

FACT SHEET

Food safety in Taiwan

1. Background

1.1 In recent years, Taiwan has witnessed a series of food safety incidents in which some common food products made by leading manufacturers were found to be tainted with banned substances. These included discovery of toxic plasticizers in a wide range of processed food products and beverages, as well as adulteration of olive oil with cheaper substitutes and adding an illegal colouring agent to make the oil greener.

1.2 Against the above, the Legislative Yuan amended the food safety law twice during 2013-2014 to increase penalties on malfeasance by food manufacturers and establish a better protection system. This fact sheet highlights the food safety regulatory framework in Taiwan, with special reference to the revamped monitoring regime and new food labelling provisions under the amended law.

2. Responsible authorities

2.1 In Taiwan, the responsibilities for food safety are shared by the Council of Agriculture ("COA") and the Taiwan Food and Drug Administration ("TFDA") under the Ministry of Health and Welfare.¹ In general, COA and its agencies are charged with overseeing raw materials production such as fresh produce, fisheries and poultry, whereas TFDA deals with post-market monitoring of food safety issues.

¹ The Ministry of Health and Welfare was established in July 2013 as a result of the merger of the Department of Health, the Department of Social Affairs, the Child Welfare Bureau, the Domestic Violence and Sexual Assault Committee, the National Pension Supervisory Committee, and the National Research Institute of Chinese Medicine. The mission of the Ministry is to promote the health and well-being of all citizens.

2.2 On the local level, the municipal and county/city governments act as the local regulatory and enforcement authorities. They are responsible for handling food business registration, prescribing regulations on food business sanitation, conducting examination, sampling or testing of food at place of manufacturing, as well as imposing fines on food businesses that violate the food safety law.

2.3 After the recent outbreak of food safety incidents, the Executive Yuan took the lead in October 2013 to establish the Food Safety Joint Inspection and Confiscation Task Force to integrate the efforts of the Ministry of Health and Welfare, COA, the Ministry of Economic Affairs and local governments on food monitoring. The Task Force is responsible for, among other things, carrying out inspection work, informing the public of food products that fail inspections, and enforcing follow-up measures.

Council of Agriculture

2.4 COA acts as the competent authority at the central level on matters relating to the agricultural, forestry, fishery, animal husbandry and food industries. It is also responsible for guiding and supervising its provincial and municipal offices working in these areas. Food policies formulated by COA are implemented by a number of agencies under its purview, namely the Agriculture and Food Agency, the Bureau of Animal and Plant Health Inspection and Quarantine, and the Fisheries Agency², each of which is entrusted with statutory responsibilities to assist COA in carrying out its functions.

² The Agriculture and Food Agency is responsible for the regulation of agricultural food industry and promotion of agricultural food safety, whereas the Bureau of Animal and Plant Health Inspection and Quarantine is entrusted with conducting quarantine inspection on fresh produce, meat, poultry and pet food. For the Fisheries Agency, it is tasked to regulate the aquaculture food safety by drafting and supervising policies, law and regulations relating to fisheries.

Taiwan Food and Drug Administration

2.5 TFDA was established on 1 January 2010 as an agency within the former Department of Health (now the Ministry of Health and Welfare). Modelled after the Food and Drug Administration of the United States, TFDA's mission is to "ensure food and drug safety, to begin a new technology era, and to create a safe consumer environment." The creation of TFDA combined four former Department of Health bureaus – Food Safety, Food and Drug Analysis, Pharmaceutical Affairs, and Controlled Drugs – into one unified entity for the regulation of food products, pharmaceuticals, biologics, medical devices and cosmetics.

2.6 On food regulation, TFDA is responsible for matters including (a) formulating food safety policies, laws and regulations; (b) examining, registering and licensing food products; (c) testing, inspecting and examining imported food; (d) laboratory accreditation and risk assessment; and (e) implementing consumer protection measures.

