10 Annex

Annex I. Summary of Great Events

Time	Summary
January 1	Establish "*Act governing the management of food advertisements and promotions of food not suitable for long-term use of children*"
January 8	Establish "The complex import regulation containing F01 in "Import commodity classification of Republic of China"
	Revise "Import regulations containing 508 in Import commodity classification of Republic of China"
	The abolition of regulations governing 77 commodities on the "List of Commodities Subject to Export/Import Restriction"
January 12	Revise " Import regulations for commodities containing F01 and F02 category list Import commodity classification of Republic of China"
January 18	Revise "Standards for atomic dust or safe radiation contamination tolerance in food" and change to "Standards for atomic dust or radiation contamination tolerance in food"
January 21	Revise partial articles of "*Regulations for Application of Health Food Permit*"; the new application for health food registration has two-stage reviews, i.e. initial and secondary reviews.
	Establish "Guidelines for Assignment of Combination Products"
February 1	Revise " Import regulations for commodities containing "F01" and "F02" category list Import commodity classification of Republic of China"
February 4	Revise "Standards for vegetables, fruits and plants heavy metals limitations"
February 17	Establish "Hygienic standards for processing aids"
	Revise Table 1 of Article 2 and Table 2 of Article 3 in the "Application scope, limitation, specifications and standards for food additives"
February 19	Establish "Cosmetics must not contain Estradiol, Estrone and Ethinyl estradiol"
March 1	Revise "*Regulations for Implementation of Outer Box and Package Insert Format of Western Over-the-Counter Drugs*"
March 4	Establish the "General names of food additives"
March 8	Establish the "Food additives shall significantly label registration number of product"
March 9	Revise "The Complex Import Regulation Containing F01 in Import Commodity Classification of Republic of China"
March 11	Establish "*Act governing certification and validation of food sanitation and safety management system*"
March 18	Revise "Standards for pesticide residue limits in avian and livestock products" and change to "Standards for pesticide residue limits in animal products"; revise "Standards for pesticide residue tolerance"
March 23	Revise *"Import Regulations Containing "508" in Import commodity Classification of Republic of China*"
	Establish "Hygienic standards for edible bovine and sheep fat"
April 1	Establish "Baby wipes" are subject to management as cosmetics
April 6	Revise part of the articles in the "*Review standards for medicinal products registration*", which the primary amendments focusing on strengthening quality management of the main API

Time	Summary
April 6	Establish “Operational Directions for Law Suits Reimbursement by Food Safety Protection Foundation, Ministry of Health and Welfare”
April 15	Revise “Fees for registration review and certification issuance of food and food additives” and change to “Fees for registration review, related matters and certification issuance of food and food additives”
April 18	Revise “Food utensils, containers or packaging items required for labeling” and promulgate “*Regulations related to food utensils, containers or packaging labeling*”
April 21	Revise “*Food Businesses Shall Mandatorily Conduct Tests and Meet the Minimum Testing Cycle and Other Relevant Matters*” and change to “*Food Businesses Shall Enact Food Safety Monitoring Plan and Mandatorily Conduct Test and Meet the Minimum Testing Cycle and Other Relevant Matters*”
April 22	Revise “The Instruction of the Import Regulation F02"
	Establish “Application limitations of edible hydrogenated oils”
April 25	Revise “*Efficacy Assessment Method of Health Food for Protecting the Liver (Chemically Induced Liver Damage)*" ,and rename the Method as "*Efficacy Assessment Method of Health Food for Protecting the Liver*”
April 29	Revise “Hygienic standards for material gum arabic” and change to “Specifications for material gum arabic”
May 6	Revise “Medicinal products suitable for rare disorders prevention and control as well as *Pharmaceutical Affairs Act*”, add “”Taliglucerase alfa” (Injection; 200U/vial), which the indication is “Type 1 Gaucher's Disease”
	Establish “Operational Directions for Donations to Food Safety Protection Foundation, Ministry of Health and Welfre”
May 7	Host “2016 Medical and pharmaceutical products conference for business and trade provisions: The updated reformation and perspectives in pharmaceutical administration”
May 9	Revise Table 1 of Article 3 and Table 5 of Article 6 in the “*Standards for Pesticide Residue tolerance*”, add and revise 6 pesticide residue tolerances in 40 vegetables, fruits and corn products.
May 10	Revise “*Specific Food from Japan Must Submit Certificate of Radiation Test before They Enter the Food Inspection Application”*
May 19	Establish “Regulations for recovering unjust benefits of food businesses based on the *Food Safety Act* Article 49.2,” to recover unjust benefits from the businesses
June 3	Actively participate in the “2016 National Anti-drug Meeting” hosted by Ministry of Justice and assist in activity planning and preparations
June 6	Host “Management regulations and Practice Seminar of Online Food Trade between Taiwan and China”
June 15	Establish the “*Regulations on Fluorine Labeling for Prepackaged Food Grade Salt Products*”
June 24	Establish the “*Regulations Governing the Product Names and Labeling of Chocolate”*

