Journal of Food and Drug Analysis, Vol. 20, No. 4, 2012, Pages 734-743
doi:10.6227/jfda.2012200302

A Review on Safety Inspection and Research of Plastic Food Packaging Materials in Taiwan

YA-MIN KAO*

Food and Drug Administration, Department of Health, Executive Yuan, Taipei, Taiwan, R.O.C.

(Received: March 29, 2012; Accepted: July 30, 2012)

ABSTRACT

Plastics for food packaging are polymers made from monomers and with additives to enhance the technical properties of final products. Some non-reacted monomers and potential mobile additives may be present in plastic products, and may migrate into contact with foods during storage, cooking or serving as potential sources of contamination. For the regulation of these compounds, the residual and migration limits are set by the authority in Taiwan, based on their extent of migration from plastic products and their toxicological properties. This report reviewed the management for 7 kinds of common plastic food packaging materials, including polyethylene, polypropylene, polyethylene terephthalate, polystyrene, polyvinylchloride (PVC), polycarbonate and plastics with formaldehyde as raw materials for synthesis, and their sanitation inspection from 1983 to 2010. A total of 1,623 food-contact plastic samples have been inspected according to the Sanitation Standard for Food Utensils, Containers and Packages announced by the Taiwan Department of Health. Among them, 99 samples and 52 samples were not in accordance with the regulation of the material test and the migration test, respectively. These samples mostly had printing ink on the food-contact surfaces or have rough and cracking surfaces due to incomplete process of final products. In addition, endocrine disruptors in plastics, such as phthalates, bisphenol A and nonylphenol, were studied. Testing methods of those compounds have been developed, and the migration tests for the related food-contact plastic products were also conducted. The results indicated PVC-made products were worth being noticed in respect of phthalates and nonylphenol, and consumers should avoid using PVC-made products for fatty foods.

Key words: plastic, food packaging material, polyethylene, polypropylene, polyethylene terephthalate, polystyrene, polyvinylchloride, polycarbonate, plastics with formaldehyde as raw materials for synthesis, material test, migration test, endocrine disruptor, phthalates, bisphenol A, nonylphenol

INTRODUCTION

Plastics with light, strong, lustrous, odorless, waterproof, gas-barrier and other characteristics have been widely used as food utensils, containers and packages to protect food from chemical and microbiological spoilage during production, transportation and storage. They are made from simpler molecules, or monomers mainly through polymerization. For different purposes, various additives, such as plasticizers to change the physical, mechanical and chemical properties, and stabilizers to prevent the deteriorations of products, are used in the manufacturing process(1). In view of toxicological properties of the non-reacted monomers and some potential mobile additives such as plasticizers and stabilizers, safety standards of these compounds for the material and migration tests of plastic food packaging materials are set by the authority in Taiwan. These regulations not only limit the amount of these harmful substances in plastic materials but also prevent their excessive migration into foods.

According to the Sanitation Standard for Food Utensils, Containers and Packages announced by the Department of Health in Taiwan, food-contact plastic products shall meet the general requirement and the classification requirement of plastics(2). Both requirements include the material test and migration test. The material test is a destructive test to analyze the contents of heavy metals, such as lead and cadmium, remaining monomers and additives, such as plasticizers and stabilizers. The migration test is to estimate the extent of migration of substances into food. It is carried out according to the type of food and the temperature of food during processing or cooking to select the migration solvents and migration conditions. The solvents, also called food simulants, including water, 4% acetic acid, 20% ethanol and n-heptane, are used to simulate the type of food. The migration condition for water and 4% acetic acid are both set at 60°C for 30 min or 95°C for 30 min. The latter condition is for products which are heated to higher than 100°C during food processing or cooking. For 20% ethanol and n-heptane,

* Author for correspondence. Tel: +886-2-2787-7704;
Fax: +886-2-2653-1256; E-mail address: kaoamy@fda.gov.tw

the migration conditions are set at 60°C for 30 min and 25°C for 1 h, respectively.

Because of the wide variety of plastic food utensils, containers and packages, the Food and Drug Administration in Taiwan (TFDA) and the former Bureau of Food and Drug Analysis (BFDA) have implemented the investigation and research on the safety of various types of plastic products for food packaging since 1983. The common plastic food packaging materials includes polyethylene, polypropylene, polyethylene terephthalate, polystyrene, polyvinylchloride, polycarbonate and plastics with formaldehyde as raw materials for synthesis. The present report reviewed the inspection and research results for the above mentioned types of plastic food packaging products.

POLYETHYLENE AND POLYPROPYLENE

Polyethylene and polypropylene, abbreviated as PE and PP, are thermoplastic polymers made from polymerization of ethylene and propylene, respectively and are widely used in food packaging. They are odorless, tasteless and acid-base resistant, while PP has better heat-resistant. The common products are plastic bags, wrapping films, preserving boxes, dairy containers, microwave containers, etc. The testing items for these products as shown in Table 1 include lead and cadmium for the material test and consumption of potassium permanganate, heavy metals and residues after evaporation for the migration test(2).

