIII" supplement (3)**

Category	Number of articles	Briefing on the contents of the addition and amendment to the "Eighth Edition of the Chinese Pharmacopoeia" supplemental articles (3)
New Monographs	199	1.The test methods and acceptance criteria for nitrosamine impurities in sartan-type active pharmaceutical ingredients were added to provide real-time important information. 2.The following were added：Application of Nuclear Magnetic Resonance Spectroscopy, Mid-Infrared Spectroscopy, Ultraviolet-Visible Spectroscopy, Capsules-Dissolution Testing and Related Quality Attributes, Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use, Analytical Procedures Recombinant Therapeutic Monoclonal Antibodies, Validation of Alternative Microbiological Methods, etc. 3.Documented the eight active pharmaceutical ingredients such as Potassium Cresolsulfonate, Granisetron, Calcipotriol Monohydrate, Travoprost which were developed and manufactured by domestic companies, to promote the development of domestic industries.
Monographs in Amendments	136	
Active pharmaceutical ingredients with domestic characteristics	8	
New General Chapters	31	
General Chapters in Amendments	29	
Total	403	

Table 12 **Additional TFDA Analytical Test Methods Form in 2019**

Test method category	Test method name	Stipulate/ Amendment
Food promulgated methods (25 articles, 640 items)	1.Method of Test for Marine Biotoxins in Foods - Test of Neurotoxic Shellfish Poison 2.Method of Test for Heavy Metals in Bottled (Packaged) Drinking Water and Ice Cubes 3.Method of Test for Food Additive Specifications - Sodium γ-Polyglutamate	Stipulation
	4.Method of Test for Food Additive Specifications - Potassium Sorbate 5.Method of Test for Food Additive Specifications - Benzoic Acid 6.Method of Test for Antioxidants in Foods - Multiple Analysis 7.Method of Test for Preservatives in Foods 8.Methods of Test for Specifications of (6S)-5-Methyl-tetrahydrofolic acid, Glucosamine Salt as Food Raw Material 9.Method of Test for Veterinary Drug Residues in Foods - Test of Multiresidue Analysis of β-Agonists 10.Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (5) 11.Method of Test for Food Additive Specifications - Sodium Benzoate 12.Method of Test for Food Additive Specifications - Sodium Erythorbate 13.Method of Test for Veterinary Drug Residues in Foods - Test of Flunixin and Tolfenamic acid 14.Method of Test for Veterinary Drug Residues in Foods - Method for Multiresidue Analysis (2) 15.Method of Test for Food Additive Specifications - Sodium Propionate 16.Method of Test for Food Additive Specifications - DL- Malic Acid 17.Method of Test for Food Additive Specifications - Sodium DL-Malate 18.Method of Test for Food Additive Specifications - Gellan Gum 19.Method of Test for Food Additive Specifications - Calcium Propionate 20.Method of Test for Food Additive Specifications - Calcium Chloride 21.Method of Test for Food Additive Specifications - Acesulfame Potassium 22.Method of Test for Food Additive Specifications - D-Sorbitol 23.Method of Test for Food Additive Specifications - Lactic Acid 24.Method of Test for Food Additive Specifications - Glycine 25.Method of Test for Food Additive Specifications - Propionic Acid	Amendment