Time	Summary
June 29	Revise Table 1 in Article 2 and Table 2 in Article 3 of “Application scopes, limits, specifications and standards of food additives”, add nutritional additive KF and NaF in small-packed (≤1000g) salt for family use, and establish application limits as well as specifications and standards
July 4 to July 8	Participate in the “2016 PIC/S Official Committee Meeting and Annual Conference” hosted by PIC/S at Manchester, UK
July 11	Establish “Regulation for Drug Shortage Management”
	Host “International provisions and clinical performance evaluation conference for *In vitro* diagnostic medical devices”
July 14	Release and revise Table 1 in Article 3 and Table 5 in Article 6 of “Standards for pesticide residue tolerance”, revise the contents , add and revise 59 pesticide residue tolerance in 376 vegetables, fruits and corn products, and add jackfruit in the category of big berries
July 15	Promulgate “List of Legally Permitted Cosmetic Colorants” and abolish “Regulations for the use of new legal cosmetics coloring list”
August 1	Revise “*Expedited Review Process for New Drug Registration*”
August 2	Host “2016 International Symposium on Cosmetics Regulation”
	Revise “*Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China*”
August 9	Revise the tables in Article 2 of the “ Regulations Governing the Allocation and Purchase Limitation of Schedule I and II Controlled Drugs”
August 23	A grand open of “food safety information platform”, including information such as “theme issues”, “food labeling consultation platform”, “food businesses registration platform”, “food information”, “the purposes of food additives” and “myth buster”
September 6	Revise part of the regulations in the "list of examples of proper and inadequate sentences examples of cosmetics claimed effects" and change to “Enumeration of expressions that are appropriate or inappropriate to be claimed for cosmetics"
September 6	Establish “*Regulations governing the trace and track system for medicinal products* ”
September 8	Establish “*Act governing specific medicinal product project approval for manufacturing and import*”
September 22	Revise “Standardized package insert of topical dermal preparations containing Diclofenac”
	Promulgate “Good Hygienic Practice Guidelines for food manufacturers of anka products”
	Host the ceremony of “2016 Innovation Award for Medical Devices” and encourage physicians investing in basic development
September 25	Host an activity to promote the idea of “Read the label of three types of medicinal products” on Safe Medication Day (September 25)
October 4	Promulgate “Revisions of Chinese package insert of medicinal products containing nifedipine”