Lead is a heavy, low melting and bluish-gray metal. At high level of exposure, lead can severely damage the brain and kidneys in adults or children and ultimately cause death. High level exposure to lead may also cause miscarriage in pregnant women and damage men's organs responsible for sperm production(3). The International Agency for Research on Cancer (IRAC) has determined that lead is probably carcinogenic to humans(4). Cadmium is a soft and silver-white metal. Exposure to high cadmium level from foods and drinking water may lead to stomach irritation, vomiting, diarrhea and kidney damage. For a long time exposure to lower level of cadmium can also cause bones to become fragile and break easily(5). The IRAC has classified cadmium as a human carcinogen(4).

Table 1. The regulation of PE-made and PP-made products in the Sanitation Standard for Food Utensils, Containers and Packages

Item	Sanitation limit
Material test	
Lead	100 ppm
Cadmium	100 ppm
Migration test	
Water	
Consumption of $KMnO_4$	10 ppm
Residues after evaporation	30 ppm
4% Acetic acid	
Heavy metals	1 ppm (as lead)
Residues after evaporation	30 ppm
20% Ethanol	
Residues after evaporation	30 ppm
n-Heptane	
Residues after evaporation	30 or 150 ppm*

* 30 ppm is for containers and packages of oils and fatty foods, and 150 ppm is for products which are heated to not higher than 100°C during food processing and cooking.

As to the migration test, consumption of potassium permanganate with water as a solvent, is an assay for the amount of easily oxidized organic matter migrated from plastic products and the migration limit was set at 10 ppm. For heavy metals, 4% acetic acid is used as a solvent to analyze whether the harmful metals migrated into acidic foods and the migration limit was set at 1 ppm as lead. Residues after evaporation is used to analyze the amount of organic compounds being migrated into various solvents, which simulate different types of foods, i.e., 4% acetic acid for foods with a pH≦5, water for those with a pH > 5, 20% ethanol for alcoholic beverages, and *n*-heptane is for oils and fatty foods.

BFDA had conducted the sanitation inspection for a total of 374 PE-made and PP-made food containers and packages including heat-resistance bags, microwave containers, dairy containers, bottled water and mineral water containers, wrapping films, preserving boxes, small plastic bottles for

Table 2. The sanitation inspection results of PE-made and PP-made food utensils, containers and packages in Taiwan

Year	Type of sample	No. of sample	No. of non-conforming sample		Ref.
			Material test	Migration test	
1985	Heat-resistant bags	201	0	2	6
1991	Microwave containers	3	0	0	7
1991	Bottled water and mineral water containers	23	0	0	8
1992	Dairy containers, wrapping films, microwave containers, bags, preserving boxes	74	0	0	9
1996	Small plastic bottles for beverage	27	0	0	10
1997	Plastic bags used for steaming buns	36	8	8	11
1997	Children's tableware	10	0	0	12

beverage, plastic bags for steaming buns and children's tableware from 1985 to 1997[6-12]. The results are shown in Table 2. A total of 8 samples of plastic printed bags for steamed buns with lead levels and residues after evaporation and 2 samples of heat-resistant plastic bags with residues after evaporation failed to meet the sanitation limits. There was a significant positive correlation ($r = 0.8045$, $p < 0.01$) between the lead contents of the 8 plastic printed bag samples and their residues after evaporation. Although the heavy metal levels from the 8 samples in the migration test were all in line with the migration limit, the surface printing inks would be dissolved to contaminate the food. Hence, consumers should avoid using printed plastic products to contact foods.

POLYETHYLENE TEREPHTHALATE

Polyethylene terephthalate, abbreviated as PET, is a thermoplastic polymer resin. Because of its toughness, transparency and excellent gas barrier properties, PET is used to produce plastic bottles which are widely used for soft drinks, mineral water, tea, juice, wine, etc. Some microwave containers are made from C-PET (crystallized PET), with the characteristic of fully crystallized. Because this kind of material is extremely stiff and high-temperature resistant, it is used to make utensils used in microwave oven. PET is mainly synthesized by condensation of terephthalic acid and ethylene glycol catalyzed by antimony or germanium compounds in the process, therefore metal residues may be found in the final products[1].

