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Crisis of food safety, plasticizer in drinks, maleic anhydride starch in snacks and chlorophyllin copper complex in olive oil- the strategy that rescued

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Abstract
During 2011-2013, there happened three food scandals in Taiwan: the use of the plasticizer, di(2-ethylhexyl) phthalate (DEHP) as the cloudy agent; the production of maleic anhydride-modified starch; and the adulteration of chlorophyllin copper complex in some vegetable oils. Taiwan FDA (TFDA) immediately adopted these seizure strategies: 1) to immediately off-shelve, recall, and incinerate the prohibited products, 2) to prosecute these manufacturers and fine the guilty, 3) to update assay method and instruments, 4) to issue novel regulation, and 5) to organize specific committee to proceed a nation-wide survey and the re-education program for the gross dealers and retail sellers. A food safety committee in Taichung City was specifically recruited for management for the food additives, we urging the gross and retail sellers to compile more strict management and control on food materials. Four successive inspections were set on showing advanced regulations. Conclusively, the problem of food safety is an internationally wide concern. As some additives are allowed in a certain countries, while prohibited in the others, the need to establish a generalized worldwide standard and frequent re-education would be timely required.

Keywords: food safety, plasticizer, Taiwan FDA (TFDA), chlorophyllin copper complex (C.C.C.)

Introduction

During 2011 to 2013, there happened three food scandals in Taiwan (The Central News Agency, 2011a, 2011b) [38-39]. The first was the use of the plasticizer, di(2-ethylhexyl) phthalate (DEHP) to substitute palm oil for the traditionally used cloudy agent (People's Daily Online, 2011) [30]. The second was the use of legally prohibited maleic anhydride-modified starch to manufacture the Chinese traditionally popular cuisine (Press Releases, 2013; TFDA, 2013) [31, 36-36], and the third was the use of unapproved illegal additive, chlorophyllin copper complex (C.C.C.) as the coloring agent in some vegetable oils, in particular, the olive oils (Lee, 2013) [22].

In mid May 2011, Taiwanese authorities reported that two Taiwanese companies (People's Daily Online, 2011) [30], Yu-Shen Chemical Co. and Pin-Han Perfumery Co., had been incorporating for many years the plasticizer, DEHP, to substitute the popularly used palm oil cloudy agent in food and drinks with the aim to keep cost down, improve profits (People's Daily Online, 2011; Lee, 2011) [30, 21], and moreover, to prolong shelf life and the taste feeling (Taipei Times, 2011a) [33].

Soon after, 10 more products were found to contain excessive levels of plasticizers by Taipei City's Food and Drug Division (Ma, 2011) [27]. The government health units at once launched the nation's largest-ever action to secure food safety by checking up to 16,000 food makers and outlets and off-shelved over 20,000 foods, beverages, fruit juices, bread, sports drinks, tea, and jam suspected to be contaminated with DEHP (Ma, 2011; Uy, 2011; The Taipei Times, 2011b) [27, 45, 34] (Figure 1).

The Taiwan Government's action was immediate. Before the end of May 2011, the government began the seizures of contaminated products and at the same time announced a ban from exporting (Whats On Xiamen, Inc., 2011) [47].

In December 2013, reports received by Taiwan Food and Drug Administration (TFDA) revealed there may be some manufacturers using unapproved maleic anhydride-modified starch as a flour substitute and a modifier (TFDA, 2013) [35-36]. Further searching indicated that some food starch used for manufacturing special Chinese snacks in the night markets supplied by a starch gross dealer in Tainan City (Taiwan) was found to contain maleic anhydride. The supplier was investigated regarding the 300 tons of tainted starch, an earlier inspection in November had found 32 tons (Want China Times, 2013) [46].

On November 13 of 2013, TFDA announced that chlorophyllin copper complex (C.C.C.), a prohibited additive, was discovered in 12 cooking oils manufactured by some major local oil companies including Fwusow Industry Co., Tai-Sun Enterprise Co., and others involving Ting-Hsin International Group (TA-Tung) Chang-Chi Foodstuff Factory Co. (Figure 2) and Formosa Oilseed Processing Co., Ltd. (Lee, 2013) [22]. Inspection indicated that the source of chlorophyllin copper was originated from the Spanish olive oil imported by Fwusow and Tai-Sun. However until then TFDA had not received any official document from the Spanish government.