Time	Summary
October 5	List of Article 102 of *Pharmaceutical Affairs Act* remote areas where practicing pharmaceutical personnel are not available
October 6	Revise "*Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China*"
October 12	Promulgate "Regulations for Chinese package insert amendments on dose forms of systemic administration (oral intake, injections and suppositories) of NSAIDs (except aspirin) prescriptions"
October 14	Establish "Guidelines of Cosmetics for Safe Children Use"
October 19	TFDA food cloud was rewarded of 4 star certificate of the Euro Cloud Star Audit (ECSA), Secretary-General of TFDA attended the ceremony for certification
October 24	Host the conference of "2016 Global health forum in Taiwan – Medicinal Product Accessibility and Quality Management"
	Host the conference of "APEC Seminar on the International Cooperation Experiences in Addressing Trade and Regulatory Issues of Medical Products"
October 26	Revise Table 1 in Article 3 and Table 5 in Article 6 of "*Standards for Pesticide Residue Tolerance*", add and revise pesticide residue tolerance of 14 pesticides in 85 vegetables, fruits and corn products
November 1	Revise "*Import Regulations Containing 508 in Import Commodity Classification of Republic of China*"
November 8	Establish "Technical Guidelines for Cosmetics UVA Sunscreen Performance Tests (Human Subject Test)" and "Technical Guidelines for Cosmetics Sunscreen Performance Tests (Human Subject Test)"
November 10	Host the international conference "2016 International Conference on TPP/RCEP, Medical Products and Food Safety"
November 16	Promulgate "Regulations for package insert outer box format of Over-the-counter drugs – Staged (in years) schedules and measures"
November 23	Promulgate "Revision of Chinese Package Insert of Corticosteroid Injections"
November 30	Host 2016 "Seminars of ASEAN Medicinal Products Provisions"
December 6	Establish "*Pharmaceutical Affairs Act* Article 2.2 - List of essential medicinal products "
December 12	Revise Article 3, Table 1 of "*Standards for Pesticide Residue Tolerance*", add and revise 8 pesticide residue tolerances in 25 vegetables and fruits, and define pesticide residue of Metolachlor.
December 14	Revise "*The Food Businesses Which Import Food and Genetically Modified Food Raw Materials Shall Keep the Relevant Records, Documents and Electronic Files or Databases of the Imported Products*"
	Host the wrap-up presentation of "Improvement of Food Distributors Management" during 2016
December 19	Revise "*Regulations of Labeling Requirements for Special Dietary Food for Patients*", and rename the regulations as "Regulations Governing the Labeling of Formula for Certain Disease"
December 26	Revise part of the regulations for "*GMP (Part I. General Principles) and (Part II. API)*"

Annex II. Important Outcomes and Statistics

Table 1. Statistics of permits for health food and genetically modified (GM) food

Heath food permit issued (Type 1 and Type 2)					GM food permit issued	
Year	Type 1	Type 2	Year permits issued	Cumulative permits issued	Year permits issued	Cumulative permits issued
2007	24	-	24	111	3	17
2008	33	-	33	144	2	19
2009	26	6	32	176	18	37
2010	16	4	20	196	3	40
2011	17	6	23	219	13	53
2012	22	8	30	249	9	62
2013	14	13	27	276	10	72
2014	26	15	41	317	12	84
2015	22	5	27	344	32	116
2016	25	7	32	376	11	127

Note 1: There are two types of registration for health foods.

Type 1 (individual case review): Suppliers must provide testing results and proof of food safety and healthcare functions. The approval permit number shall be Wei Bu Chien Shi Kui Tzu No. Axxxxx.

Type 2 (standard specification review): Product must comply with the specifications and standards stipulated by the Ministry of Health and Welfare (MOHW). The approval permit number shall be Wei Bu Chien Shi Kui Tzu No. xxxxxx

Note 2: As of December 2016, 376 permits were issued for health foods, including 312 permits for Type 1 approvals and 64 permits for Type 2 approvals. 37 of the permits were voided (include termination as a result of permit expiration, revocation of the permit, or permit merging). As of the end of 2016, the number of approved permits issued is 339.

Note 3: As of December 2016, 127 permits were issued for GM foods, of which 9 permits were for products no longer in production or were not extended. As of the end of 2016, the number of approved permits issued is 118.

Table 2. Statistics of approved medicinal products 2007-2016

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	
2007	422	32	454	6	115	121	22	47	69	0	16	16	0	0	0	660
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	264	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	682

Table 3. Statistics of imported food inspection

Year	Number of registered lots	Total net weight(x 10k tons)	Number of inspected lots	Growth rate (%)	Testing rate (%)	Number of non-compliant lots
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

Note : Growth rate refers to the increased percentage of registered and inspected number of the year compared to previous year.

Table 4. Statistics of controlled drug licenses

Year	Item	
	Controlled drugs registration licenses (institutions and companies)	Controlled drugs prescription license (persons)
2007	12,360	37,792
2008	12,465	39,467
2009	12,830	41,157
2010	13,266	42,619
2011	13,745	44,469
2012	14,149	45,844
2013	14,511	47,391
2014	14,857	49,059
2015	15,148	51,111
2016	15,413	52,757

Table 5. Business statistics of controlled drug manufacturers

(Unit: thousand dollars)