Antimony is a silvery white metal often used in combination with lead and zinc, found in metal alloys, paints, ceramics, and fireworks. The most widely used antimony compound is antimony trioxide which is used as a catalyst in the production of PET[13]. Antimony trioxide can cause lung tumors by inhalation exposure in animals. Women exposed to antimony trioxide may have an excess incidence of premature births and spontaneous abortions and their children's growth may be retarded[14]. It has been classified as a possible human carcinogen by the IRAC[4]. Germanium is a hard, lustrous, gray-white and brittle metalloid. Germanium dioxide, one of germanium compounds, is used as a catalyst in production of PET resin[13]. Prolonged ingestion of germanium dioxide may cause kidney damage including kidney dysfunction, kidney tubular degeneration, and germanium accumulation in humans. Other adverse effects are anemia, mucle weakness, and peripheral neuropathy[15]. Because there is no cancer data in humans, germanium dioxide is not considered a human carcinogen by IRAC.

For sanitation management of PET-made products, the migration limits of antimony and germanium are set at 0.05 and 0.1 ppm, respectively as shown in Table 3.

BFDA conducted the sanitation inspection for 20 samples of PET-made microwave containers and bottled water and mineral water containers in 1991[7,8]. The results are shown in Table 4. All of the samples complied with the sanitation standard. Because most of these products are not resistant to high temperatures and their heat-resistant temperatures are mostly in the range of 60 to 85°C, it is not appropriate to be used for high-temperature foods or foods requiring heating.

POLYSTYRENE

Polystyrene, abbreviated as PS, with low-cost, acid and alkaline resistant, and gas barrier properties is mostly used to make disposable tableware such as cups, plates, bowls, lunch boxes and instant noodle bowls. During the synthesis process of PS, the first step is the reaction of benzene with ethylene oxide to form ethylbenzene, which is dehydrogenated into styrene monomer, and the latter is polymerized to produce PS[1]. Some non-reacted monomers and impurities in raw materials, such as toluene, *n*-propylbenzene, propylbenzene, etc., may remain in the final products and they have certain

Table 3. The regulation of PET-made products in the Sanitation Standard for Food Utensils, Containers and Packages

Item	Sanitation limit
Material test	
Lead	100 ppm
Cadmium	100 ppm
Migration test	
Water	
Consumption of $KMnO_4$	10 ppm
Residues after evaporation	30 ppm
4% Acetic acid	
Heavy metals	1 ppm (as lead)
Antimony	0.05 ppm
Germanium	0.1 ppm
Residues after evaporation	30 ppm
20% Ethanol	
Residues after evaporation	30 ppm
n-Heptane	
Residues after evaporation	30 ppm

Table 4. The sanitation inspection results of PET-made food containers in Taiwan

Year	Type of sample	No. of sample	No. of non-conforming sample		Ref.
			Material test	Migration test	
1991	Microwave containers	3	0	0	7
1991	Bottled water and mineral water containers	17	0	0	8

toxicities. Exposure to high levels of toluene may affect the brain and nervous system, and also cause kidney, liver and lung damage, while low to moderate levels of toluene can cause tiredness, confusion, weakness, drunken-type actions, memory loss, nausea and loss of appetite[16]. For management of this kind of products, the standard limit for the sum of these volatile compounds, including styrene, toluene, ethylbenzene, *n*-propylbenzene and isopropylbenzene, was set at 5,000 ppm, and that in foaming products is set at 2,000 ppm, among which the levels of styrene and benzene shall not be more than 1,000 ppm, as indicated in Table 5.

BFDA has conducted the sanitation inspection for a total of 450 PS-made products including disposable tableware, dairy containers, instant noodle containers and children's tablewares from 1983 to 1998[9,12,17-20]. The results are shown in Table 6. In addition to 17 samples of foaming products in the material test, including 16 with styrene residues and one with ethylbenzene residues, and 10 samples with residues after evaporation in the migration test failing to meet the standard limits, the rest were all in accordance with the regulation. These findings indicated that the failure rate of PS-made products has decreased over years. It means that the quality of raw materials and the process conditions have improved considerably. Owing to the heat-labile property of PS, such kind of products should not be used for high temperature foods.

Table 5. The regulation of PS-made products in the Sanitation Standard for Food Utensils, Containers and Packages

Item	Sanitation limit
Material test	
Lead	100 ppm
Cadmium	100 ppm
Volatile compound*	5,000 or 2,000 ppm
Styrene	1,000 ppm
Ethylbenzene	1,000 ppm
Migration test	
Water	
Consumption of $KMnO_4$	10 ppm
Residues after evaporation	30 ppm
4% Acetic acid	
Heavy metals	1 ppm (as lead)
Residues after evaporation	30 ppm
20% Ethanol	
Residues after evaporation	30 ppm
n-Heptane	
Residues after evaporation	240 ppm

* Volatile compounds represents the sum of styrene, toluene, ethylbenzene, *n*-propylbenzene and isopropylbenzene in which 2,000 ppm is for foaming products.