Test method category	Test method name	Stipulate/ Amendment
Recommended method for food test (43 articles, 433 items)	1.Method of Test for Polycyclic Aromatic Hydrocarbons in Foods 2.Method of Test for Animal-Derived Ingredients in Foods - Qualitative Test of *Dissostichus* spp. 3.Method of Test for Animal-Derived Ingredients in Foods - Qualitative Test of *Hippoglossus* and *Reinhardtius* spp. 4.Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Soybean Event FG72 (UI:MST-FGØ72-2) 5.Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Soybean Event MON87751 (UI: MON-87751-7) 6.Method of Test for Fluoride and Chloride in Foods 7.Methods of Test for Food Microorganisms - Test of Enterobacteriaceae 8.Method of Identification for Rosin as Hair Removal Agents for Foods 9.Method of Test for Sudan Dyes in Foods (2) 10.Method of Test for Methylsulfonylmethane in Foods in Tablet and Capsule Form 11.Method of Test for Pesticide Residues in Foods - Rapid Screening Mass Spectrometry Technique 12.Method of Test for Residual Dioxins and Dioxin-Like Polychlorinated Biphenyls in Hairy Crabs (GC-MS/MS Method) 13.Method of Test for Pesticide Residues in Foods - Test of Paraquat, a Herbicide 14.Method of Test for Veterinary Drug Residues in Foods - Test of Fluralaner 15.Method of Test for Residual Solvents in Foods in Tablet Form 16.Method of Test for Pesticide Residues in Honey - Test of Carbendazim, Fluvalinate and Iprodione 17.Method of Test for Heavy Metals in Vegetables, Fruits, Jams and Jellies 18.Method of Test for Heavy Metals in Mushrooms 19.Method of Test for Total Hydrocyanic Acid in Cassava Products 20.Method of Test for Veterinary Drug Residues in Foods - Test of Tiamulin (2) 21.Method of Test for Glycidyl Esters in Edible Oils and Fats 22.Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Pecan 23.Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Filbert/Hazelnut 24.Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Walnut 25.Method of Test for Plant - Derived Ingredients in Foods - Qualitative Test of Cashew 26.Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of Hormones 27.Method of Test for Dimethyl sulfoxide in Raw Material ethylsulfonylmethane 28.Method of Test for Pesticide Residues in Vegetable Oil - Multiresidue Analysis 29.Method of Test for Veterinary Drug Residues in Foods - Multiresidual Analysis of β-Lactam Antibiotics 30.Method of Test for Veterinary Drug Residues in Foods - Test of Closantel 31.Method of Test for Hydroxytyrosol in Foods in Tablet and Capsule Forms 32.Method of Test for Vitamin K_3 in Milk-Based Infant Formula	Stipulation

Test method category	Test method name	Stipulate/ Amendment
Recommended method for food test (43 articles, 433 items)	33.Method of Test for Niacin in Milk-Based Infant Formula 34.Method of Simple Check for Residual Lipid, Starch and Alkyl Benzene Sulfonate on Tablewares 35.Method of Test for Sudan Dyes in Foods 36.Method of Test for Phosphate in Foods 37.Method of Test for Colorants in Foods - Multiple Analysis (2) 38.Method of Test for Melamine in Foods 39.Methods of Test for Food Microorganisms - Test of Lactic Acid Bacteria - *Enterococcus faecium* 40.Method of Test for Sennosides in Foods 41.Method of Test for Methylsulfonylmethane in Foods in Tablet and Capsule Form 42.List of Recommended Methods of Test for Pesticide Residues in Foods 43.Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (6)	Amendment
Recommended test methods for cosmetics and medical devices (5 articles, 66 items)	1.Method of Test for Imperatorin, 5-Methoxypsoralen, 8-Methoxypsoralen, 6-Methylcoumarin, Musk Ambrette, Safrole and Trioxysalen in Cosmetics 2.Method of Identification for Asbestos Fibers in Cosmetics 3.Method of Test for Residual Cross-linking Agents in Hyaluronic Acid Dermal Fillers – Test of 1,4-Butanediol Diglycidyl Ether	Stipulation
	4.Method of Test for Ingredients in Cosmetics 5.Method of Test for Banned and Restricted Dyes in Cosmetics	Amendment
Recommended methods for testing drugs and controlled drugs including illegal drugs) (5 articles, 76 items)	1.Method of Analysis for Synthetic Phenethylamines in Urine 2.Determination of *N*-Nitroso-*N*-Methyl-4-Aminobutyric Acid in Sartan Drug Substances and Drug Products	Stipulation
	3.Method of Test for Synthetic Cathinones in Urine (2) 4.Determination of *N*-Nitroso-*N*-Methyl-4-Aminobutyric Acid in Sartan Drug Substances and Drug Products 5.Determination of *N*-Nitrosodimethylamine and *N*-Nitrosodiethylamine in Medicines	Amendment