Year	Total income	Income from selling	Revenue Remittance to the National Treasury
2007	436,341	433,122	107,105
2008	477,133	470,627	101,441
2009	507,794	505,340	138,473
2010	484,762	483,169	145,956
2011	491,524	489,523	116,414
2012	494,672	491,909	120,000
2013	513,092	510,119	120,000
2014	533,320	527,940	120,000
2015	593,448	586,406	120,000
2016	701,254	670,480	100,000

Table 6. Audition statistics of food inspection carried out by local government health bureaus and departments

Year	Labeling inspection			Sampling tests			Inspection of Good Hygienic Practice(GHP)				
	Number of inspection	Number of compliant items	Compli-ance rate (%)	Number of sampling	Number of compliant items	Compli-ance rate (%)	Number of inspection	Number of consulation request of corrections within a deadine	Number of penalty	Number of businesses forced to close	Number of businesses brought to justice
2008	795,119	778,931	98.0	43,545	40,916	94.0	143,779	34,177	65	81	6
2009	874,959	857,355	98.0	38,770	36,158	93.3	150,675	32,463	92	18	6
2010	796,758	781,645	98.1	38,056	35,394	93.0	136,456	28,967	131	5	3
2011	806,324	796,795	98.8	42,372	40,132	94.7	117,420	35,013	6	12	0
2012	683,956	676,930	99.0	41,956	39,998	95.3	118,681	49,587	75	13	0
2013	635,121	628,266	98.9	40,898	38,608	94.4	123,476	51,324	31	21	0
2014	523,045	517,051	98.9	41,085	39,206	95.4	130,005	61,066	38	143	2
2015	340,347	338,200	99.4	47,078	44,916	95.4	119,927	54,979	82	11	0
2016	424,402	422,085	99.5	49,800	47,726	95.8	112,382	52,151	3	13	0

Table 7. Statistics for controlled drugs inspection

Year	Items		
	Number of inspection	Number of violations	Violation rate (%)
2007	16,451	232	1.41
2008	16,241	270	1.66
2009	16,355	245	1.50
2010	15,154	196	1.29
2011	15,270	147	0.96
2012	16,214	202	1.25
2013	16,197	211	1.30
2014	17,057	304	1.78
2015	17,454	371	2.13
2016	17,145	437	2.55

Table 8. Statistics of food outbreaks

Year	Number of outbreaks	Food poisoning cases		Number of outbreaks by vehicles					
		Number of cases	Death toll	Aquatic products and its processed products	Meats, eggs dairy products and its processed products	Cereal, vegetables, fruits and its processed products	Confectionery and candies	Compound cooking food and others	Vehicle unidentified (Integrated)
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	3	2	3	56	404

Table 9. Lot release of biologics

Year	Vaccines and toxoids				Blood preparations		Antitoxin and antiserum products				Other biologics		Annual summary	
	Domestic products		Import		Import		Domestic products		Import		Import			
	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose
2007	67	6,134,626	117	6,447,752	141	955,060	5	7,429	4	24	15	309,017	349	13,853,908
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

Table 10. Statistical analysis of the surveillance of pesticide residues, veterinary drug residues, fungi toxins and heavy metals in food

Year	Monitoring of Agricultural chemical residues		Veterinary drugs		Monitoring of Mycotoxins		Monitoring of heavy metals	
	Total cases	Conformity rate (%)	Total cases	Conformity rate (%)	Total cases	Conformity rate (%)	Total cases	Conformity rate (%)
2007	1,761	95.9	359	94.4	-	-	-	-
2008	1,765	88.2	252	92.1	-	-	-	-
2009	1,894	89.6	266	95.1	-	-	-	-
2010	2,051	90.5	330	98.2	-	-	161	100.0
2011	2,110	89.0	481	90.9	-	-	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

*Source: TFDA 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 11. Statistics of post-market quality surveillance in medicinal products

Year	Medicinal products		Biologics		Chinese medicine*		Annual summary	
	Number	Non-conformity rate (%)	Number	Non-conformity rate (%)	Number	Non-conformity rate (%)	Number	Non-conformity rate (%)
2007	295	2.37	0	0	480	-	775	2.37
2008	164	16.46	0	0	1,000	-	1,164	16.46
2009	180	1.11	0	0	720	-	900	1.11
2010	198	3.03	0	0	660	-	858	3.03
2011	230	8.70	23	0	664	3.13	917	6.94
2012	168	4.76	23	0	629	4.70	820	4.41
2013	173	1.16	26	0	544	3.47	743	1.75
2014	90	3.33	148	0	134	2.99	372	1.88
2015	212	0	0	0			212	0
2016	88	5.7					88	5.7

*The background values of heavy metals, pesticide residue and aflatoxin in Chinese Medicine are presented as "-".