POLYVINYLCHLORIDE

Polyvinylchloride, abbreviated as PVC, is cheap, transparent, acid and alkaline resistant, low gas-permeable, and can be made into a variety of products with different hardness based on the proportion of modulation. It has been widely used in food packaging. The products include wrapping films, transparent boxes, etc. PVC is produced by polymerization of vinyl chloride monomers. It can be made softer and more flexible by addition of plasticizers, and stabilizers such as fatty acid metal salts and dibutyltin compounds are used to prevent the products from deterioration or yellowing, and to enhance its transparency[1].

Vinyl chloride is a manufactured substance mostly used to produce PVC. It was also used as a coolant, and as a propellant in spray cans and in some cosmetics. Long-term exposure to vinyl chloride can lead to liver, brain, mammary gland and blood cancer[21]. The IRAC has determined that vinyl chloride is carcinogenic to people[4]. Dibutyltin compounds, including dibutyltin dilaurate, dibutyltin oxide, etc., is a generic term for compounds in which butyl groups are covalently boned to a tin atom. Exposure to high levels of dibutyltin compounds may cause immune alteration by reducing thymus weight and size, and directly interfering with proliferation of thymocytes. Dibutyltin compounds may also induce developmental and reproductive effects to animals when administrated during pregnancy[22]. Since there is no cancer data in humans, dibutyltin compounds are not classified as carcinogens to humans by the IRAC.

Because there are residues of non-polymerized vinyl chloride monomer, plasticizers and stabilizers in the manufacturing process, for sanitation management, the residual limit

Table 6. The sanitation inspection results of PS-made food utensils, containers and packages in Taiwan

Year	Type of sample	No. of sample	No. of non-conforming sample		Ref.
			Material test	Migration test	
1983	Disposable tableware	113	9	10	17
1988	Disposable tableware	61	4	0	18
1992	Dairy containers	12	0	0	9
1996	Instant noodle containers	86	3	0	19
1997	Children's tableware	8	0	0	12
1998	Disposable tableware	170	1	0	20

of vinyl chloride in the material test was set at 1 ppm, and the limits of plasticizers as cresyl phosphate and stabilizers as dibutyltin compounds are set at 1000 ppm and 50 ppm (as dibutyltin dichloride), respectively as shown in Table 7.

BFDA had conducted the sanitation inspection for a total of 413 PVC-made products including lunch boxes, wrapping films, oil bottles, bottled water and mineral water containers from 1985 to 1994(8,23-25). The results are shown in Table 8. Among the 66 samples failing to meet the standard limits of the material test, there were 53 samples with vinyl chloride monomer residues and 16 samples with dibutyltin levels, which included 3 samples failing in both items. In addition, 8 samples with residues after evaporation in the migration test were not in accordance with the regulation. Owing to the material of PVC containing the chlorine element, the suspected vinyl chloride monomers are easily released into the environment to harm the public health during manufacturing, packaging, recycling and reproducing process. Coupled with surging environmental consciousness in recent years, the food manufacturers have turned to use PE, PP or PET for food packaging. Hence, it is rare to find PVC-made products used for food packaging except wrapping films.

Table 7. The regulation of PVC-made products in the Sanitation Standard for Food Utensils, Containers and Packages

Item	Sanitation limit
Material test	
Lead	100 ppm
Cadmium	100 ppm
Vinyl chloride	1 ppm
Cresyl phosphate	1,000 ppm
Dibutyltin compounds	50 ppm (as dibutyltin dichloride)
Migration test	
Water	
Consumption of $KMnO_4$	10 ppm
Residues after evaporation	30 ppm
4% Acetic acid	
Heavy metals	1 ppm (as lead)
Residues after evaporation	30 ppm
20% Ethanol	
Residues after evaporation	30 ppm
n-Heptane	
Residues after evaporation	150 ppm

PVC uses plasticizers to keep its products flexible and scalable during the process. The common plasticizers includes phthalate esters, adipate esters, phosphate esters and sebacate esters(1). Because phthalate esters have potential health hazards, such as short term oral exposure to high levels of diethylhexyl phthalate (DEHP) may interfere with sperm formation and delay sexual maturity in aminals(26), and their linkage with PVC is not chemically bonded, they will be gradually released into contact with foods depending on the type of foods and the temperature during food processing or cooking. In view of this, BFDA has conducted research programs to establish the testing method for 12 plasticizers, including 10 phthalate esters and 2 adipate esters, in PVC-made products for food packaging, and to investigate the levels of those in 40 PVC-made products including 23 wrapping films and 17 food containers from 1990 to 1991(27,28). The results are shown in Table 9. All of the 23 wrapping film samples were found to contain adipate esters including diethylhexyl adiphate (DEHA) found in 10 samples at the level of 16.24 ~ 20.41%, and diisononyl adipate (DINA) in 13 samples at the level of 20.82 ~ 23.56%. Four samples of 17 food containers were detected to contain 2 kinds of plasticizers including DEHP found in 2 samples at the level of 1.79 and 1.81%, and DINA found in 2 samples at the level of 2.38 and 2.55%. Because wrapping films are softer than food containers, the addition of plasticizers in wrapping films could be more than those in food containers in manufacturing process. Three wrapping films and 4 food containers containing plasticizers were selected to carry out the migration test. The results are also shown in Table 9. There were a large number of plasticizers being migrated into *n*-heptane, a solvent used to simulate oils and fatty foods, and the migration amounts of those from the wrapping film samples and food container samples accounted for 13.0 ~ 25.7% and 64.7 ~ 99.8% of the total amounts, respectively. Especially, those in the wrapping films were up to almost 100% migration for DEHA. Hence, consumers should avoid using PVC-made products to contact oils and fatty foods, or foods to be heated by microwave to prevent foods from being contaminated by plasticizers. For health concerns, the migration limits of two phthalate esters including DEHP and dibutyl phthalate (DBP) in *n*-heptane for plastic food-contact products were set at 1.5 ppm and 0.3 ppm, respectively by the Department of Health in 2010.