Appendix 3 Important Achievements and Statistics Over the Years

Table 1 Statistics of imported food inspection

Year	Inspection Number of Batches	Total net weight (x10k tons)	Batches tested	Growth rate (%)	Testing rate (%)	Number of non-compliant lost
2011	420,602	717.7	29,801	-	7.1	289
2012	461,665	754.5	38,793	9.8	8.4	467
2013	514,710	713.3	38,460	11.5	7.5	557
2014	616,286	796.6	48,704	19.7	7.9	664
2015	640,003	900.5	50,149	3.9	7.8	953
2016	674,991	882.9	52,722	5.5	7.8	915
2017	694,372	896.9	56,604	2.9	8.2	808
2018	682,575	895.0	58,915	-1.7	8.6	820
2019	718,766	925.7	58,108	5.3	8.1	786

Remarks: TFDA started to conduct food import inspections in 2011 years, so there was no growth rate in that year.

Table 2 Statistical analysis of the surveillance of pesticide residues, veterinary drug residues, fungi toxins and heavy metals in food

Year	Monitoring of pesticide residues		Monitoring of veterinary drug residues		Monitoring of fungi toxins		Monitoring of heavy metals	
	Total products	Conformity rate (%)	Total products	Conformity rate (%)	Total products	Conformity rate (%)	Total products	Conformity rate (%)
2010	2,051	90.5	330	98.2	194	96.4	161	100.0
2011	2,110	89.0	481	90.9	141	90.8	162	100.0
2012	2,363	89.8	572	93.0	356	96.1	410	100.0
2013	2,340	88.9	861	95.5	421	97.9	472	99.2
2014	2,528	87.2	830	95.7	461	97.4	801	99.4
2015	3,087	88.7	1,745*	98.2	512	94.3	601	99.0
2016	3,341	89.1	2,278*	98.6	515	97.5	601	99.5
2017	4,465	87.0	2,732*	99.0	591	97.1	650	99.5
2018	4,467	89.0	3,580*	99.1	570	99.4	553	99.4
2019	5,164	90.6	4,260*	99.5	800	95.1	611	99.2

*Source: TDFA high-risk project “Testing plans for veterinary drug residues in food” and “Testing plans for veterinary drug residues” jointly conducted with local government Health Bureaus.

Table 3 Statistics on food poisoning over the years

Year	Number of Outbreaks	Food poisoning cases		Number of food poisoning cases classified by foods					
		Number of patients	Number of Death	Aquatic products and their processed products	Meat, eggs, dairy and their processed products	Grain, fruits and vegetables and their processed products	Cake, Candy	compound cooking foods and other types	Total of causes with undefined foods
2007	248	3,231	0	4	6	7	0	13	218
2008	272	2,924	0	10	3	2	2	19	236
2009	351	4,642	0	4	2	3	4	43	296
2010	503	6,880	1	12	2	10	4	56	420
2011	426	5,819	1	23	5	9	1	73	315
2012	527	5,701	0	19	8	9	2	66	423
2013	409	3,890	0	10	7	9	1	22	338
2014	480	4,504	0	18	12	6	3	60	381
2015	632	6,235	0	17	3	7	1	53	551
2016	486	5,260	0	18	4	2	2	56	404
2017	528	6,232	0	7	3	7	0	44	467
2018	398	4,616	0	5	2	5	1	30	358
2019	503	6,944	2	13	5	5	1	26	458

Table 4 Statistics of licenses for health food and genetically modified food over the years

Issued health food licenses (individual case review and specification standard review)					Issued genetically modified food licenses	
Year	Individual case review	Specification standard review	Number of issued licenses in the year	Total number of issued licenses	Number of issued licenses in the year	Total number of issued licenses
2008	33	-	33	144	2	14
2009	26	6	32	176	13	27
2010	16	4	20	196	3	30
2011	17	6	23	219	13	43
2012	22	8	30	249	9	52
2013	14	13	27	276	10	62
2014	26	15	41	317	12	74
2015	22	5	27	344	33	107
2016	25	7	32	376	11	118
2017	31	0	31	407	12	130
2018	20	3	23	430	10	140
2019	21	3	24	454	9	149

Note:

1:Two kinds of review process are provided for registration of health food.

