



## Special Project

- Section 1 Establishment of the Food and Drug Crime Platform for Inter-departmental Investigation
- Section 2 The Establishment of TFDA Rumor Buster to Clarify Rumors
- Section 3 The Progression of the National Laboratory

## Establishment of the Food and Drug Crime Platform for Inter-departmental Investigation

Establish inter-departmental collaboration

Meetings on establishment

Discussion forum on the “Enforcement in combating the crime cases involving food and drugs”



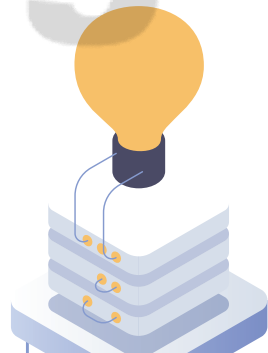
## Plans for Procuratorate & Other Agencies

Procuratorate

Judicial police institutions

Health institutions

Other Agencies and Organizations



## The Refinement of the National Laboratory Software

Active engagement in International Laboratory Activities

Amendment on testing methods and affirmation on international proficiency test, which was recognized as International Laboratories



## The establishment of Rumor Buster to dispel myths

Actively collects rumors

→ Consult professionals for accurate answers

→ Instant reminder to eradicate rumors

→ Terminate rumors

06

## Special Project

To improve the efficiency on investigating food and drug crime, an inter-departmental platform has been established to integrate resources from diverse departments, and demonstrate government's active role in combating related crime. To address folk prescriptions and rumors spreading online, TFDA established a "Rumor Buster" online, which clarify rumors with scientific evidences, and resolve public concerns. Moreover, TFDA continuously enhanced national laboratories facilities, and participated in international laboratory events. Through interacting and sharing techniques and experiences with other countries, we strengthen our professional and technical capacities.

### Section 1 Establishment of the Food and Drug Crime Platform for Inter-departmental Investigation

#### Origin of Policy

In order to safeguard the nation in terms of food and drug safety, TFDA established high quality lifestyle and a healthy consumption environment, as well as uplifted the efficacy in processing food and drug related crimes. The Taiwan High Prosecutors Office and the TFDA are expecting to integrate various agencies through the establishment of the Food and Drug Crime Platform, providing active and specific security check on food and drug cases, in order to exhibit the Government's determination in strict prosecution in such aspects.

#### Implementation Measures

In recent year, the frequency of criminal cases involving food and drugs elevated, which engaged a number of areas ranging from tampering with the expiration date, counterfeit or forgery, applying unauthorized additives into pseudo-drugs, changing drug labels and others. Hence, the Health institution and police departments have to work closely together. TFDA and the

Taiwan High Prosecutors Office has drafted a “*Procuratorate's execution plan for the inspection of criminal cases involving food and drugs,*” and integrated resources among the Prosecutors Office, the Health departments, the judicial police departments to establish a communication platform for food and drug related crimes. Relevant courses are as follow:

### **1. Meeting with the Taiwan High Prosecutors Office to establish inter-departmental collaboration**

On June 2, 2017, Director Hsiu-Mei Wu from the TFDA met with the attorney general Tien-Cheng Wang from the Taiwan High Prosecutors Office, to discuss the details of formulating communication platform for criminal cases involving food and drugs. The Taiwan High Prosecutors Office suggested that by referring to the current co-operation between the Council of Agriculture and the Environment Protective Administration, the platform between the Procurators Office and TFDA can as well become a sustainable operation.

### **2. The meeting of establishing “Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs”**

On June 22, 2017, TFDA drafted the “*Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs.*” Additionally, on July 14, TFDA attended the meeting held by the Taiwan High Prosecutors Office for the “Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs,” which explained the backgrounds involved in the established plans, as well as aspects in which the prosecutors should take action of. Discussion on each individual action plan was done. Upon completing the amendments on the same day, District Prosecutors Office, local governmental Department of Health and other relevant units were provided with related information, in order to collect suggestions and feedbacks.

### **3. Preparatory meeting for the discussion forum on “Enforcement in combating the crime cases involving food and drugs”**

On August 8, 2017, the attorney general Tien-Cheng Wang from the Taiwan High Prosecutors Office led his team to visit TFDA. During the meeting, details (time, location and work allocation) on “Strengthening of combating the criminal cases involving food and drugs” were discussed.