Table 8. The sanitation inspection results of PVC-made food utensils, containers and packages in Taiwan

Year	Type of sample	No. of sample	No. of non-conforming sample		Ref.
			Material test	Migration test	
1985	Lunch boxes	202	40[a]	—[b]	23
1991	Lunch boxes, wrapping films, oil bottles	98	13	8	24
1991	Bottled water and mineral water containers	30	13	0	8
1994	Oil bottles, bottled and mineral water containers	83	0	0	25

[a] Only for vinyl chloride analysis.
[b] Not implemented.

Table 9. The results of plasticizer investigation for PVC-made food containers and packages in Taiwan

Year	Type of sample	No. of sample	Material test		Migration test	
			Plasticizer	Amount (%)	Plasticizer	Amount (%)[a]
2001	Wrapping films	20	DEHA (8)[b]	16.24 ~ 20.41	—[c]	—
			DINA (12)	20.82 ~ 23.56	—	—
2002	Wrapping films	3	DEHA (2)	16.24, 18.77	DEHA (2)	16.20, 18.73
			DINA (1)	20.70	DINA (1)	13.39
	Bottles	17	DEHP (2)	1.79, 1.81	DEHP (2)	0.46, 0.32
			DINA (2)	2.38, 2.55	DINA (2)	0.31, 0.40

[a] Migration amount in *n*-heptane.
[b] Number in parentheses represents the number of samples found to contain plasticizers.
[c] Not implemented.

Table 10. The sanitation inspection results of PC-made food containers in Taiwan

Year	Type of sample	No. of sample	No. of non-conforming sample		Ref.
			Material test	Migration test	
1987	Insulated cups	48	0	0	29
1991	Bottled and mineral water containers	27	0	0	8
1999	Feeding bottles	30	0	0	30
2010	Feeding bottles, sealed jars, preserving boxes, water bottles	15	—[a]	0[b]	32

[a] Not implemented, except for bisphenol A.
[b] Only for bisphenol A analysis.

POLYCARBONATE

Polycarbonate, abbreviated as PC, with the characteristics of transparent, heat resistant and impact resistant, is often used for food packaging such as baby bottles, water bottles, etc. PC is synthesized by the transesterification reaction of bisphenol A and diphenyl carbonate or by the reaction of bisphenol A and phosgene (carbonyl dichloride)[(1)]. Before 2009, the Sanitation Standard of Food Utensils, Containers and Packages has not been amended, the inspection of PC-made products is in accordance with the items of the general requirement of plastics. BFDA has conducted the sanitation inspection for a total of 105 PC-made products including insulated cups, bottled water and mineral water containers and feeding bottles from 1987 to 1999[(8,29,30)]. The results indicated that all the samples complied with the standard limits as shown in Table 10. The regulation has been amened to set the migration limits of PC-made feeding bottles and PC-made products except feeding bottles in 2009 and 2010, respectively.