Individual case review: The applicants shall provide related documents, including food safety, health care effects, etc. and issued number is Wei Bu Chien Shi Tzu No. Axxxxxx.

Specification standard review: Products shall comply with Ministry of Health and Welfare specifications and standards. The issued number is Wei Bu Chien Shi Kui Tzu No. xxxxxx.

2. As of December 2019, the total number of issued licenses for health food was 454 (including 384 in type one and 70 in type two), of which 64 were invalid licenses (including expired, revoked and combined). As of the end of 2019, the number of valid licenses was 390.
3. As of December 2019, there were 149 licenses for genetically modified foods, of which 0 of them will be discontinued or not be extended. As of the end of 2019, the number of valid licenses was 149.

Table 5 Statistics of approved medicinal products every year

Year	Generic drugs			Active pharmaceutical ingredients			Novel drug			Biologics			Orphan drugs			Total
	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	
2008	383	44	427	13	59	72	18	76	94	1	25	26	2	2	4	623
2009	449	47	496	5	91	96	24	56	80	0	17	17	0	2	2	691
2010	323	41	364	15	69	84	11	77	88	2	14	16	0	0	0	552
2011	220	52	272	20	172	192	17	46	63	1	24	25	0	2	2	554
2012	256	60	316	8	203	211	20	42	62	2	25	27	0	9	9	625
2013	247	51	298	7	105	112	23	14	37	0	1	1	0	3	3	451
2014	263	122	385	24	80	104	28	62	90	1	11	12	1	2	3	594
2015	175	86	261	18	81	99	27	90	117	0	35	35	3	5	8	520
2016	202	84	286	48	191	239	12	141	153	0	16	16	1	3	4	698
2017	196	90	286	28	193	221	20	120	140	1	15	16	2	16	18	681
2018	154	48	202	8	166	174	34	97	131	1	29	30	0	12	12	549
2019	171	50	221	4	147	151	36	63	99	0	23	23	2	3	5	499

Table 6 Number of valid GMP/QSD registration letters for medical devices every year

Year	Valid GMP registration letters	Valid QSD registration letters
2010	236	1,340
2011	486	2,777
2012	531	3,065
2013	568	3,213
2014	565	3,057
2015	685	3,640
2016	669	3,800
2017	704	3,925
2018	748	4,177
2019	792	4,338

Table 7 Statistics of approved licenses for medical device and cosmetics over the years

Year	Medical devices				Specific-Purpose Cosmetics	
	Number of issued license in the year	Total number of licenses	Domestic licenses	Imported licenses	Number of issued license in the year	Total number of licenses
2010	3,920	30,140	5,905	24,235	1,437	13,436
2011	4,047	33,865	6,857	27,008	1,519	14,979
2012	3,592	32,821	7,057	25,764	1,482	12,340
2013	3,827	35,705	8,079	27,626	1,456	13,799
2014	3,605	37,967	8,952	29,015	1,565	14,570
2015	3,743	40,579	9,678	30,901	1,558	14,902
2016	3,818	43,328	10,329	32,999	1,172	15,674
2017	3,940	46,797	11,203	35,594	1,142	16,643
2018	3,985	45,890	11,172	34,718	1,220	15,365
2019	3,770	45,839	11,332	34,507	1,257	14,710

Remarks: 6,253 licenses were announced to be cancelled in 2018; 4,653 licenses were announced to be cancelled in 2019.