Several countries and regions have banned Taiwanese food imports into their countries. To name few, China (Chinese mainland) authorities banned 812 products from the original 22 in list from Taiwan, which included sports drinks, tea, jam, juices, and other beverages, later, China upgraded the banned list to cover 1004 products (Jiang, 2011a; Jiang, 2011b) [17-18]. Hong Kong authorities started monitoring its residents for contamination (Lim, 2011) [23]. They banned two types of Taiwanese sports beverage called 'Speed'. Hong Kong's health secretary Chow Y. stated that because the ingestion of the carcinogen will be a health risk, he supported an outright ban of the DEHP agent (Lim, 2011) [23]. Macau health authorities found the antacid Scrat Suspension gave a positive reaction for DIBP who later issued a notice of recall to local importers and pharmacies, and at the same time, Standard Chem. & Pharm Co. also notified its retailers to pull the product off the shelves in Taiwan and Macau (The China Post, 2011a) [42]. In Malaysia, the Malaysian authorities found some bubble tea products contaminated with DEHP and urged the importers to halt importation and distribution of the products in Malaysia. The Philippines authorities banned DEHP affected products and carried out investigations of importers to ensure affected products were recalled (Kastner, 2011) [20]. Vietnamese health authorities raided and restricted importation of Taiwanese contaminated products (The Central News Agency, 2011c) [40]. South Korea banned products affected by DEHP from Taiwan (AFP, 2011b). In USA, California-based 99 Ranch Market, one of the largest Asian grocery chains in the United States, removed the plasticizer-contaminated beverages, from Taiwan, off the shelves (The China Post, 2011b) [43]. To solve these emergent cases, we recruited a special committee to work with the TDFA to raise several strategies hoping to restore the reputation of Taiwanese foods.

Materials and methods

Seizuring the prohibited products

For case of illegal cloudy agent (the plasticizer DEHP), before the end of May 2011, TFDA immediately commanded official seizures of contaminated products and in the meanwhile announced a ban from exporting the related raw materials (Whats On Xiamen, Inc., 2011) [47].

Off-Shelving the prohibited products and subject to incineration

For case of the prohibited maleic anhydride-modified starch, no sooner than the case of maleic anhydride-derived starch occurred, TFAD in 2013 ordered all tainted food products be immediately off-shelved and subject to incineration (TFDA, 2013) [35-36].

Raising the alert action

And at the same time, a nationwide risk alert action was established to enhance food safety inspections and management (TFDA, 2013) [35-36].

An 'Inter-Ministry Task Force on Food Safety' was also immediately recruited after the tainted food products were found.

Amending and renewing the 'Act of Food Sanitation'

For the case of the prohibited maleic anhydride-derived starch, The Legislative Yuan (Taiwan) passed an amendment to the Act Governing Food Sanitation on 31 May, 2013, with the aim to strengthen food inspection and management and introduce tougher penalties.

In parallel, TFDA successfully developed the test method for copper chlorophyllin complex contaminant with the cooking oils. TFDA, biding with the Act Governing Food Sanitation, announced that all contaminated cooking oils must be off-shelved immediately. On confirmation, the local health authorities also appeared at the oil manufacturers' for further investigations (Lee, 2013) [22].

Issuing a warning briefing

The ministry of Foreign Affairs (Taiwan) also organized a briefing for the diplomatic corps on June 4th, 2013 with updated information on the food safety situation in Taiwan. And at the immigration custom, the government also implemented the border control measures whereby any company that is found to have manufactured products containing unapproved additives or industrial starch are urged to show food safety certificate before it is imported or exported. The Taiwan Government hopes these rapid and transparent response measures can safeguard food safety and rebuild the reputation of Taiwan's food products.

Issuing a high penalty fine

For case of olive oil adulterated with unapproved chlorophyllin copper complex (C.C.C.), the Authorities ordered the cooking oil producer, (Ta-Tung) Chang-Chi Foodstuff Factory Co. (a factory located in local Changhua County, Taiwan), to halt at once the manufacturing of all prohibited products containing unapproved or prohibited additives including olive oil, grape seed oil and others (Hsiao, 2013) [13]. The company also faced a fine amounting at least to NT$28 million (US$950,900) as accused by the Local Government of Changhua County (Hsiao, 2013) [13]. Alternatively, among the 59 types of cooking oil products seized by the authorities from Chang-Chi's factory, 36 were found with mislabeling. Thus should the company be fined, the maximum penalty, by count NT$200,000 for per case, the extra fine could amount to NT$7.2 million.

At the same time, Chang Chi's peanut oil was also found to be only a 100% adulterated, i.e. not containing any trace of 'natural peanut oil'. Which in reality was actually only a mixture of canola oil and salad oil and spiked with flavoring essence; its grape seed oil includes sunflower oil; and its chili oil was not made of red chilis, but of only chili pepper extracts, salad oil and flavoring essence (Hsiao, 2013) [13]. While its sesame oil was actually 100% adulterated canola oil (Hsiao, 2013) [13].

Specific committee established for further inspection and guidance

By then, TFDA of Executive Yuan of Taiwan extended budgets to each local city, urging to establish Specific Committee, composed of members with industrial and academic backgrounds. This whole project was executed by Chinese HAZARD ANALYSIS CRITICAL CONTROL POINTS Development Association (Chinese HACCP Development Association). As a co-executor, The Health and Sanitation Bureau of Taichung City organized this Specific Committee. The task of such a Specific Committee was 1) to give guidelines to the contemporary Gross dealer to set up a

positive and correct knowledge; and 2) to instruct the Retail sellers set up a safer material flowchart and a good segment to avoid the unsafe contamination or mix-up of the Food grades with the Chemical industrial grades (Lin *et al*., 2013; 2014) [24-25]. In addition, the Consumer's Association and most of the consumers all rejected the purchase of any brand of cooking oil products manufactured by (TA-Tung) Chang Chi Foodstuff Factory Co.