3. Legal framework

3.1 In Taiwan, it was not until 2014 that all food products were governed by the *Act Governing Food Sanitation* 《食品衛生管理法》 that had been in force since 1975. The scope of the *Act* covered the interpretation of food, food additives, food equipment and cleanser, safety and sanitation control, labelling and advertisement, inspection and sanction, and penal provisions on violation of the *Act*. In response to the recent food safety concerns and incidents, the *Act Governing Food Sanitation* was amended twice during 2013-2014 and renamed the *Act Governing Food Safety and Sanitation* 《食品安全衛生管理法》 on 28 January 2014.

3.2 The *Act Governing Food Safety and Sanitation* aims to improve Taiwan's food safety regulatory framework through measures such as (a) introducing stricter food quality control management; (b) increasing the penalties for violation of the *Act*; and (c) establishing the principles for setting up a protection fund for victims of tainted foods.

Stricter food quality control management

3.3 The *Act Governing Food Safety and Sanitation* requires food producers to certify the safety of all food product ingredients they use or sell, including all raw materials, half-finished products and end products. They shall either undertake accreditation testing themselves or commission a certified accreditation laboratory to do the test. Any food manufacturer violating the requirement shall be fined between NT\$30,000 (HK\$8,070) and NT\$3 million (HK\$807,000) and risks having his or her licence suspended or revoked.

Increased punishment for food safety violations

3.4 To deter food manufacturers from committing illegal conducts, the *Act Governing Food Safety and Sanitation* increases the maximum fine for involvement in the production or sale of food products that are adulterated, fraudulent or harmful to human health from NT\$15 million (HK\$4 million) to NT\$50 million (HK\$13.5 million). The *Act* also stipulates that a fine of up to NT\$4 million (HK\$1.1 million), up from the previous maximum of NT\$200,000 (HK\$53,800), shall be imposed on the offense of false, exaggerated or misleading labelling, promotion, or advertising of food products.

3.5 In addition, the *Act Governing Food Safety and Sanitation* increases criminal penalty for adulteration, counterfeiting and use of food additives which are not approved by TFDA. The maximum term of imprisonment is raised from three to five years. If death results from the offence, the offender may be sentenced to life imprisonment.

3.6 The *Act Governing Food Safety and Sanitation* also introduces a new provision stating that if a person is found guilty of willfully committing a crime covered by the *Act*, any of his or her property generated from such an offence must be either returned to the victims or confiscated. Where confiscation is not possible, other assets or property commensurate to the value of the illicit profits shall be confiscated instead.

Food safety protection fund

3.7 To compensate consumers and finance relevant class-action lawsuits relating to food safety, the *Act Governing Food Safety and Sanitation* adds a new provision authorizing the Ministry of Health and Welfare to set up a food safety protection fund. The fund is financed from a variety of sources, including fines paid by violators of the *Act* and government appropriations.

4. Food monitoring measures

4.1 The Taiwanese government monitors food industry's compliance with food legislation primarily through (a) the conduct of inspection activities on local food establishments and imported food; (b) the establishment of a food safety control system within the food business; (c) award for reporting contraventions; (d) classification of food safety incidents; and (e) the implementation of a traceability system. The recent outbreak of food safety incidents has resulted in a tightening of food monitoring measures with the amendment of various relevant regulations to restore consumer confidence.

Inspection of local food establishment

4.2 Regular inspection of local food establishments are conducted by the Bureau of Animal and Plant Health Inspection and Quarantine and local governments. The former is responsible for the inspection of livestock and poultry slaughterhouses and meat cutting plants, whereas the latter are responsible for the examination of the sanitation conditions and records of food service establishments. Any food business that is suspected of violating the food safety standards and regulations may be ordered to have its operation suspended and products confiscated.

Inspection of imported food

4.3 In January 2014, the Ministry of Health and Welfare amended the *Regulations of Inspection of Imported Foods and Related Products* 《食品及相關產品輸入查驗辦法》³ to set out, among other things, the following three methods for inspection of imported food:

- (a) randomly-selected batch inspection whereby inspection is performed based on a 2-10% inspection rate;
- (b) reinforced randomly-selected batch inspection whereby inspection is performed based on a 20-50% inspection rate; and
- (c) batch-by-batch inspection whereby the inspection is carried out for each submitted batch of product, i.e. 100% testing rate.