Table 8 Controlled drug licenses and inspection statistics over the years

Year	Statistics of controlled drug licenses		Statistics of controlled drug inspections		
	Controlled drug registration	Controlled drug license (persons)	Number of inspections	Number of violations	Violation rate (%)
2008	12,465	39,467	16,241	270	1.66
2009	12,830	41,157	16,355	245	1.50
2010	13,266	42,619	15,154	196	1.29
2011	13,745	44,469	15,270	147	0.96
2012	14,149	45,844	16,214	202	1.25
2013	14,511	47,391	16,197	211	1.30
2014	14,857	49,059	17,057	304	1.78
2015	15,148	51,111	17,454	371	2.13
2016	15,413	52,757	17,145	437	2.55
2017	15,682	54,831	17,230	588	3.41
2018	15,493	56,405	17,598	482	2.74
2019	15,905	58,840	17,678	621	3.51

Table 9 The domestic and overseas pharmaceutical companies that passed the inspection over the years

Year	Domestic Western Medicine Preparation Factories that Passed the GMP(#1)	Domestic Western Medicine Preparation Factories that Passed the PIC/S GMP (#2)	Total number of foreign manufacturers complying to PIC/S GMP
2008	151	-	-
2009	154	5	-
2010	155	22	527
2011	149	33	720
2012	145	44	760
2013	140	57	820
2014	98	98	870
2015	-	120	893
2016	-	127	936
2017	-	137	937
2018	-	141	943
2019	-	143	937

Remarks:1. The compiled data are before 2012, given all modern pharmaceutical manufacturers have to be in line with the standards of PIC/S GMP since 31/12/2012.
2. In order to follow the administrative schedule of PIC/S GMP, Taiwan and international collect the data since 2009 and 2010 separately.

Table 10 Statistics of post-market quality monitoring for drugs and cosmetics

Year	Drugs		Biological medicine		Traditional Chinese medicine		Medical devices		Cosmetics	
	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)
2008	164	16.46	0	0	1,000	▲	12	91.67	54	7.41
2009	180	1.11	0	0	720	▲	45	11.11	87	14.94
2010	198	3.03	0	0	660	▲	28	42.86	51	29.41
2011	230	8.70	23	0	664	3.13	14	21.43	204	0.49
2012	168	4.76	23	0	629	4.70	132	15.15	109	16.51
2013	173	1.16	26	0	544	3.47	200	6.50	100	3.00
2014	90	3.33	148	0	134	2.99	216	4.63	520	5.19
2015	212	0	0	0	-	-	46	0	251	2.79
2016	88	5.70	-	-	-	-	193	0	329	1.52
2017	114	4.39	-	-	-	-	57	19.30	102	7.84
2018	348	1.10	-	-	-	-	58	3.40	180	2.80
2019	109	1.70	-	-	-	-	58	13.80	170	1.18

Remarks:1.The investigation of heavy metals, pesticide residues and aflatoxin in traditional Chinese medicine were for background values survey, which is indicated by "▲".
2."-" indicated that there is no quality monitoring plan implemented for this category.

Table 11 Statistics of lot release procedures for biological drugs over the years

Year	Vaccines and toxoids				Blood preparations		Antitoxin and antiserum				Other biopharmaceutical products		Annual Summary	
	Domestic		Imported		Imported		Domestic		Imported		Imported			
	Batch	Dosage	Batch	Dosage	Batch	Dosage	Batch	Dosage	Batch	Dosage	Batch	Dosage	Batch	Dosage
2008	47	4,209,083	159	9,001,470	130	1,019,543	2	2,926	3	27	14	232,549	355	14,465,598
2009	61	6,815,963	139	9,364,656	123	1,013,093	5	5,979	1	20	17	189,915	346	17,389,626
2010	46	5,870,554	115	6,881,397	116	894,973	4	5,923	2	31	18	281,084	301	13,933,962
2011	54	5,182,280	137	5,710,140	113	1,003,875	3	4,025	2	30	20	296,183	329	12,196,533
2012	53	4,509,491	146	6,711,965	115	960,004	3	4,348	1	20	22	498,230	340	12,684,058
2013	64	4,149,722	161	7,201,090	134	988,939	4	5,512	1	20	25	166,494	389	12,511,777
2014	72	3,705,462	155	7,607,454	121	962,552	6	8,440	0	0	27	332,558	381	12,616,466
2015	123	5,808,339	163	7,548,124	146	1,137,717	3	3,234	0	0	22	226,082	457	14,723,496
2016	58	4,122,437	152	6,773,750	146	1,363,462	9	6,078	2	19	29	422,944	396	12,688,690
2017	47	3,459,630	189	8,796,311	152	1,253,072	4	3,103	1	20	28	317,449	421	13,829,585
2018	69	4,923,435	202	8,509,618	145	1,175,986	3	2,976	1	15	33	214,220	453	14,826,250
2019	46	4,159,810	172	8,927,748	167	1,562,290	6	5,897	1	50	40	326,283	432	14,982,078