Results and discussion

For case of prohibited cloudy agent, the plasticizer DEHP

A fast, simple and reliable method for the analysis of DEHP in PVC products was developed using a one-step Soxhlet extraction prior to HPLC determination. The linear range from 1.25 μ/g to 250 mg/g of DEHP in PVC was found sufficient to cover the normal concentrations encountered. The reliability of the method is comparable to that described was in ASTM method (Fung and Tang, 1994) [9].

Further, by the new assay method, ten new products found to contain excessive levels were pineapple sauce from Shih Hung Foodstuffs Co. (16.99 parts per million (ppm) of DEHP); peach juice from Trojan Corp. (48 ppm DEHP; 41.5ppm of diisononyl phthalate, DINP); vegan Sa Cha sauce (342.9 ppm DINP); Santa Cruz's "100% organic lemon juice" (7.2ppm diisodecyl phthalate, DIDP); an infant diet probiotic enzyme product from Liang Chun International Co. (159.7 ppm DEHP; 14.8 ppm DINP); Guangming pills from Wellslifes Biotech Co. (12.7 ppm DEHP; Huiyo food capsules from NatureWise Biotech & Medicals Corp with 24.1 ppm DEHP; 39.5 ppm of di-isodecyl phthalate, DIDP); tuna fish oil capsules from Hsu Yin Co, (31.4 ppm DEHP); Toona sinensis sauce (1,545.6 ppm DINP); and mushroom sauce from Cheng Tai Soysauce Foodstuffs Co. (1,944.2 ppm DINP).

Later, the action of government safety prosecution was extended to syrups, tablets, pastries, and powders (Taipei Times, 2011b) [34]. By May 27, 2011, "up to 465,638 bottles of DEHP-tainted beverages were pulled out from store shelves. Also, up to 270,822 boxes and 68,924 packs of powdered probiotics and 28,539 kilos of fruit juices, fruit jam, powder and syrup, and yoghurt powder were off-shelved" (Galarpe, 2011) [10].

According to Chen Li-Chi, the Division director of TFDA, "although the Cheng-Tai Soysauce products contained 200 times excessive DEHP over the regulated by the TFDA standards, preliminary inspections have pointed to the plasticizer to be originating from the plastic film inside the bottle cap and not directly adulterated into the food."

Plasticizers are chemical additives used to make plastic more pliable, but they were illegally used as food additives to act as clouding agents — a kind of food additive used to increase 'pale white' outer look of drinks, making them look more appealing and sparkling (Hongkong Taiwan News, 2012) [12]. Taiwanese prosecutors alleged that one of the companies Yu-Shen acting as at the centre of the crisis had been using 5 tonnes of DEHP every month for purpose of manufacturing clouding agents and supplied them to food processing firms and pastry shops (Kastner, 2011) [20]. For decades, in fact there were 95 Taiwanese manufacturers had been using the DEHP ingredient (Kastner, 2011) [20] and a further 244 ingredient manufacturing firms also had been using the DEHP (Kastner, 2011) [20].

In recent years some concern has arisen internationally in relation to some phthalates, as a result, some have been banned in Europe and in the United States. Australian research has identified a minimal risk in relation to one phthalate, DEHP. A ban has been introduced prohibiting certain products that contain DEHP above a prescribed level (Australian Competition & Consumer Commission, 2015) [3]. The European Union (EU) began to take action on phthalates, as a precautionary measure, in 1999. Regulations have been amended many times since then, but currently the EU bans the use of six phthalate esters in toys and children's products that might be placed in the mouth, at levels greater than 0.1 per cent of the total object weight. The phthalates subject to this regulation are: di-2-ethylhexyl phthalate (DEHP or DOP), dibutyl phthalate (DBP), Butyl benzyl phthalate (BBP), di-isononyl phthalate (DINP), di-isodecyl phthalate (DIDP), and di-n-octyl phthalate (DNOP) (Fig. 3). The EU has also applied limitations to the use of these phthalates in general food contact applications (packaging and closures) and medical device applications. In addition, several phthalates have been listed as 'substances of very high concern' (SVHC) requiring reporting of their content in articles exported into the EU under the REACH regulations (Australian Competition & Consumer Commission, 2015) [3].

