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## Case Report

# A review on the response and management of the plasticizer-tainted food incident in Taiwan



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## ABSTRACT

While conducting an inspection project on counterfeit drugs in 2011, the Taiwan Food and Drug Administration (FDA) discovered a probiotic product that was contaminated with the plasticizer di-(2-ethylhexyl) phthalate (DEHP). After a thorough investigation, it was confirmed that the plasticizer had been deliberately added to the clouding agent as a substitute for an emulsifier. The illegal use of DEHP contaminated a broad range of foods and nutraceutical products. Subsequent investigation revealed that another plasticizer, di-isononyl phthalate (DINP), was also used. Some contaminated food and beverages had already been exported abroad. This caused panic in the public in Taiwan and drew international attention. The government thus initiated emergency response actions for this food safety incident. Actions were undertaken to perform food source control, to strengthen monitoring and surveillance of the production and marketing chain, to adopt a proactive approach in communicating with the public, and to trade in a highly transparent manner. The Act Governing Food Sanitation was also revised to impose harsher penalties on unscrupulous companies and thereby ensure food safety with more consolidated and stricter regulation. The effort has regained the consumer confidence in Taiwanese products.

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## 1. Introduction

Plasticizers are added to plastics, concrete, wallboard, cement, gypsum, and other products to increase the flexibility or fluidity of a material. There are various categories of plasticizers [1]. Phthalic acid esters are the most widely used plasticizers and include di-(2-ethylhexyl) phthalate (DEHP), di-isononyl phthalate (DINP), di-isodecyl phthalate (DIDP),

butyl benzyl phthalate (BBP), di-n-butyl phthalate (DBP), and diethyl phthalate (DEP). The plasticizers DEHP and DINP are often added to polyvinyl chloride (PVC) to create a wide range of products such as floor boards, decorations, food packages, and medical devices [2]. The plasticizers DEP and DBP are commonly used in cosmetics as perfume solvents and fixatives [3]. Using plasticizers as food additives is never allowed.

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Phthalates can be easily released to the environment from plastic products. They are ubiquitous contaminants in food, indoor air, soils, and sediments [4]. The human body (primarily urine) can quickly excrete DEHP [5]. Some kinds of phthalates are endocrine disrupting substances such as DEHP, DBP, and BBP. These have been identified as toxic to animal development and reproduction [6,7].

## 2. Event description

During an inspection of counterfeit drugs by the Taiwan Food and Drug Administration (TFDA) in April 2011, a probiotic product was found to contain a high concentration of DEHP. Further analysis confirmed that the clouding agents used had been adulterated with DEHP. The source of the clouding agents was traced by TFDA. In mid-May 2011, it was determined that a clouding agent manufacturer, the Yu Shen Chemical Company, was adulterating its clouding agents with DEHP as a substitute for palm oil to reduce the production cost. The TFDA immediately asked the Ministry of Justice to help track down the number of products that were involved. During the investigation, the TFDA found another manufacturer, the Pin Han Perfumery Company, that was adulterating clouding agents by adding another plasticizer, DINP.

## 3. Crisis management

### 3.1. Emergency response initiation

The TFDA immediately organized an emergency response team and launched an investigation to track down how many products were involved. All tainted or suspected products were removed from the shelves for public health protection. The government convened a cross-agency meeting and an intra-agency incident management team was established on May 19, 2011. The task force was formed

by the Department of Health (DOH), Environmental Protection Administration (EPA), Ministry of Economic Affairs (MOEA), Ministry of Justice (MOJ), Ministry of Finance (MOF), and the Consumer Protection Commission (CPC). The DOH held a press conference on May 23, 2011 to announce the event and urge all food industries to check thoroughly and recall the tainted products for consumer protection.

### 3.2. “D-Day” set and countermeasures taken by the government

To prevent the contaminated products from entering the market and to restore public confidence, on May 28, 2011, the DOH announced its Guideline for Handling Foods Contaminated with Plasticizers. May 31, 2011 was then designated as “D-Day”, which was the due date that all plasticizer-tainted products needed to be removed from store shelves. Safety certificates that indicated the product was not contaminated with the plasticizer needed to be supplied for five categories of foods: sports drinks, juices, tea beverages, jams, fruit pastes, and jellies, and supplied for food supplements in capsules, tablets, and powder form, if they contained a clouding agent. Food products without safety certificates were prohibited from being sold starting on May 31, 2011.

In addition, local health authorities conducted inspections of food and drink manufacturers and vendors in all counties and cities. A total of 49,652 retail stores were inspected. As a result, 29,337 items from 4076 stores were ordered to be removed from shelves.

The DOH and the regional health authorities continued monitoring the manufacturers and retailers for products containing contaminated clouding agents and continued tracking their product flows. Authorities also reinforced inspections on commercial food products to keep products off the market contaminated with illegal ingredients. Nearly 900 food products from 425 companies were using plasticizer-tainted clouding agents supplied by the Yu Shen Chemical Company or by the Pin Han Perfumer Company (Fig. 1).