Bisphenol A is a raw material to make PC. Due to its estrogenic property, it is well known as an endocrine disruptor and may affect the reproductive and neural development of fetuses and infants[(31)]. In view of this, BFDA conducted a study on the residues of bisphenol A in feeding bottles and its migration test in 1999[(30)]. In addition to the testing method of bisphenol A being developed, the results showed that the residual amounts of bisphenol A in 30 feeding bottle samples were in the range of 0.7 ~ 70.2 ppm. One sample containing high residues of bisphenol A was selected to implement the migration test to assess its possible migration level into the solvents including water, 4% acetic acid, 20% ethanol and *n*-heptane. The result showed that no bisphenol A being found in *n*-heptane, the migration levels of the rest of 3 solvents were in the range of 1.14 ~ 1.71 ppb. The results may be related to its higher solubility in ethanol, and at high temperature, more bisphenol A will be migrated in water and 4% acetic acid. But they all met the migration limit of bisphenol A in feeding bottles, 30 ppb, set by the Department of Health in 2009. TFDA also inspected the safety status of 15 PC-made food containers including feeding bottles, sealed jars, preserving boxes and water bottles in 2010[(32)]. The results as also shown in Table 10 indicated that only 2 samples were found to contain residual bisphenol A at the level of 16.8 and 58.3 ppm, but no migration of bisphenol A were found in the migration test, which all met the migration limit of bisphenol A in PC-made products for food packaging set in 2010 as shown in Table 11. The above results suggest that PC-made food containers are found to have residual bisphenol A, but the level of its migration into food is very low. Hence, consumers don't need to be overly concerned about the safety of this kind of products.

PLASTICS WITH FORMALDEHYDE AS RAW MATERIALS FOR SYNTHESIS

Plastic tableware with colorful and bright gloss, the quality and touch feeling of porcelain and the property of not easily broken is mostly made from formaldehyde as raw materials for synthesis. This kind of material is classified into three groups: melamine resin, urea resin and phenol resin. They are hard and thermosetting plastic materials made from formaldehyde with melamine, urea or phenol under alkaline heating to form network structures of high molecular polymers, and if necessary, decorated with floral patterns laminated with print paper under pressure, and finally pressed a layer of glitter powder to make the surface bright and glossy[1]. If the hardening process is incomplete, it would cause roughness on the surface, develop bubbles and cracks, and result in detectable residues of formaldehyde, phenol or melamine.

Formaldehyde is a colorless, flammable gas at room temperature. It has a pungent, distinct odor and may cause a burning sensation to the eyes, nose, and lungs at high concentrations. Severe pain, vomiting, coma, and possible death can occur after drinking large amount of formaldehyde. Exposure to high levels of formaldehyde in air can cause nose cancer in aminals[33]. The IRAC has determined that formaldehyde is probably carcinogenic to humans[4]. Phenol is a colorless-to-white solid when pure. Commercial phenol is a liquid that evaporates more slowly than water. It has a distinct odor that is sickeningly sweet and tarry. Long-term exposure to high levels of phenol by inhalation can cause heart, kidney, liver and lung damage in animals[34]. Because there is no evidence that phenol causes cancer in humans, the IRAC determined that phenol is not classifiable as to its carcinogenicity to humans[4].

For sanitation management of this type of products, the migration limits of formaldehyde and phenol were all set to be negative. In addition, the Department of Health has announced the regulation of melamine for the melamine-made products in 2012. The migration limit of melamine was set at 2.5 ppm as shown in Table 12.

BFDA has conducted the sanitation inspection for a total of 194 formadehyde-made plastic products including plates, bowls, spoons and children's tableware in 1986 and 1997[12,35]. The results are shown in Table 13. Among these samples, 8 of them were found with lead or cadmium, whose levels failed to meet the standard limits, and 23 of them were found with illegal colorants, consumption of potassium permanganate, heavy metals, residues after evaporation or formaldehyde, which were not in line with the regulation. Further inspecting the surfaces of these non-conforming products, they were mostly rough, with bubbles or uneven floral patterns on the food-contact surfaces. In addition, the relationship between the migration temperature and the migration levels of formaldehyde was also investigated. It indicated that the higher the migration temperature, the more amounts of formaldehyde were migrated. It is suggested that consumers should avoid using this type of plastic products, especially those with rough or cracking surface, to contact hot foods.

In 2008, a melamine-tainted baby formula incident happened in China, which caused 6 infants dying from

Table 11. The regulation of PC-made products in the Sanitation Standard for Food Utensils, Containers and Packages

Item	Sanitation limit
Material test	
Lead	100 ppm
Cadmium	100 ppm
Migration test	
Water	
Residues after evaporation	30 ppm
Consumption of $KMnO_4$	10 ppm
Bisphenol A	30 ppb* or 0.6 ppm
4% Acetic acid	
Residues after evaporation	30 ppm
Heavy metals	1 ppm (as lead)
Bisphenol A	30 ppb* or 0.6 ppm

* 30 ppb is for feeding bottles.

Table 12. The regulation of plastics with formaldehyde as raw material for synthesis in the Sanitation Standard for Food Utensils, Containers and Packages

Item	Sanitation limit
Material test	
Lead	100 ppm
Cadmium	100 ppm
Migration test	
Water	
Phenol	Negative
Formaldehyde	Negative
4% Acetic acid	
Residues after evaporation	30 ppm
Melamine*	2.5 ppm

* Only for melamine-made products.