The acute toxicity of DEHP is low in animal models: 30 g/kg in rats (oral) and 24 g/kg in rabbits (dermal) (Lorz *et al*., 2005) [26]. Concerns instead focus on its potential as an endocrine disruptor (Ohashi *et al*., 2005) [29]. Exposure to DEHP has been associated with obesity, asthma, and low testosterone levels (Martinez–Arguelles and Papadopoulos, 2015) [28]. Di-(2-ethylhexyl) phthalate (DEHP), a ubiquitous plasticizer and a known endocrine disruptor, altered DNA methylation patterns in the adrenal gland of adult male rats exposed to DEHP *in utero* (Martinez–Arguelles and Papadopoulos, 2015) [28]. Chromosomal region that houses genes controlling immune responsiveness is a primary target of DEHP. Because DEHP is rapidly cleared from the body, the effects observed in the adult are likely epigenetic in origin (Martinez–Arguelles and Papadopoulos, 2015) [28]. Hot spots of DNA methylation changes primarily within CpG islands followed by shelf regions of the genome known to control regional gene expression (Martinez–Arguelles and Papadopoulos, 2015) [28]. DEHP phthalate exposure early in life induces epigenetic changes that may be linked to altered gene expression and function in the adult (Martinez–Arguelles and Papadopoulos, 2015) [28]. In addition, DEHP has some binding affinity for ERalpha, neither epoxidized soybean oil nor tris(2-ethylhexyl)trimellitate (an alternative to DEHP) has any affinity for ERα (Ohashi *et al*., 2005) [29].

Fears that toxic chemicals were ingested by children when chewing plastic toys prompted the European Commission to order a temporary ban on phthalates in 1999, as decided by the Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) (http://www.intertek.com/uploadedFiles/Intertek/Divisions/Consumer_Goods/Media/PDFs/Sparkles/2011/sparkle559.pdf). Until 2004, EU banned the use of DEHP along with several other phthalates (DBP, BBP, DINP, DIDP and DNOP) in toys for young children (EurActiv.com. (2004) [5] (Figure 3). In 2005, the Council and the Parliament compromised to propose a ban on three types of phthalates (DINP, DIDP, and DNOP) (Figure 3). And by then more products than initially

planned have been affected by the directive (EurActiv.com., 2005) [6]. In 2008, six substances were added to the Candidate List including Musk Xylene (Figure 3), 4,4'-Methylenedianiline (MDA), hexabromocyclododecane (HBCDD), DEHP, BBP, and DBP (http://www.intertek.com/uploadedFiles/Intertek/Divisions/Consumer_Goods/Media/PDFs/Sparkles/2011/sparkle559.pdf). In 2011, six substances have been listed for Authorization in Annex XIV of REACH by Regulation (EU) No 143/2011 (http://www.intertek.com/uploadedFiles/Intertek/Divisions/Consumer_Goods/Media/PDFs/Sparkles/2011/sparkle559.pdf). According to the regulation, phthalates including DEHP, BBP and DBP will be banned from February 2015 (European Solvents Industry Group., 2011) [8]. In 2012, Denmark decided to ban four industrial chemicals including DEHP, DBP, DIBP and BBP (EurActiv.com., (2012) [7] (Figure 3) and it takes effect in 2015. In 2012, France became the first country in EU to ban the use of DEHP in paediatircs, neonatology and maternity wards in hospitals the ban will come into effect on 1 July 2015 (http://healthierhospitals.org/media-center/news-updates/france-first-eu-country-ban-use-dehp-paediatrics-neonatology-and-maternity).

For case of maleic anhydride-modified starch

The testing method for examination of maleic anhydride-modified starch was also soon established. Preliminary testing on commercial formulation also gave the final product with an elastic texture. Seventy four samples including relevant starches and starch based products such as sweet potato balls, tapioca balls, taro balls, etc. were tested and five of them showed positive maleic acid reaction (TFDA, 2013) [35-36].

According to the regulation of FDA, maleic anhydride (Figure 4) can be used when food is to come in contact with packaging materials and transforms to maleic acid when water is added (Press Releases, 2013) [31]. It is approved by the FDA of the U.S. and the EU as an indirect food additive and may also be present in trace amounts of lawful food additives such as maleic acid, fumaric acid, etc. (Press Releases, 2013) [31].

Free maleic anhydride also poses relatively low-risk environmental hazards, an important feature for those applications. Exposure to maleic anhydride may cause respiratory tract, eye irritation, skin irritation and respiratory irritation. Maleic anhydride is a skin and respiratory sensitizer (Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management).

Maleic anhydride (Eq. 1 in Figure 4) is a low hazard profile chemical. Maleic anhydride rapidly hydrolyzes to form maleic acid in the presence of water and hence environmental exposures to maleic anhydride are not expected to occur. Maleic anhydride and maleic acid (Eq. 1 in Figure 4) are biodegraded under aerobic conditions in sewage sludge and in soil and water as well (Wikipedia, the free encyclopedia).

Maleic anhydride reacts with hydroxyl groups present in the starch molecule to produce the maleic anhydride-modified starch (Figure 4). Theoretically, maleic anhydride (normally 0.5-1.0% only) will be completely consumed in the reaction provided the amount of maleic anhydride used was stoichiometrically far less than the equivalent of –OH groups present in starch available for reaction. The linking bridges can be intermolecular (Eq. 2 in Figure 4) or intramolecular (Eq. 3 in Figure 4) in nature. In reality, under such conditions, no excess free maleic acid could remain after reaction. In addition, subsequent rinsing would have removed all the trace residual free maleic anhydride, implicating the positive reaction of maleic anhydride in the sample starch to be due to incomplete washings. Biochemically, the few cross linking bridges newly formed in the modified starch would not provoke any toxic effect.