Table 12 Statistics on the number of certified laboratories and certified items in calendar years

Year	Food certification Laboratory		Medicated/Cosmetics certification laboratory		Cosmetics certification laboratory		Drug abuse certification laboratory		GLP certification testing institution	
	Number of households	Number of items	Number of households	Number of items	Number of households	Number of items	Number of households	Number of items	Number of households	Number of items
2008	18	280	3	16	-	-	13	9	1	3
2009	23	298	7	55	-	-	13	9	8	16
2010	41	421	24	230	-	-	13	9	9	19
2011	55	481	26	248	-	-	13	9	16	26
2012	61	637	29	405	-	-	13	9	18	42
2013	58	632	31	536	-	-	13	9	20	58
2014	61	665	30	488	-	-	14	9	17	49
2015	72	789	30	370	-	-	15	9	15	53
2016	81	1,046	34	379	-	-	14	9	15	44
2017	87	1,124	37	367	-	-	14	9	14	55
2018	95	1,264	36	365	-	-	16	9	13	56
2019	100	1,364	29	303	15	51	16	25	15	56

Note: The Medicated/Cosmetics certification laboratory was divided into pharmaceutical certification laboratory and cosmetics certification laboratory in response to the implementation of the "*Cosmetic Hygiene and Safety Act*" on July 1, 2019.

Table 13 Unlawful drug seizure rate and drug advertisement advertising violation rate over the years

years	Illegal drug seizure rate (%)	Advertising violation rate (%)
2010	11.81	13.90
2011	4.59	6.10
2012	2.35	5.15
2013	1.97	5.46
2014	1.81	5.18
2015	1.14	5.04
2016	1.03	4.83
2017	0.73	4.86
2018	0.90	4.90
2019	2.66	4.89

Remarks:
1. The collaborative team for busting the counterfeit, fake or poor drugs was established in April 2010.
2. A total of 841 illegal drug cases were seized in 2019 with a total fine of NTD 4.495 million, the seizure rate decreased from 11.81 % in 2010 to 2.66% in 2019.
3. The number of violations in food, drugs and cosmetics by the health authorities was 6,275 in 2019, with a total fine of NTD185.51 million. The advertisement violation rate decreased from 13.90% in 2010 to 4.89% in 2019.

Table 14 Statistics on the operations of controlled drug manufactures over the years

Unit (thousand dollars)

Year	Income	Expenditure	Pay to the national treasury
2008	477,135	348,335	101,441
2009	507,794	359,321	138,473
2010	484,762	268,215	145,956
2011	491,524	321,823	116,414
2012	494,672	329,731	120,000
2013	513,092	340,359	120,000
2014	533,320	290,570	120,000
2015	593,448	284,359	120,000
2016	701,254	324,564	100,000
2017	791,580	439,074	50,000
2018	823,305	604,566	120,000
2019	881,881	631,176	120,000

Angle

Appendix 4 TFDA Publications in 2019

Serial number	GPN	Topic	Responsible unit	Type	Publication year/ month
1	1010800570	2019 Drug abuse cases at the workplace and prevention Q&A manual	Division of Controlled Drugs	books	2019/04
2	1010801423	2019 Drug Abuse Prevention Guide	Division of Controlled Drugs	books	2019/08
3	2010103850	Annual Report on Food Import Management and Inspection	Division of Food Safety	books	2019/09
4	1010802257	The supplemental articles for the eighth edition of the Chinese Pharmacopoeia (3)	Division of research and analysis	books	2019/12
5	1010802361	Prevention case of drug abuse Handbook: Stay Away From Drugs	Division of Controlled Drugs	Digital publications	2019/12
6	1010802362	Food inspection technology and frequently asked questions	Division of research and analysis	books	2019/12
7	1010802620	GO together with cosmetics, play and beauty for myth analysis	Division of Medicated Cosmetics	Digital publications	2019/12
8	2010002894	Annual Report of Foodborne Outbreaks and Prevention	Division of Food Safety	Books and digital publications	2019/12
9	2010301353	TFDA Annual Report	Division of Planning & Research Development	Continuity (Journal)	2019
10	2010302286	TFDA Annual Report (English version)	Division of Planning & Research Development	Continuity (Journal)	2019
11	2008200056	Journal of Food and Drug Analysis (JFDA)	Division of Planning & Research Development	Continuity (Journal)	2019
12	49094052333	Drug and Food Safety Weekly	Division of Planning & Research Development	Continuity (Journal)	2019