Table 13. The sanitation inspection results of plastics with formaldehyde as raw material for synthesis for food packaging in Taiwan

Year	Type of sample	No. of sample	No. of non-conforming sample		Ref.
			Material test	Migration test	
1986	Plates, bowls, spoons	112	8	18	34
1997	Children's tableware	82	0	5	12
2009	Melamine-made tableware	52	—[a]	1[b]	36

[a] Not implemented.
[b] Only for melamine analysis.

kidney stones and other kidney damage. The issue has raised concerns about food safety in Taiwan. Because melamine is used to produce the formaldehyde-melamine resin, BFDA conducted a study on its migration test of 52 melamine-made tableware in 2009(36). Except the testing method of melamine being developed, the results as also shown in Table 13 indicated only one sample were found to release melamine at a level of 4.8 ppm into 4% acetic acid, and those released from the rest of 51 samples were all less than 1.7 ppm. These findings were used as the basis for setting the migration limit of melamine of 2.5 ppm in 2012.

NONYLPHENOL ANALYSIS OF FOOD-CONTACT PLASTIC PRODUCTS

Nonylphenol, an industrial product, is widely used in cleaning agents as raw materials for the production of nonionic surfactants. It is also a stabilizer or a dispersant by direct addition to plastics and rubber, and as a raw material of tris(nonylphenol) phosphate (TNPP), which is an antioxidant for plastics and is synthesized by the reaction of nonylphenol and phosphorus trichloride(37). Nonylphenol with persistent toxicity and estrogenic properties has been regarded as an endocrine disruptor(38). There is a doubt that nonylphenol may be released from the residues or the hydrolysis of TNPP in the plastic products and migrated into contact with foods.

Today, there is no regulation for nonylphenol in plastic food packaging materials around the world. To understand the residual nonylphenol in food-contact plastic products, BFDA has developed the testing method of nonylphenol by high performance liquid chromatography and investigated the residual amounts of nonylphenol in a total of 35 samples which belong to 9 kinds of plastic materials in 2007(39). The results are shown in Table 14. Fifteen samples were found to contain nonylphenol at the levels of 0.6 ~ 2,002 ppm. Among them, PVC-made products contained higher residual amounts of nonylphenol. Five samples containing residual nonylphenol were selected to implement the migration test. The results are shown in Table 15. Except one PE-made sample found no nonylphenol migrated in the migration test, the other 4 samples, especially the PVC-made products, were found considerable amount of nonylphenol migrated into *n*-heptane, which was used to simulate oils and fatty foods. The migration percentages of nonylphenol from the 4 samples were in the range of 50 ~ 107% based on their residual amount in samples. It also indicated that the higher the residual nonylphenol in the product, the more nonylphenol were migrated from it.

For the evaluation of the human exposure to nonylphenol from the packacking material, the following estimation was used(40). If the PVC-made wrapping film sample No.15 in Table 15 was used for fatty foods, such as using 200 cm^2 of this sample to wrap a 100 g portion of cheese, and the portion may get 0.153 mg of nonylphenol. When this portion of cheese was eaten by a person with 60 kg by weight every day, it would correspond to the value of 0.0025 mg/kg bw/day. The no observable adverse effect level (NOAEL) of nonyphenol for reproductive toxicity in rats was 13 ~ 19 mg/kg bw/day(41), so this calculated value indicated the safety

Table 14. 2007 survey results of the residual levels of nonylphenol in plastic food containers and packages

Type of material	No. of sample	Residual level (ppm)
PE	12	ND[a] ~ 25.7 (7)[b]
PP	7	ND ~ 2.9 (2)
PS	4	ND ~ 3.4 (1)
PVC	3	78.4 ~ 2,022 (3)
PVDC	3	ND ~ 29.8 (1)
PET	2	ND ~ 0.8 (1)
PC	2	ND
PMMA[c]	1	ND
PMP[d]	1	ND

[a] Not detected, < 0.3 ppm.
[b] Number in parentheses represents the number of samples found to contain nonylphenol.
[c] Polymethylmethacrylate.
[d] Polymethyl pentene.

Table 15. The concentrations of nonylphenol migrated from plastic food utensil, container and package samples in the migration test

Migration solvent	Condition	Concentration (ng/mL)				
		No. 5[a] (PVC)	No. 11 (PVDC)	No. 15 (PVC)	No. 17 (PVC)	No. 23 (PE)
Water	60°C, 30 min	ND[b]	2.3	40.8	ND	ND
	95°C, 30 min	2.7	2.6	81.5	0.8	ND
4% Acetic acid	60°C, 30 min	0.6	3.0	76.5	0.6	ND
	95°C, 30 min	5.6	4.1	124.5	2.1	ND
20% Ethanol	60°C, 30 min	5.6	6.1	230.0	2.8	ND
n-Heptane	25°C, 60 min	233 (99)[c]	3.6 (71)	383.3 (50)	13.5 (107)	ND

[a] Sample number, and its material shown in parenthesis.
[b] Not detected, < 0.5 ng/mL.
[c] Value in parenthesis is the migration percentage, based on its residual level in the sample.

margin of about 5,200 ~ 7,600. The risk of the presence of nonylphenol in PVC-made products was low, but PVC-made products contain high contents of additives compared to other packing materials. Hence, consumers should avoid using PVC-made products to contact fatty foods to prevent excessive intake of undesirable substances.