U.S. EPA research shows that rats that were daily given food containing 100 mg/kg of maleic acid for 2 years were found not to have kidney damage. Other studies on animals indicate that a single dose (9 mg/kg) of maleic acid will cause kidney toxicity in dogs, but dosages of 117 mg/kg, 191 mg/kg, or 29 mg/kg fed to rats, mice, and monkeys, respectively, did not indicate any renal toxicity, which shows that sensitivity to maleic acid varies with different animals (Press Releases, 2013) [31].

For case of olive oil adulterated with unapproved chlorophyllin copper complex

No sooner, TFDA successfully developed a test to discover the amount of copper chlorophyllin complex (C.C.C.) contained inside cooking oil (Lee, 2013) [22]. TFDA Division Director J.L. Feng said that according to the Act Governing Food Sanitation, all cooking oils that contain C.C.C. must be off-shelved immediately (Lee, 2013) [22]. On receiving the inspection report, TFDA officials immediately phoned the local health authorities to visit the oil manufacturers for further investigations (Lee, 2013) [22].

Chlorophyllin copper complex

Oil soluble chlorophyll copper complex has part of the magnesium replaced by copper. Water soluble chlorophyllin copper complexhas part of the magnesium replaced by copper and its methyl and phytyl ester groups replaced by sodium and potassium (Harrison *et al*., 1954; Joint FAO/WHO Expert Committee, Rome 4-13 June, 1974) [11, 19]. Any toxic effects are therefore, in part, due to free ionisable copper present in the complex. Sodium potassium chlorophyllin copper complex (NaKC.C.C.) (4% total Cu, 0.25% ionic Cu), in concentrations above 0.1% of the diet, appears as chlorophyllin and Cu^{2+} ions in the plasma (Harrison *et al*., 1954) [11]. The ingested chlorophyll was excreted in the faeces as calcium complex. No copper storage occurred in liver, kidney or spleen of rats at dietary levels of 0.1% or 1% of NaKC.C.C. (Harrison *et al*., 1954) [11]. Guinea-pig fed 0.5% or rats fed 3% of NaKC.C.C. in their diet showed no evidence of scurvy (Harrison *et al*., 1954) [11].

In the acute toxicity, neither mice given 2500 mg/kg bw NaKC.C.C. orally for seven days (Worden *et al*., 1955, Harrison *et al*., 1954) [49, 11], nor guinea pigs, rabbits, cats and dogs, when administered NaKC.C.C. 1000 mg/kg bw orally daily for seven days, did show any ill effects (Worden *et al*., 1955) [49]. Harrison *et al*. indicated that NaKC.C.C. has an LD_{50} of 7000 mg/kg bw to mouse (per os); and that of C.C.C. is 190 mg/kg bw (Harrison *et al*., 1954; Joint FAO/WHO Expert Committee, Rome 4-13 June, 1974) [11, 19]. Usually, for use as color additive in the olive oil. According to the Food and Drug Administration (FDA) of USA, the incorporation of C.C.C. to olive oil and grape seed oil to make them look green is sanctioned for use as a food additive

by the UN's Codex General Standard for Food Additives and many countries. However, this said additive has not been cleared for use in edible oil products in Taiwan, the TFDA said, adding that Taiwan follows global standards in excluding its use in edible oil.

No sooner, the Spanish government issued an official document to TFDA. After opening a re-investigation, Changhua County Public Health Bureau commanded Tai-Sun Co. to modify his label as cooking oil products. Although Tai-Sun Co. yielded and changed the labels, he still claimed it to be pure olive oil made in Spain. By then, TFDA did not have any technology to judge the truth. Tai-Sun Co. considered to commit a legal action against the local media reporting false information about this event (Lee, 2013) [22]. According to the report held in the Joint FAO/WHO Expert Committee, Rome 4-13 June, 1974 [19]. The acute toxicity of C.C.C. depends on different animal models (Worden *et al*., 1955; Tomino, 1958) [49, 44]. Offspring of six female rats fed 1% of NAKC.C.C. for 19 weeks exhibited locomotory difficulties and skeletal muscle defects (Reber & Willigan, 1954). Five female guinea-pigs received 0.5% NaKC.C.C. in their drinking-water for 11 weeks without ill-effects or pathological change (Harrison *et al*., 1954) [11].

While in long-term chronic studies with rats, the results revealed no evidence of copper toxicity or deposition in liver, kidney or spleen (Harrison *et al*., 1954; Worden *et al*., 1955) [11, 49]. The copper in these complexes is firmly bound. Though increased plasma levels of copper have been reported there is no significant tissue storage nor is there any evidence of destruction of ascorbic acid. Chlorophyll copper complex has higher toxicity when given via parenteral but this has no toxicological significance if this colour is used by the oral route. The level causing no toxicological effect is 3% in diet, i.e. 3% (= 30,000 ppm) in the diet equivalent to 1500 mg/kg bw for rat. Which translates the acceptable daily intake for man to be 0-15 mg/kg bw. It is worth mentioning, around June 15th of 2011, only roughly 900 products containing plasticizer DEHP had been recalled from nearly 40,000 Taiwanese retailers. Some media, including in *The Economist*, solemnly declared that Taiwan's historical glorious reputation as 'a reliable and safe food manufacturing country' in fact has been totally ruined and vanished (The Economist, 2011) [41].