Table 12. Important outcomes of food and drug testing technology in 2016

Category	Outcomes	Benefits
Food chemistry and biology	1. Complete establishing testing methods for inorganic arsenic in algae and heavy metals such as Methylmercury in aquatic animals, animal components in tuna species, natural toxins such as gibberellins in corn products, labeling conformity of heat-resistant plastic containers/packaging materials, nitrofuran metabolites in honey, multi-residue pesticides in poultry and livestock products (60 items) and radionuclide components 2. Complete adding and revising testing methods for food additives such as antioxidants and Ferrous ammonium phosphate 3. Establish 4 tests for new GM food categories and publish 2 recommended tests for GM food 4. Establish 6 test methods for Streptococcus pyogenes and probiotics	Announced 60 testing methods, including a total of 262 items in 2016 to enhance laboratory testing capacity and protect food quality and safety in Taiwan
Medicinal products	1. Complete establishing analytical methods for 12 types antibiotics (69 items), such as β-lactams 2. Establish analytical methods for cardiovascular drugs, mirror isomers and impurities 3. Complete established 13 standards and spectrum database 4. Use UPLC-Q-LIT and GC-MS to establish analytical methods for 20 synethic cannabinoids and 20 synthetic cathinones in urine respectively 5. Establish 55 LC-Q-TOF protocols for drug abuse testing and complete 600 urine sample analyses 6. Establish identification methods for Artemisiae scopariae Herba materials and analytical approaches as well as LC-MS for tonic Chinese medicinal preparations	1. Applied to clinical practices such as medicinal products routine tests, clinical determinations for drug abuse and criminal identification 2. Establish standards and spectrum database for comparing test results and meet the techniques for drug abuse 3. Apply to Chinese medicines identification, testing and quality management
Biologics and advanced biotechnology medicinal products	1. Establish the 2nd generation of HCV genotype 1 viral nucleic acid standard candidates and working standard candidates 2. Establish initial sandwich ELISA analysis for quantifying the antigen loads in EV71 vaccines 3. Establish ELISA analysis for detecting the contents of E protein in JapENnc vaccines 4. Establish the analytical platform of Neutralization Test for Rabies Virus Fluorescent Antibody Virus 5. Use LC-Q-TOF to establish testing methods and database of advanced protein medicinal products such as growth hormones and Herceptin	1. Establish national standards for the development and quality control of molecular diagnostic preparations 2. Applicable to EV71 vaccine potency evaluation *in vitro* vaccine potency tests 3. Establish quality assessment on domestic inactived JapENnc vaccines to replace traditional potency test using animal challenging models 4. For potency test of domestic human rabies vaccines 5. For post-market product quality surveillance
Medical devices and cosmetics	1. Establish testing method for the safety of stair-climbing device 2. Establish thermal safety assessment method for medical thermal pad 3. Establish emission rate testing method for infrared medical device 4. Perform safety assessment of mobility device such as medical wood stick 5. Establish testing methods for 25 forbidden components of hair dye and 14 forbidden pigments of cosmetics 6. Establish testing method for *in vitro* degradation of subcutaneous hyaluronic acid implants 7. Establish testing method for nanoparticles in cosmetics such as TiO_2 8. Perform "Comparison research of international cosmetic products containing nanoparticles"	The results can be applied to post market surveillance to ensure the safety and performance of medical and cosmetic products