³ The Chinese title of the *Act* was previously known as 《輸入食品及相關產品查驗辦法》.

4.4 The initial testing frequency or inspection rate is determined by TFDA. In the instance of a single violation, the inspection frequency of the same commodity imported by the same importer will be increased, e.g. from 2-10% regular random inspection rate to 20-50% reinforced random inspection rate. Following two consecutive violations, inspections will increase from the elevated 20-50% rate to 100% or batch-by-batch inspections. If the same cause of the violation on the same commodity continues to occur, TFDA may require a "plan of improvement" from the source exporters or country. If the improvement plan is still deemed unsatisfactory, TFDA may temporarily suspend imports from the relevant source.

4.5 For imported food items which are considered to have a high degree of safety risk⁴, they are subject to systematic inspection as prescribed under the *Regulations for Systematic Inspection of Imported Food* 《輸入食品系統性查核實施辦法》 promulgated by the Ministry of Health and Welfare in January 2014. The regulations empower TFDA to inspect the food safety management systems adopted by the exporting countries. TFDA may request an exporting country to provide documents for review and, if required, on-site inspection may be conducted to complement the document review. Shipment from the exporting country is allowed only if its food safety management system is assessed to be equivalent to that of Taiwan after the systematic inspection.

Food safety control system

4.6 In order to promote preventive food safety in the food industry and comply with the international standards, the *Regulations on Food Safety Control System* 《食品安全管制系統準則》 was enacted on 11 March 2014 whereby food businesses are required to set up their own food safety control team comprising at least three members. The team members must include the responsible person for the food business concerned and a professional with food technician certification for the management and supervision of food safety. Moreover, all team members must have at least 30 hours training on food safety and obtained qualified certificates from training institutions authorized by the Ministry of Health and Welfare. Those who fail to comply with the requirement will be fined between NT\$60,000 (HK\$16,140) and NT\$15,000,000 (HK\$4 million). In severe circumstances, a food business may have its licence suspended or revoked. Once the licence is revoked, the food business concerned cannot apply for a new licence within one year.

⁴ For example, animal guts, bladders, stomachs and parts are considered as high-risk food items.

Award for reporting contraventions

4.7 In an effort to provide better incentives and enhance protection for whistleblowers, anyone who reports cases in contravention of the *Act Governing Food Safety and Sanitation* will be awarded 5% to 10% (formerly only 5%) of the amount of fine imposed. A new provision under the *Act* is also added to protect whistleblowers by extending the guarantee of protection of the confidentiality of a whistleblower's identity data to protection in court proceedings as well.

Classifications of food safety incidents

4.8 The Executive Yuan has put in place a classification system to classify the degree of seriousness of food safety incidents. Such a system is to alleviate public concern by clarifying the gravity of each incident as quickly as possible. There are four classes in the system:

- (a) Class 1 is for the most serious incidents where food products contain ingredients that are harmful to humans;
- (b) Class 2 is for incidents where the food production process violates the *Act Governing Food Safety and Sanitation*, but the food in question may not immediately cause harm to human health;
- (c) Class 3 is for incidents involving adulterated products; and
- (d) Class 4 is for incidents involving mislabelling of food products.

Taiwan Agriculture Food Traceability System

4.9 Many countries have implemented food traceability systems to allow consumers or administrative authorities to trace the origins or ingredients of food products. In line with international practices, Taiwan enacted the *Agricultural Production and Certification Act*《農產品生產及驗證管理法》 in 2007 to provide for the establishment of the Taiwan Agriculture Food Traceability System ("TAFT") by COA.

4.10 TAFT is an online databank that provides extensive consumer information. Consumers can trace the information of agricultural products back to their producers or manufacturers. "Traceability", as defined under Article 3 of the *Agricultural Production and Certification Act*, is "the ability to trace the information on an agriculture product through specified stages of cultivation, processing, packaging, distribution and marketing, which can be demonstrated by keeping complete records that could be made known to the public."