### **4. Discussion forum on the “Enforcement in combating the crime cases involving food and drugs”**

On October 18, 2017, the Taiwan High Prosecutors Office and the TFDA co-hosted a discussion forum for “Strengthening the security checks on criminal cases involving food and



Figure 6-1 Discussion forum on the “Enforcement in combating the criminal cases involving food and drugs”

drugs” (Figure 6-1). The Ministry of Health and Welfare minister Shih-Chung Chen and the Minister of Justice minister Tai-San Chiu attended the meeting in person. A total of 108 people from Executive Yuan's food safety office, Council of Agriculture Executive Yuan, Environment Protective Administration, Primary and Secondary Prosecutors Office, the Prosecutor Office of the Ministry of Justice, Investigation Bureau, National Police Administration, the Seventh Special Police Corps of the National Police Agency and the Ministers and representatives from each local Department of Public Health and others attended the “Communication platform for criminal cases involving food and drugs” meeting. In particular, resolutions on the amendments for the “Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs” was done and reported to the Ministry of Justice for approval prior to execution.

## Outcomes and Benefits

On April 17, 2018, the Taiwan High Prosecutors Office reported the “Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs” to the Ministry of Justice for approval. The formulated plan allowed both the Procuratorate and the Health institution to have necessary information, which would act as a foundation when establishing a collaboration platform between the Procuratorate and the police departments for command and coordinating the communication, investigation and press releases when facing food and drugs related crimes in the future.

## Section 2 The Establishment of TFDA Rumor Buster to Clarify Rumors

### Origin of Policy

Due to the uprise of Social media and mobile communication apps, the rumors over food, drugs, cosmetics, and medical devices are widely spread. Since those rumors can influence the general public, TFDA establishes a “Rumor Buster” web page on the TFDA official website (www.fda.gov.tw), to stop rumors from spreading and provide people with accurate food and drug information, including professional advice and scientific evidence.

### Implementation Measures

#### 1. Actively collects rumors and allows open submission from the general public

Rumors are collected through active search on the Internet and media, questions raised by the general public through TFDA’s “Public service mailbox” or Good Articles of Food and Drug website’s “Rumors submission box,” as well as collaborating with other external professionals. After collecting the public’s doubts regarding foods and drugs, relevant scientific information are compiled, and articles addressing public concern are written. Finally, before uploading the articles online, experts from TFDA would thoroughly review the articles.

#### 2. Consults professionals for accurate answers

Professionals from different fields, such as medical, pharmaceutical, toxicology, risk evaluation, nutrition, food sciences, and others, are consulted for professional advice and accurate solutions.

#### 3. Builds instant reminders to eradicate rumors

TFDA incorporates the public concerns from the current news, for instance, imported food from radiation-affected area during Japan’s nuclear disaster. TFDA addresses related rumors timely and successfully attracts the general public to visit the “Rumor Buster” web page.

The TFDA also provides clarification towards repetitive rumors, such as “Food Barcodes Starting with ‘8’ Indicate GMO,” “Mushroom Toxicity Caused 17 Deaths in Hospitals,” “Eating Persimmon and Crab Together will Cause Toxicity,” and “MSG is Toxic,” on the “Rumor Buster” web page. If any similar rumors emerge, people can go to either this web page or Good Articles of Food and Drug website’s “Rumors Submission Box” to search for relevant articles. The e-newsletter is available for subscription from TFDA official website for those who would like to obtain first-hand information from the “Rumor Buster” web page.

# Angle

## 4. Terminates rumors by advocating “Stop, Listen and Check”

Many unproven folk remedies can cause harm. TFDA encourages people to establish a healthy lifestyle, exercise adequately, maintain a healthy weight, and get correct information for nutrition intake.

TFDA promotes a 3-step tip “Stop, Listen and Check” to eradicate rumors. The first step is to “Stop the Repost of Rumors.” When the messages are not clarified for validity, stop spreading the messages so that the rumors would not be spread. The second step is to “Read and Learn from Accurate Information.” People should go straight to the “Rumor Buster” web page, check answers from similar rumors, gain the correct knowledge, and clarify the truth. The third step is to “Listen to Experts’ Advice to Clarify Doubts.” When people see health-related rumors, they should first consult the doctors for clarification. It is essential to follow doctors’ advice in terms of treatment. Do not believe in folk remedies or false advices, which may delay the best timing for treatment. Also, never pass unverified information to friends and families.