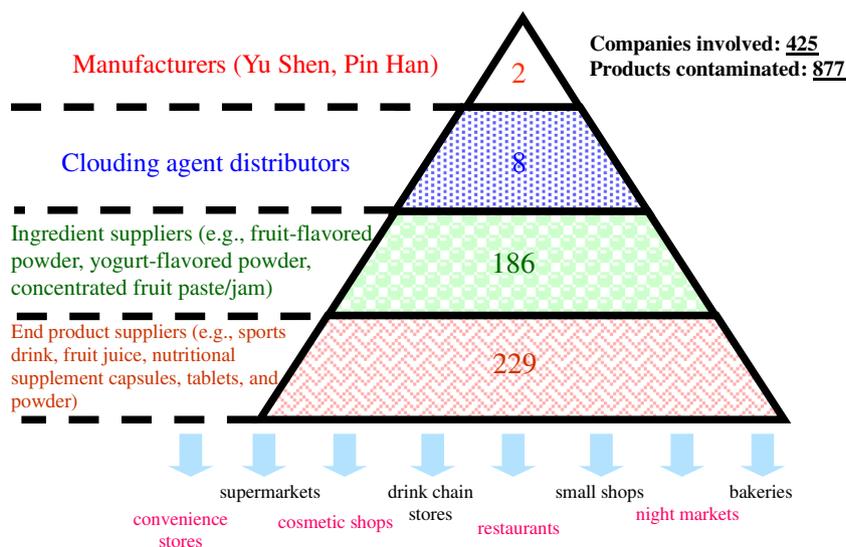


Fig. 1 – Supply chain of plasticizer-tainted food products.

**Table 1 – Range of DEHP and DINP levels in different categories of raw materials.**

Category	No. of samples	No. of tainted samples	Tainted rate (%)	Plasticizer concentration (ppm), range (no.)	
				DEHP	DINP
Clouding agent	46	17	35.4	18,816–113,402 (13)	37,356–107,912 (5)
Spices	239	72	30.1	1.6–9,421 (66)	1.6–2,437 (9)
Concentrated juice	536	117	21.8	1.5–3,296 (116)	1.5–208 (20)
Jam	43	12	27.9	2.0–119,914 (10)	4–2,193 (7)
Other raw materials	171	21	12.4	2.9–987,927 (20)	4.1–12.9 (2)
Total	1,035	239	23.1	(225)	(43)

DEHP = di-(2-ethylhexyl) phthalate; DINP = di-isononyl phthalate.

To ensure that contaminated products would not return to store shelves, local health authorities gathered contaminated products and monitored their destruction. The confiscated plasticizer-tainted food products were destroyed beginning on June 11, 2011 and completed on July 28, 2011 so that compromised products could not return to the market.

### 3.3. Countermeasures for the exportation of related products

The TFDA notified the International Food Safety Authorities Network (IFSAN) of the World Health Organization (WHO) and the Rapid Alert System of Food and Feed (RASFF) of the European Union (EU) about the products and relevant companies during its ongoing investigations on clouding agents containing DEHP and DINP from the Yu Shen Chemical Company and the Pin Han Perfumery Company, respectively. The importing countries of said products were also immediately notified to take responsive measures. Tainted products had been exported to 22 countries, including the United States, Canada, Costa Rica, Brazil, Argentina, Germany, the United Kingdom, Australia, New Zealand, South Africa, Egypt, Philippines, Malaysia, Brunei, Singapore, Indonesia, Marshall Island, Vietnam, China, Hong Kong, Macau, and Japan. The plasticizer crisis had a devastating effect on the “made in Taiwan” (MIT) brand image, and substantially impacted the domestic food and drink industries. On June 3, 2011, the MOEA announced that authoritative certificates were required for the exportation of food products in the five aforementioned categories.

### 3.4. Mobilization of laboratory capacity

The TFDA established a method for analyzing phthalate plasticizers in foods by using liquid chromatograph/tandem mass spectrometer (LC/MS/MS). The surveillance reference level was tentatively set to 1 ppm for rapidly screening contaminated products. The testing capacity of 34 private laboratories accredited by TFDA was 2630 samples per day, and the testing capacity of the 15 government laboratories—including the laboratories of the TFDA, EPA, MOEA, and Council of Agriculture—was 550 samples per day.

In total, 3091 samples collected by regional health authorities were sent to the TFDA and cooperative government laboratories from May 12, 2011 to July 15, 2011. Of these, 1035 samples of raw materials (which included clouding agents, spices, concentrated juice or jam) were tested and 239 (23.1%) samples were tainted with phthalate (Table 1). For the final products, 2056 samples of sports drinks, tea beverages, juices, jams, fruit pastes, jellies, capsules, tablets, powders, and other products were tested; 212 samples (10.3%) were tainted with phthalate (Table 2).