To be realistic, in some countries, a certain kinds of food additives are "generally recognized as safe" and can enter the food supply directly without so much as a quick review by the Food and Drug Administration (Chemical Cuisine -Learn about Food Additives). Such different regulation and control system may cause safety problem to look seriously in one country, but completely safe in the other.

Table 1: Defaults of the gross and retail sellers found by the HACCP Committee during the first run inspection in Taichung City (Taiwan).*

Demanded items	Gross dealer/Retail seller													
	YF	GT	CG	CF	TS	HT	ZS	DM	EH	CC	TC	LS	YC	RH
purchase management	X	X	X	X			X	X		X			X	
labeling	X	X	X	X	X	X	X	X	X	X	X	X	X	X
5S system	X					X				X				X
factory sanitation	X					X	X				X			
shop sanitation	X	X	X	X	X	X	X							
stock sanitation		X	X		X		X	X	X		X			
height, stock site		X	X	X	X	X	X	X	X	X		X	X	
health checking	X	X	X	X	X	X				X		X		X
PSSM†	X	X	X	X		X	X					X		
staff training program	X	X		X		X								
sanitary uniform	X													
pathogen prevention record		X				X						X		
Temp and RH‡ record				X	X	X	X			X	X	X	X	
Sum	10	9	7	8	7	10	8	4	3	6	4	6	4	4

*Project executed by Lin *et al*. (2013) [24] (A sub-program of Chinese HACCP Development Association). †PSSM: Personal self-sanitation management. ‡RH: relative humidity.

Table 2: Defaults of the gross and retail sellers found by the HACCP Committee during the second run inspection in Taichung City (Taiwan).*

Demanded items	Gross dealer/Retail seller													
	YF	GT	CG	CF	TS	HT	ZS	DM	EH	CC	TC	LS	YC	RH
defaults (first run) un-amended		X		X	X				X			X		
origin control					X		X			X				
origin & import certificate			X	X		X			X					
effective license	X	X	X	X					X			X		X
food additive 3S management					X	X	X							
specific person				X		X								
specific area					X	X	X	X				X	X	
specific record	X	X	X	X	X	X					X		X	X
RCP‡	X			X		X	X					X		
RCP regulation				X	X			X				X		
RCP status		X												
Sum	2	4	3	6	5	6	4	2	3	1	1	4	2	2

*Project executed by Lin *et al*. (2013) [24] (A sub-program of Chinese HACCP Development Association). ‡RCP: repacking & change packing

Table 3. Defaults of the gross and retail sellers found by the HACCP Committee during the third run inspection in Taichung City (Taiwan).*

Demanded items	Gross dealer/Retail seller													
	YF	GT	CG	CF	TS	HT	ZS	DM	EH	CC	TC	LS	YC	RH
defaults (second run) un-amended				X					X					
manufacturing selling record				X	X							X	X	
SRMR#			X											
flow of selling					X									
selling record														
RCP‡												X		X
RCP regulation							X							
RCP status														
LSFC†			X	X							X			
clear compartment				X	X		X						X	
clear labeling							X							
others		X									X			
able listed in Fadenbook		X	X									X		
Sum	0	2	3	4	3	0	3	0	1	0	2	3	2	1

*Project executed by Lin *et al*. (2013) [24] (A sub-program of Chinese HACCP Development Association). ‡RCP: repacking & change packing of additives. †LSFC: labeling & separation: food additives/industrial chemicals. #SRMR: standard and record for merchandise replenishing

Table 4: Defaults of the gross and retail sellers found by the HACCP Committee during the fourth run inspection in Taichung City (Taiwan).*

Demanded items	Gross dealer/Retail seller													
	YF	GT	CG	CF	TS	HT	ZS	DM	EH	CC	TC	LS	YC	RH
Defaults (third run) un-amended		X	X	X	X							X		
able listed in Fadenbook				X										
RCP‡														
RCP regulation														
RCP status														
others														
RRMS†				X										
others					X									
Sum	0	1	1	3	2	0	0	0	0	0	0	1	0	0

*Project executed by Lin *et al*. (2013) [24] (A sub-program of Chinese HACCP Development Association). ‡RCP: repacking & change packing of additives. †RRMS: record established for right manufacturing and selling flow.