### Outcomes and Benefits

Currently, more than 300 articles have been posted on the Rumor Buster’s web page in response to the rumors. Among them, articles on food-related rumors account for about 60%, followed by drugs, cosmetics, and medical devices in the sequential order. TFDA official website has now accumulated 3.9 million visitors; articles are being referenced more than 1900 times by the national, internal and electronic platforms (Figure 6-2). Moreover, in order to allow the correct information to reach to the public, TFDA uses its official website, Facebook fan pages (Food utility players, Good Articles of Food and Drugs and other media platforms), easy debriefing packages, images and vibrant clips.

TFDA will continue to provide information on various food and drugs topics in response to the up rise of mobile commination apps, internet forums, and social media. People are welcomed to repost the information the TFDA provides with families and friends, and be smart consumers.



Figure 6-2 Diverse pathway to Obtain Accurate Food and Drug Information

## Section 3 The Progression of the National Laboratory

### Origin of Policy

TFDA is responsible for the inspection work, inspection methods research, investigation and research, standard product supply and technical support on national drug, food, cosmetics, and other. Moreover, TFDA actively promotes the sustainable development of the national laboratory, and marches towards the road of excellence.

### Implementation Measures

#### 1. The Refinement of the national laboratory software

As technology advances, patterns of crimes change each day. Purchases of multiple precision instruments and equipment such as mass spectrometers and spectrum analyzers (Figure 6-3 and Figure 6-4) are planned. Quick and precise testing methods are pro-actively developed to be provided to private laboratories for their reference and training sessions or workshops for testing methods, facilitate sharing of R&D results and experiences of national laboratories, and accordingly enhance the ability of national laboratories to identify and differentiate accidents or unknown substances.

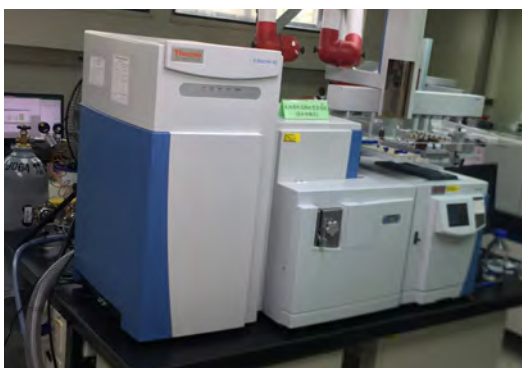


Figure 6-3 Q Exactive GC-MS/MS System



Figure 6-4 Orbitrap Fusion Lumos Tribid Mass Spectrometer (Lumos)

## Angle

### 2. The Progress of active engagement in international laboratory activities

TFDA not only hosts the international and domestic seminars and expert meetings, but also actively attends in the international laboratory activities for the topics on illegal additives, genetic modification, emerging pollutants, adulteration and unidentified micro-organisms.

The 110<sup>th</sup> AOAC annual meeting took place in Atlanta, Georgia, USA, approximately 900 experts and scholars from around the world attended. TFDA delivered a presentation entitled “Worldwide Perspectives on Contaminants Testing in Food and Environmental Samples Using Advanced Analytical Techniques” and “New Blood 2017—Developing Methods for the Detection of Chemical Residues, Contaminants and Important Analytes” in the meeting and gave a keynote speech in a arranged meeting on “Fipronil Egg Scandal in Taiwan,” which showcase the capabilities of Taiwan in the testing and analytical field and establish exchange channels with international experts.

TFDA was assigned to Cyprus and Strasbourg, France to take part in the 15<sup>th</sup> and 16<sup>th</sup> OCCLs meetings. During the meetings, we actively engaged in the proficiency tests and peer reviews of analytical methods and other activities. Regarding the results of post-market surveillance program, we provided our experience for OCCLs as references. Additionally, our staff members were assigned to the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) to participate in the study for in vitro test technique on sun protection factor (SPF) of sunscreens, which also benefit our organization for promoting skills of examination in this field (Figure 6-5)



Figure 6-5 Participating in the “15<sup>th</sup> and 16<sup>th</sup> Online Laboratory Meeting of the EU Official Cosmetic Quality Control”

# Angle

TFDA staff members attended the 26<sup>th</sup> International Biomechanics Workshop held in the Brisbane Convention & Exhibition Center (BCEC). We presented “Biomechanical Study of Hybrid Fusion and Non-Fusion Cervical Disc Replacement Surgeries–A Finite Element Analysis”, “In Vitro Enzymatic Degradation Measurement of Hyaluronic Acid Implants Using Rheology” and other poster papers, and received recognition from other foreign research teams. Additionally, Internet resource networks were established with the Australian specialists and other relevant companies, allowing our Government to acquire opportunities for prior arrangement on “New South bound Policy.” (Figure 6-6)



Figure 6-6 The 26<sup>th</sup> International Biomechanics Workshop, announcement of the Biomechanics and Mechanical inspection techniques.