### 3.5. Risk communication, health education and medical consultation service

The TFDA website provided real-time recall information for plasticizer-tainted products, health risk information, questions and answers (Q&A), and other related information. Twenty consumer hotlines for the public were also

**Table 2 – Range of DEHP and DINP levels in different categories of end products.**

Category	No. of samples	No. of tainted samples	Tainted rate (%)	Plasticizer concentration (ppm), range (no.)	
				DEHP	DINP
Sports drink	56	13	23.2	9.1–34.1 (11)	13.7–14.0 (2)
Tea drink	193	5	2.6	2.0–60.0 (5)	2.0 (1)
Juice drink	235	3	1.3	2.4–14.6 (3)	—
Jam, fruit paste, jelly	227	4	1.8	2.0–2.4 (2)	2.0–4.2 (3)
Capsules, tablets, powder	605	140	23.1	1.5–1675 (127)	1.5–465 (28)
Other	475	23	4.8	1.5–128 (31)	1.7–46.8 (17)
Total	2,056	212	10.3	(179)	(51)

DEHP = di-(2-ethylhexyl) phthalate; DINP = di-isononyl phthalate; ppm = parts per million.

established to answer questions and to relieve consumers' concerns. In addition, a daily press was held at 3:30 PM to illustrate the monitoring progress of the event.

The DOH has moreover introduced a "5 Less, 5 More" slogan to the public to reduce plasticizer exposures in daily life. "5 Less" implies: less plastics; less flavorings; less unnecessary medicines or nutritional supplements; less processed fruit juice, fruit jelly, snacks, and cakes with artificial filling or other desserts; less animal fat; and less oil and internal organs. By contrast, "5 More" suggests: more hand washing prior to eating; more water intake instead of bottled beverages; more natural fruits and vegetables consumption; more exercise to accelerate metabolism; and more breastfeeding to avoid pacifiers.

Clinical consultations were also established in 131 hospitals, and more than 4100 consultations were provided. Of these patients, 54 (1.3%) people were further transferred to special clinics. For long-term tracking of the health effects, the National Health Research Institute is planning a study on plasticizer epidemiology and risk assessment.

#### 4. National food safety conference

To restore public confidence in food safety and to rebuild the image of the MIT food industry, the DOH held a National Food Safety Conference on June 21, 2011 and June 22, 2011. To strengthen Taiwan's food safety policies, experts and professionals from government bodies, industries, and academia were invited to review the food safety crisis and to discuss quality control issues on food additives and materials management. To rebuild consumer confidence, the conference concluded with three major proposals to improve food safety.

##### 4.1. Industry upgrade

A mandatory registration system should be established to accredit and superintend food manufacturers. The industries should establish autonomous management and certification systems in the private sector. The inspections, continuing education systems, and research capabilities should be strengthened, and the government should support the establishment of a food additive manufacturers association.

##### 4.2. Policy support

The conference recommended that the government establishes a strong legal basis for food safety management and provides adequate human and financial resources. The administrative regulations governing the practices of food additives, the classifications of food additives, and certification systems for food technologists should be revised or established. The auditing and inspection capacity of the central and regional authorities should be improved and traceability systems for food additives should be strengthened.

**Table 3 – Tolerable daily intake of five common plasticizers.**

Plasticizer	TDI (mg/kg bw/day)
DEHP	0.05
DBP	0.01
DINP	0.15
BBP	0.5
DIDP	0.15

BBP = butyl benzyl phthalate; DBP = di-n-butyl phthalate; bw = body weight; DEHP = di-(2-ethylhexyl) phthalate; DIDP = di-isodecyl phthalate; DINP = di-isononyl phthalate; TDI = tolerable daily intake.

#### 4.3. Social responsibility

The industry is also responsible for safeguarding food safety to protect consumers. Effective risk communication practices are important in reducing public panic.

### 5. Strengthening policies and ending the crisis

The amendment to the Act Governing Food Sanitation was passed by the Legislature Yuan and announced on June 22, 2011. A penalty on illegality was imposed. The DOH established a comprehensive system for the compulsory registration of food additives to strengthen the tracking and management of food additives. The EPA moreover tightened the control over the category of phthalate plasticizers and the suppliers who have to apply for permission prior to selling plasticizers.

On July 13, the DOH announced the tolerable daily intake (TDI) levels for five common plasticizers (Table 3). The TDIs can be used to assess the risk associated with a specific plasticizer-tainted food product, and to judge whether the amount of plasticizer exposure is harmful to human health. Through the cooperation of the DOH, the prosecutor's office, and all other responsible agencies, all plasticizer-tainted products have been removed from the market and destroyed. Investigations have shown that no more companies were implicated and no more products had to be removed from shelves since June 14, 2011. The DOH thus withdrew the lists of companies and products suspected of using clouding agents contaminated with plasticizers, and declared the crisis control measures were ended beginning on August 1, 2011.

### 6. Conclusion

The plasticizer crisis caused a significant economic and social impact in Taiwan, including strong social disapproval leading to extensive debate and criticism of food safety management. It undermined consumers' trust in the government and devastated the image of Taiwanese products abroad. The food industry must place public health ahead of production cost saving. Health officials have called on the industry to strengthen internal oversight, employ food safety professionals, and establish standardized processes. The industry, consumers, and government must work together to protect food safety.

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