Appendix 5 Related Websites

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
1	Taiwan Food and Drug Administration	https://www.fda.gov.tw	The system includes introduction of agencies, business areas, announcements, special Section of Rumor Buster of Food and Drugs, to provide the public with faster services with accurate information.	
2	Online application and the diverse service platform	https://oap.fda.gov.tw	The online application and the diverse service platform integrate various application services of TFDA, to provide a single online application service window with multiple ways of payment for the public.	
3	Food and Drug Open Data Platform	https://data.fda.gov.tw	TFDA Open Data Platform provides original information regarding food and drugs for external access and applications, to enhance the operating transparency of TFDA's governance policy.	
4	TFDA News	http://article-consumer.fda.gov.tw/default.aspx	"TFDA News" is based on the three topics such as "safe eat out foods, safety of drugs, medical devices and cosmetics," to provide the latest and most accurate food safety information and articles and most correct and practical knowledge for the public.	
5	Food and Drug Consumer Service Network	https://consumer.fda.gov.tw	Provide the public with integrated services regarding food and drug related information.	
6	Taiwan' s International	https://tifsan.fda.gov.tw/workflow/login.jsp	A platform that allows TFDA to communicate internal data, report public opinions and exchange relevant information with public health bureau.	
7	Food and Drug Safety Authority Network	https://fadenbook.fda.gov.tw	A digital system established by government agencies to manage the food and drug business operators in the industry.	
8	The registration platform for food and drug business operators	https://ftracebook.fda.gov.tw	The relevant electronic records can be uploaded to the system, including product information, tag identification, supplier information, product flow information, etc., to trace sources of product supply or track product flow.	
9	Food Traceability Management Information System	http://fsas.fda.gov.tw/	This system has included all regulations, specification documents and related interpretation orders of the Act Governing Food Safety and Sanitation, for the general public to review and search online.	
10	The interpretation and query system for the Act Governing Food Safety and Sanitation	http://tsfa.fda.gov.tw/	To simplify the inquiry operation of the "Standards for Scope, Application and Limitation of Food Additives," this system has organized and created a database for the general public to review and search online.	

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
11	System for Searching the Drafts of Food Additive Standards	http://www.foodlabel.org.tw/FdaFrontEndApp#	In addition to the "Nutrition Labeling Format Area" and the "Inquiry Area for Regulations and Announcements," this platform also provides consulting services of food labeling for businesses operators in the industry and public health bureau.	
12	Application System for Export of Food Sanitation Certification	https://asefsc.fda.gov.tw	This system provides online applications for the proof of exporting foods (additives) such as English health certificate, processing hygiene certificate, inspection report and certificate of free sales.	
13	Imported Food Inspection System	https://ifi.fda.gov.tw/ifi/main/ap/index.jsp	It provides functions such as inquiry of case progress for foods, Chinese herb and medicines, rubber condoms and food QR-CODE download.	
14	Product Distribution Management System	https://pmds.fda.gov.tw	An inspection data management platform for the health bureaus of local governments and TFDA; it is for the competent authorities to manage food, drugs and cosmetics in their jurisdiction.	
15	Curriculum management system of food sanitation and safety	https://foodedu.fda.gov.tw	Food hygiene workshops, HACCP workshop resources and course enquiries are available for registration from all walks of life.	
16	Food sanitation and safety management certification and validation system	https://facs.fda.gov.tw	This system mainly assists in the implementation of the Schedule 2 food quality control inspection, through the randomly assigned inspection agency by the system, the inspection process control and display of results, to improve the efficiency of inspection management.	
17	Drug registration and review Online submission Platform	https://e-sub.fda.gov.tw/dohclient/Login.aspx?ReturnUrl=%2fdohclient	This system provides online submission for drug registration and post approval changes for licence holders. Reviewers and applicants can both access this platform to review and check case progress.	
18	Trace and track system of medicinal products	https://dtracebook.fda.gov.tw	A system that offers businesses to upload medicinal products traceability or track the uploaded data.	
19	Information platform of drug provision	https://dsms.fda.gov.tw	The system provides pharmaceutical companies and medical institutes in Taiwan to report on the shortage of medicinal products to facilitate real-time assessment and handling, reduce the influences caused by the shortage of medicinal products and protect the rights of the public.	
20	National Adverse Drug Reaction Reporting System	https://adr.fda.gov.tw	The general public, medical professionals and manufacturers can use this system to report adverse drug reaction	