## Outcomes and Benefits

### 1. Testing methods amendments and affirmation of international proficiency test result

The year of 2017 had been a year of rapid developments: accurate analytical methods, amendments of 28 articles in announced food test methods, 36 articles in recommended food test methods, 6 articles in recommended cosmetic test methods (Table 6-1), publication of “the Chinese Pharmacopoeia 8<sup>th</sup> edition” supplement (1), Biopharmaceutical test standard VII, 3 training workshops for promoting testing methods, participation in the inter-international proficiency tests (18 sessions) and 2 sessions of the common calibration studies (Table 6-2). It is no doubt that our national laboratory’s ability was recognized worldwide.

Table 6-1 Addendums/Amendments on test methods of TFDA

Types of testing methods	Number of articles	Items
Announced food test methods	28	521
Recommended food test methods	36	477
Recommended cosmetics/medical devices test methods	6	64

Table 6-2 TFDA participated in international proficiency test and common calibration research

Organizer	Name of the proficiency test	Results
Central Science Laboratory (CSL), England	Food Analysis Performance Assessment Scheme (FAPAS) proficiency testing program (15 items)	Satisfactory
US Department of Agriculture (USDA)	Accuracy test for GM food testing	Satisfactory
Health Sciences Authority (HSA), Singapore	Determination of mass fraction of inorganic elements and arsenic species in brown rice flour	Satisfactory
Collaborative Testing Services, Inc. CTS	Forensics testing proficiency tests	Satisfactory
European Directorate for the Quality of Medicines (EDQM)	4 <sup>th</sup> tetracosactide CRS common calibration research <sup>a</sup>	-
TFDA	The 2 <sup>nd</sup> generation of national HCV nucleic acid standard and working standard common calibration research <sup>b</sup>	-

\*International common calibration research is indicated as “-”.

- a. A total of 6 laboratories: Germany, Switzerland, France, Denmark, Japan and Taiwan participated in the calibration study.
- b. A total of 7 laboratories from England, Germany, Japan and Taiwan participated in the calibration study.



# Angle

## 2. Becoming international laboratories

The General European OMCL Network (GEON), which was jointly established by the EU Commission and the Council of Europe in 1994, enhanced the ability of members to control over the quality of medicinal products by technical and information sharing. At present, official laboratories of the European Union, Canada, and Australia, and other countries have followed one another to become a member.

Section of Biologics, Research and Analysis of TFDA has been assigned a priority to apply for membership of the General European OMCL Network (GEON). Through rigorous dossier review and on-site audit procedures by EDQM experts, TFDA has finally been officially notified as an associate member of GEON, and become a recognized international laboratory (Figure 6-7), which could allowed for information exchange and resource sharing among the networks.



Figure 6-7

OMCL certification of internet quality management control system

## 3. Future plan and goals

TFDA will continue to take part in the In-network inspection method development, and inspection capability testing activities, as well as sharing post-market monitoring result, and cooperating with laboratory testing technology such as pharmaceuticals and cosmetics in the network to boost participation in international research opportunities for testing methods and standards. By keeping in touch with the international contacts, we are able to improve the quality and professionalism in regards to the national laboratory inspection techniques.

In order to meet the challenges in the future and enhance the safety of food safety, TFDA strived for Executive Yuan’s approval on “Explanation of the National Food Laboratory and the Education and Training Building Project” and the “Enhanced Central Food Safety Inspection Capacity” to incorporated into the prospective “Food safety construction design.” The High-order detection equipment such as Fourier transform mass spectrometry and nuclear magnetic resonance instrument and other high technologies were introduced to the laboratory, providing a fully equipped internationalized facilities, simultaneously allowing the site to be a training center for the Department of Health and local inspection personnel, as well as completing food and drug safety network at national aspect, local level and civil independent inspection.