Table 5. Overall improvement rate for each run of inspection by the HACCP Committee in Taichung City (Taiwan).*

Items	Gross dealer/Retail seller													
	YF	GT	CG	CF	TS	HT	ZS	DM	EH	CC	TC	LS	YC	RH
First run, defaults	10	9	7	8	7	10	8	4	3	6	4	6	4	4
Second run, defaults	2	4	3	6	5	6	4	2	3	1	1	4	2	2
Improvement rate, %	80	56	57	25	29	40	50	50	0	83	75	33	50	50
Third run, defaults	0	2	3	4	3	0	3	0	1	0	2	3	2	1
Improvement rate, %	100	78	57	50	57	100	63	100	67	100	50	50	50	75
Fourth run, defaults	0	1	1	3	2	0	0	0	0	0	0	1	0	0
Improvement rate, %	100	89	86	63	71	100	100	100	100	100	100	83	100	100

*Project executed by Lin *et al*. (2013) [24] (A sub-program of Chinese HACCP Development Association).

Fig 1

Fig 2

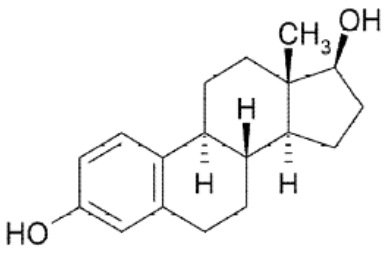
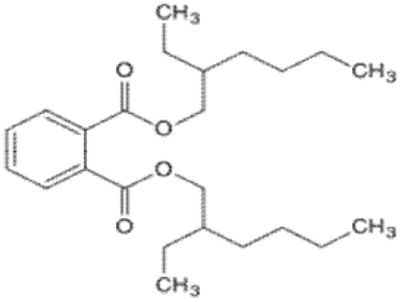
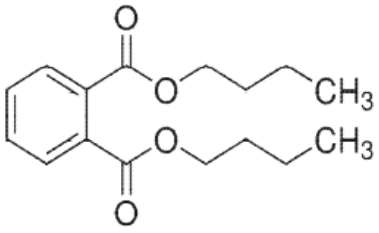
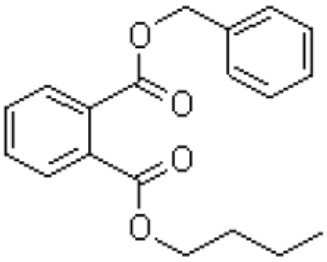
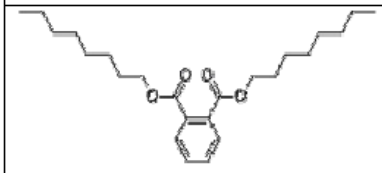
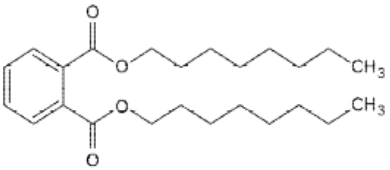
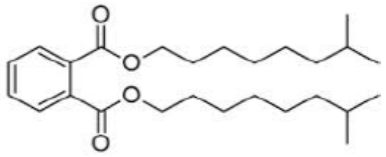
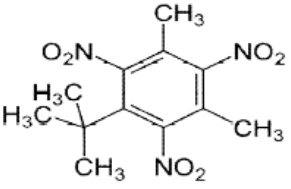
Estradiol	Di(2-ethylhexyl) phthalate (DEHP)
	
Dibutyl phthalate (DBP)	Butyl benzyl phthalate (BBP)
	
Di(n-octyl) phthalate (DNOP)	Dioctyl phthalate (DOP)
	
Diisononyl phthalate (DINP)	Musk Xylene (not a phthalate)
	