4.11 Participation in TAFT is voluntary. A participating agricultural product operator⁵ is required to pursue third-party certification and inspection of his or her production and processing practices in accordance with the requirements set out in the *Agricultural Production and Certification Act*. The third-party certifying body is responsible for performing on-site inspection to verify matters such as the agrochemicals and fertilizers used, and the credibility of data contained in the records kept by the agricultural product operator seeking certification. Upon certification approval, the agricultural product operator may register his or her products under TAFT on a batch basis, and provide traceability labels with a specific traceable code for a given batch of products.

Record keeping requirements

4.12 Under the regulations governing the certification of traceable agricultural products, certified agricultural product operators are required to keep a "journal" with the use of both text and photographs for recording details about each stage of the production process (including sowing, nursing, fertilizing, harvesting and processing) and the delivery process (including information about transportation and storage) as well. Additionally, such traceability records are required to be uploaded to an information communication technology-based system developed by COA, and made available to the public online via COA's TAFT website. At present, traceability information of five categories of food products is available through this platform, namely the agricultural, fishery, poultry, livestock and processed food categories. Consumers may get access to the relevant traceability information by keying in the product's traceable code on the TAFT website, or at kiosks in supermarkets and shopping centres.

⁵ An agricultural product operator is defined in the *Agricultural Production and Certification Act* as any person who engages in the business of production, processing, packaging, import, distribution or marketing of agricultural products and their processed products.

4.13 The necessary traceability information required to be made public by the agricultural product operator includes:

- (a) product name;
- (b) name of the agricultural operator;
- (c) location of production site;
- (d) the product's traceable code;
- (e) major operational activities;
- (f) packing date;
- (g) name of the certification body; and
- (h) valid period of certification.

5. Food labelling

5.1 Chapter 5 of the *Act Governing Food Safety and Sanitation* sets out the labelling requirements for food products and food additives sold in or imported into Taiwan. Of particular relevance is the display of the following core information conspicuously on the container or packaging of food products/food additives in Chinese and commonly used symbols:

- (a) product name;
- (b) name of the ingredients: separate labelling is required if the food product or food additive is a mixture of two or more categories of ingredients;
- (c) net weight, volume or quantity;
- (d) name of food additives: separate labelling is required in the case of a mixture of two or more food additives;

- (e) name, telephone number and address of the manufacturer or importer;
- (f) scope of use, maximum use level, and limitation of use of food additives;
- (g) country of origin;
- (h) expiry date;
- (i) nutrition label containing information such as energy, protein, fat, saturated fatty acids, carbohydrate and sodium content of the food; and
- (j) genetically modified ingredients (if any) contained.

5.2 Food additives and genetically modified ingredients are subject to additional labelling requirements as prescribed under the *Act Governing Food Safety and Sanitation*.

Food additives

5.3 Before the *Act Governing Food Safety and Sanitation* came into force, food additives were legally defined as "substances that are added to or brought into contact with foods for the purpose of coloring, seasoning, preserving...or other necessary purpose."⁶ After the enactment of the *Act Governing Food Safety and Sanitation*, "substances" is replaced by "single or compound substances" and a new sentence is added to the definition. The new sentence states: "*the additives used in compound food additives....must in every case have a permit number approved by the central competent authorities.*"

5.4 The above requirements oblige food manufacturers not only to use compound additives made from additives currently approved by TFDA, but also to register previously unlisted additives with the agency so that the ingredients can be monitored and supervised. This should help deter food manufactures using illegal compound additives (such as the use of toxic plasticizers and copper chlorophyllin) as they are now required to file product registration with TFDA.

⁶ See Article 3(3) of the *Act Governing Food Sanitation*.

Genetically modified ingredients

5.5 The *Act Governing Food Safety and Sanitation* has tightened the regulations on genetically modified food labelling by adding the definition of genetic modification as well as setting up a mandatory registration for genetic modification ingredients. Importers of registered and licensed genetically modified ingredients are obliged to establish a system for tracking the origin and dissemination of the ingredients. Manufacturers are also required to register genetically modified ingredients with TFDA to enable the authority to build a database for monitoring the ingredients used and ensuring that they are not used in excess.

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