Annex III. Publications in 2016

No.	GPN	Title	Responsible Section	Category	Date of publication
1	1010500189	Manual for Food Businesses Registration (manufacturing and processing industry)	Division of Food Safety	Books	105/1
2	1010501809	Manual for Establishing Traceability Management System of Food Services in International Tourist hotels	Division of Food Safety	Books	105/8
3	1010502002	2014 National Survey on Substance Use in Taiwan	Division of Controlled Drugs	Books	105/10
4	1010502228	2016 User's Guide for Drug Abuse Prevention	Division of Controlled Drugs	Books	105/10
5	1010502425	Chinese Pharmacopoeia 8th ed.	Division of Research & Analysis	Books	105/12
6	1010502703	Manual of Food Labeling Regulations	Division of Food Safety	Books	105/12
7	1010502791	User's Guide for Establishing Hygienic Management System for Food Suppliers	Division of Food Safety	Books	105/12
8	1010503051	Manual of food additives	Division of Food Safety	Books	105/12
9	1010503125	Manual of domestic vitamin products in tablet or capsule form	Division of Food Safety	Books	105/12
10	1010503133	Manual of hygienic management and practice on flour, starch and the upstream as well as downstream relevant industries	Division of Food Safety	Books	105/12
11	1010503134	User's Guide for GHP in brewing and fermentation industries	Division of Food Safety	Books	105/12
12	1010503147	Manual of audition, management and practice on low-acidity and acid cane food manufacturers	Division of Food Safety	Books	105/12
13	1010503170	Test standards for biologics VI	Division of Research & Analysis	Books	105/12
14	1010503179	Manual of food additive traceability system	Division of Food Safety	Books	105/12
15	2010301353	TFDA Annual Report	Division of Planning & Research Development	Series (journal)	105
16	2010302286	TFDA Annual Report (English version)	Division of Planning & Research Development	Series (journal)	105
17	2008200056	Journal of Food and Drug Analysis (JFDA)	Division of Planning & Research Development	Series (journal)	105
18	4909405233	Food & Drug Consumer Newsletter	Division of Risk Management	Series(weekly)	105

Annex IV. List of Websites

No.	Name of the website	Website	Website summary
1	TFDA	http://www.fda.gov.tw	This website introduces the administration, special functional sections, information publications, and a section on Busting Myths about Food and Drugs in order to provide the public with rapid and accurate information service.
2	Food and Drug Consumer Service Network	https://consumer.fda.gov.tw	This website publishes information and allows convenient data inquiry for people with different requirements, and includes specialized sections such as those “busting food and drug myths”, “dummies pack” and “e-books”.
3	Online Application and Public Service Platform	https://oaps.fda.gov.tw	The Online Application and Public Service Platform integrated various application services provided by TFDA to offer a single counter service to handle a diverse scope of payments, helping to facilitate online application services for the general public.
4	Imported Food Information System	https://ifi.fda.gov.tw	Allows users to enter foods, traditional Chinese medicine, condoms to make inquiries about these, check progress on their inquiries as well as download food QR-CODE.
5	Product Distribution Management System	https://pmds.fda.gov.tw	Audit data management platform for local governments, health bureaus, and departments and TFDA. Allows the competent authority to manage food, drugs, and cosmetics within their area of jurisdiction.
6	Food and Medicinal Products Business Registration Platform	https://fadenbook.fda.gov.tw	A digital data system that enables government agencies to achieve effective control over food businesses.
7	Taiwan's International Food Safety Authority Network	https://tifsan.fda.gov.tw	Platform that allows TFDA to communicate internal data, report public opinions, and exchange relevant information with local health bureaus and departments.
8	ROC Chef Certificate Information System	https://chef.fda.gov.tw	Provides educational and HACCP resources for food sanitation, an online course area, and registration services that can be used for learning purposes.
9	Post-market Quality Management System for Food, Medicinal Products, and Cosmetics	https://qms.fda.gov.tw	This system provides the public, medical staffs and companies an integrated single portal for reporting defective products for medicinal products, adverse incidents of medical devices, unintended reactions of health food products, and adverse incidents of cosmetics to facilitate reporting system.
10	Online application platform for medicinal product registration and review	https://e-sub.fda.gov.tw/dohclient	Provides businesses with a means of submitting online documents for medicinal product registration as well as change or extensions of permits and licenses. Reviewers and applicants can both access this platform to check case review progresses.
11	National Adverse Drug Reaction Reporting System	https://adr.fda.gov.tw	Allows medical institutions, pharmacies, pharmaceutical companies, and the general public to report any suspected incidents of adverse drug reactions (ADR) and facilitate post-marketing surveillance (PMS) of medicinal product safety.