Fig 3

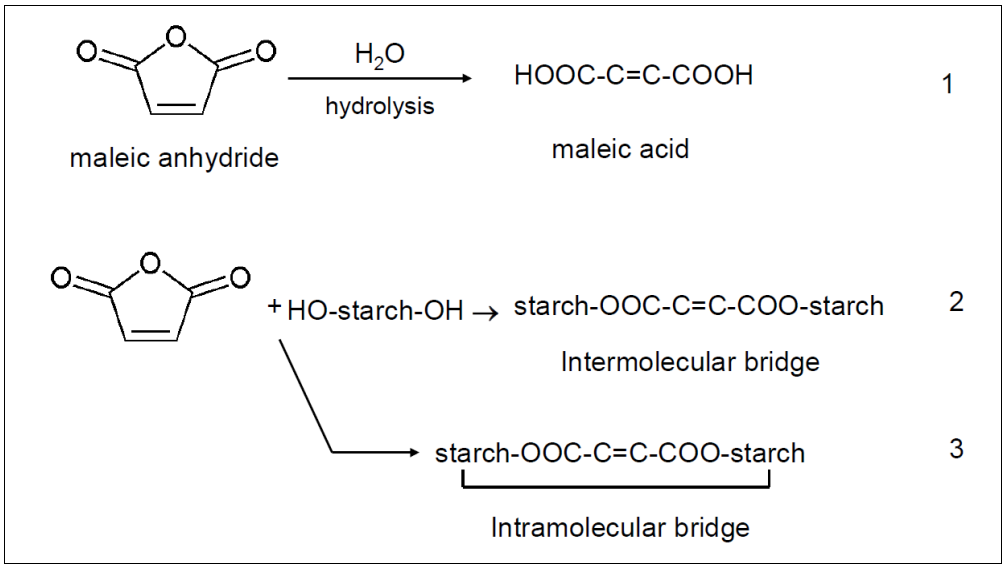


Fig 4: Maleic anhydride

Inspection and Guidance by Specific Committee

The TFDA call up for a Specific Committee to assist the retail sellers to improve their management and safety line, for which the Specific Committee raised the following steps: 1) In the first run, 'to correctly label' for the food additives was urged. 2) In the second run, the retail sellers were urged 'to consolidate the management of the supplier sources, and requested to perform the 3S-management, i.e. 'write down the Specific Record of buy- and- sell in Specific Area by Specific Authorized Person'. And 3) In the third run, the defaults found in the second run were asked to be alleviated, in particular, to correctly record the buyer's name, perform the repacking by following the safety regulation, to establish a complete compartment to isolate the stock rooms of food additives and that for the industrial chemical, and more importantly, all labels must be very clear. Finally in the fourth run, the defaults found in the third run were re-examined, especially for the fadenbook dealing with the repacking problem, the food additive manufacturing, and the seller's and buyers' records etc.

In the first run, among 14 retail sellers, a total of 90 defaults were found (Table 1). The top default was that the food additives were all incorrectly labeled (100%), the next was the food stuffs were placed on the ground without spacing an appropriate height from the ground (93%) (Table 1). In the second run, only 45 defaults remained un-amended (Table 2), among which the top one was 'non-formally -registered' (44%) and the food additives were not well controlled by the 3S regulation, i.e. specific site (44%), by specific staff, and specific record (30%). In the third run, there still left 24 defaults distributed among the 14 retail sellers, amazingly, among these, a single retail seller even exhibited 4 defaults (company CF, Table 3), and the next other 4 retail sellers all committed to 3 defaults, 2 or less defaults by nine other retail sellers, and only three retail sellers owned the honor of 'zero defects' (Table 3). The total defaults were 67% (or less) less than the first run. But there was still a single case of incorrect record of the buyer and the material flow (Table 4). After the four checking runs, the improvement rate was raised from 48.43% of the second run to 92.29% of the fourth run (Table 5), indicating a great success.

The reason of making so many defaults was mainly due to ignorance to the food additives, committing mislabeling, self-repacking, no clear and definite compartment of the food additives from the industrial chemicals, lacking the detail record of the retrieved and output merchandises. As for amelioration of these defaults to recall for the public confidence, we suggest TFDA to establish a series of training camps to be executed by the local Bureau of Health and Sanitation in each city. Based on the results, we further inspected the present status of the gross dealers and retail sellers of the food additives as well as the industrial chemicals in Taiwan. The classification was performed by index of officially registered or non-registered. We found only 45 companies were legally registered (Figure 1), while 184 companies still remained un-registered (Figure 2), making up a total of 229 (Figure 3). In which, the registered (88 companies) were all located in the five-big cities of Taiwan. While the 66% of the un-registered were also localized in the Five-Big Cities. Apparently, the Five-Big Cities also become the main castles of the non-registered companies. The type of their commercial activity involved baking powder and related facilities (132 companies), food additives (49 companies), food stuffs (20 companies, food and chemical materials 19 companies), food stuffs and additives (8 companies), and others (one single company) (Figure 4). Through such a specific inspection and instruction actions, we indeed have spread the results and related improved figures to the whole nation (Taiwan). By doing this, these improved data definitely have attracted the attention of other local cities to follow up. The outcome is the retail sellers indeed are keeping alert for the appropriate management of food additives and raw industrial chemicals with a correct concept of self-control and good selling behavior. And eventually they have reconstructed a moral model in selling and managing the food additives, carefully avoiding the contamination of industrial chemicals into the food additives. In addition, this action certainly has inspired the basic social responsibility of the retail sellers and issued good health protection for the nationwide.

In the second project (Lin *et al*., 2014) [25], we extended the inspection to the whole nation (Tawan) to have covered 31 Gross dealers/Retail sellers (7 in the northern part, 13 in the middle Taiwan, and 11 in the southern Taiwan). After four times inspection and re-training, the improvement was rather apparent. The overall number of defects were soon reduced from 59 to 4 (the northern part); from 64 to 10 (the middle Taiwan); and from 79 to 13 in the southern part (Lin *et al*., 2014) [25].

Conclusively, these food scandals implicated that the problem of food safety is an internationally wide concern. We strongly yelled for the need to establish a generalized worldwide standard, which becomes urgently in need as the internationally interchanging of information, immigrant, technology, and commercialized chemicals and goods have become increasing, fast and large scaled. In parallel, the assay methods for new materials as well as new additives must be always up-dated. The management of food materials and immediate retail selling records should be fulfilled whenever the trading is finished. Independent and sanitary stock room for food materials and additives is also urged in order to improve the quality and storage condition. Moreover, education and training for the dealers of food materials and additives have to be strengthened with update and frequent follow-up.

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