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21	Controlled Drugs Management Information System	https://cdmis.fda.gov.tw	The institutions, business operators and related professionals with controlled drug registration certificates can apply for the pre-market controlled drugs via the system, to effectively enhance administrative efficiency and service quality.	
22	Drug Abuse Reporting System	https://dars.fda.gov.tw	The system allows healthcare facilities to promptly report any cases of drug abuse, in order to assess the trends of drug abuse and instantly understand the current status of drug abuse in Taiwan.	
23	Drug Abuse Test Report System	https://udars.fda.gov.tw	A system for the regular inspection in urine or narcotics test results of drug abuse cases by relevant domestic inspection institutions.	
24	Searching System of Approved Advertisement for Drugs and Cosmetics Management System	https://adms.fda.gov.tw/adms/PUBLIC/PQuery.asp	A system allowing the public to inquire information on approved advertisements for medical products, medical devices, and cosmetics.	
25	Post-marketing quality management system for medicinal products, food and cosmetics	https://qms.fda.gov.tw	The general public, medical professionals and manufacturers can report incidents regarding drugs, medical devices, health foods and cosmetics via the integrated and convenient notification portal.	
26	Cosmetic Product Notification Platform	https://cos.fda.gov.tw	The manufacturers or importers shall notify product information on the“Cosmetic Product Notification Platform,” so that the government agencies can better understand the products on the market and facilitate the cosmetics management regulations to meet the international standards.	
27	Online Application System of Human Organ Bank	https://oap.fda.gov.tw/B105/	The system provides online application for human organ bank, to ensure the completeness of submitted documents and enhance the application efficiency and regulatory compliance through its reminder function.	
28	Materials Transfer Support System for Disaster Rescue and Prevention	https://mrdss.fda.gov.tw/Web/	The system allows the hospitals, drug manufacturers and sales vendors, human organ banks to online report the medical resource reserves, to assist in medical supplies during the time of major disasters.	
29	Laboratory certification network	https://lams.fda.gov.tw	TFDA's certification platform for urine inspection agencies regarding food, drugs, cosmetics and drug abuse cases.	
30	Laboratory information management system	https://lims.fda.gov.tw	The inspection process can be managed online by the inspection offices in health bureaus of the local governments.	

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31	Inquiry system for advertisements in violation	https://pmds.fda.gov.tw/illegalad/	It is able to instantly and quickly reveal the illegal advertisements in food, drugs and cosmetics, to be used as a reference so that the public will not be influenced by the exaggerated advertisements.	
32	Service Email for the general public	http://faq.fda.gov.tw/	The Mailbox Service of the Director-General is an important communication channel for the public to submit their petitions and express their opinions. The intelligent inquiry service has been created to make the overall service process even more efficient and enhance the satisfaction Schedule of the public.	
33	Online System of the JFDA journal	http://jfda.researchcommons.org/journal/	It is TFDA's "JFDA Drug and Food Analysis Journal" system for domestic and foreign authors' online submission and review of journals, as well as for the online review, edit and publication of journals.	