No.	Name of the website	Website	Website summary
12	National Reporting System for Unintended Reactions of Health Food Products and Food in Capsule or Tablet Forms	http://hf.fda.gov.tw	Handles reports of unintended reactions of health foods as well as food in capsule and tablet forms reported by the general public and evaluates safety concerns.
13	Controlled Drugs Management Information System	https://cdmis.fda.gov.tw	Provides online application services for institutions, businesses, and professionals holding controlled drugs registration licenses of the aforementioned controlled drugs in order to effectively improve administrative efficiency and service quality.
14	Drug Abuse Reporting System	https://dars.fda.gov.tw	To real-time control drug abuse in Taiwan, prevent abuse exaggeration, the system allows medical institutions and drug addiction rehabilitation agencies to promptly report any cases of drug abuse and allow timely assessment of trends of drug abuse in Taiwan.
15	Urine Test for Drug Abuse Reporting System	https://udars.fda.gov.tw	A system that allows relevant testing agencies to regularly report results of urine tests or other forms of drug abuse tests.
16	Laboratory Accreditation Management System	https://lams.fda.gov.tw	A platform that allows food, medicinal products, cosmetics, and urine testing (for drug abuse) agencies to apply for accreditation.
17	Searching System of Approved Advertisement for medicinal products, medical devices and Cosmetics	http://adms.fda.gov.tw/adms/PUBLIC/PQuery.asp	Allows the public to inquire information on approved advertisements for medicinal products, medical devices, and cosmetics.
18	Illegal Advertisement Query System	http://pmds.fda.gov.tw/illegalad/	Quickly publishes results of illegal advertisement audits on food, medicinal products cosmetics and disposals for public inquiry, providing users with a reference for selecting and Purchasing products. The system also discloses details of various violations, providing the public with an accurate basis for decision making, preventing them from being influenced by exaggerated and misleading advertisements.
19	Online System of the JFDA journal	http://jfda.fda.gov.tw	Online website for paper submission and review system of the Journal of Food and Drug Analysis (JFDA). Allows authors from Taiwan or other countries to submit their papers as well as providing journal editing and paper review functions.
20	Director-General' s Mail Box	https://faq.fda.gov.tw/message/default.aspx	Provides a key channel for submitting public petitions and opinions. Smart inquiry services that have been established allows the overall service procedure to achieve effective communication and public satisfaction.
21	FDA Open Data Platform	http://data.fda.gov.tw	TFDA open data website that provides raw data related to food and drugs, which can be accessed and employed by external parties for value-added applications to facilitate the transparency of TFDA operation.

No.	Name of the website	Website	Website summary
22	Food Traceability Management Information System	http://ftracebook.fda.gov.tw	System users can upload relevant digital records that include product data, labeling and identification, supplier information, and product distribution to trace sources of product supply or track the destinations of product distribution.
23	Application System for Export of Food Sanitation Certification	http://asefsc.fda.gov.tw	This system allows online applications of English sanitation certificates, proof of sanitation of food processing, test reports, and free trade permits for food (and food additives) exports.
24	Online Application System of Human Organ Bank	https://htb.fda.gov.tw	This system provides online applications for human organs to ensure the integrity of submitted documents and facilitate application efficiency as well as provision conformity.
25	Cosmetic Product Notification Portal	https://cos.fda.gov.tw	To align cosmetic management with international standards, TFDA encourages manufacturers or importers to register their products through “Cosmetic Product Notification Portal” to facilitate the control of products on the market by the government.
26	TFDA News	http://fda-article.consumer.fda.gov.tw	“TFDA News” provides the most updated, the most accurate food and drug safety information and articles based on three themes “Safe dine out, safe medication and safe medical devices & cosmetics” to help the public obtain the most accurate and practical daily living knowledge.
27	Food sanitation and safety management certification and validation system	https://facs.fda.gov.tw	The system primarily assists the implementation of 2nd tier food quality control and enhances the efficiency of validation management through randomly designating validation institutes, controlling validation process and the presentation of results.
28	Information Platform for the Supply of Medicinal Products	https://dsms.fda.gov.tw	The system provides pharmaceutical companies and medical institutes in Taiwan to report 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.
29	Material Transfer Supporting System for	https://mrdss.fda.gov.tw/Web/	The system provides hospitals, pharmaceutical manufacturers and retailers, and human organ
30	Laboratory Information Management System	https://lims.fda.gov.tw	For the laboratories of local government and health bureaus to manage test processes through electronic systems.