CONCLUSIONS

In this report, the management and sanitation inspection for 7 common plastic food packaging materials by the authority in Taiwan were described. From the results of inspection for a total of 1,623 food-contact plastic products during 1983 to 2010, there were 99 and 52 samples not conforming to the regulation of the material test and the migration test, respectively. It also indicated that the failure rate of various kinds of products has decreased over years. For health considerations, consumers should not use those with printing-ink, rough or cracking surfaces, and PVC-made products, which may release endocrine disruptors such as phthalates and nonylphenol, to contact with high temperature or fatty foods. TFDA will continue make efforts to investigate and study the safety status of plastic food utensils, containers and packages in the market to secure the public health.

ACKNOWLEDGMENTS

The author is grateful to Mei-Hua Chang, Chieh-Yi Hsieh and Chun-Hsiung Chang for compiling information of sample inspection.

REFERENCES

1. The Pharmaceutical Society of Japan. 2000. Methods of Analysis in Health Science. pp. 575-619. Kanehara Co., Ltd., Tokyo, Japan.
2. Department of Health, Executive Yan, Taiwan, R.O.C. 2012. Sanitation Standard for Food Utensils, Containers and Packages. DOH Food No.1001303928.
3. Agency for Toxic Substances and Disease Registry. 2007. Toxicological profile for lead. U.S. Department of Health and Human Services, Public Health Service. Atlanta, GA.
4. International Agency for Research on Cancer. Agents classified by the IARC monographs, volumes 1-104. [http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf]
5. Agency for Toxic Substances and Disease Registry. 2008. Draft toxicological profile for cadmium. U.S. Department of Health and Human Services, Public Health Service. Atlanta, GA.
6. Loh, H. L., Lee, S. C. and Chou, S. S. 1987. Survey on the sanitary status of heat-resistance plastic bag for food containers. Ann. Rept. FDB Taiwan R.O.C. 5: 222-224.
7. Bai, M. J., Chu, H. and Cheng, C. C. *et al.* 1993. Investigation on the safety of plastic food containers for use in microwave ovens. J. Food Drug Anal. 1: 81-95.
8. Chang, M. H., Lin, S. J. and Su, L. C. *et al.* 1994. Sanitation status of bottled and mineral water packaging: a survey. J. Food Drug Anal. 2: 235-248.
9. Chang, M. H., Huang, C. T. and Su, L. C. *et al.* 1994. A survey on the sanitation status of polystyrene, polyethylene and polypropylene food utensils. Ann. Rept. NLFD Taiwan R.O.C. 12: 125.
10. Chang, M. H., Huang, C. T. and Cheng, C. C. *et al.* 1997. Safety evaluation of small plastic bottles for beverage. Ann. Rept. NLFD Taiwan R.O.C. 15: 143-148.
11. Kao, Y. M., Shy, R. J. and Jao, M. L. *et al*. 1998. Survey on the hygienic safety status of plastic materials used for steaming dumplings. Ann. Rept. NLFD Taiwan R.O.C. 16: 158-164.
12. Liao, M. I., Jao, M. L. and Huang, C. T. *et al.* 1999. Survey on sanitary status of children plastic table service food utensils. Ann. Rept. NLFD Taiwan R.O.C. 17: 332.
13. Thiele, U. K. 2001. The current status of catalysis and catalyst development for the industrial process of poly(ethylene terephthalate) polycondensation. Int. J. Polym. Mat. 50: 387-394.
14. International Agency for Research on Cancer. 1989. Antimony trioxide and antimony trisulfide. IARC monographs on the evaluation of carcinogenic risks to humans volume 47.
15. Tao, S. H. and Bolger, P. M. 1997. Hazard assessment of germanium supplements. Regul. Toxicol. Pharmacol. 25: 211-219.
16. Agency for Toxic Substances and Disease Registry. 2008. Toxicological profile for phenol. U.S. Department of Health and Human Services, Public Health Service. Atlanta, GA.
17. Lee, S. C., Loh, H. L. and Hua, I. J. 1984. Survey on sanitation status of polystyrene-made and paper-made products for food utensils. Ann. Rept. FDB Taiwan R.O.C. 4: 52-63.
18. Loh, H. L., Lin, S. W. and Lee, S. C. 1991. Survey on sanitation status of polystyrene cups, boxes and paper cups. Ann. Rept. NLFD Taiwan R.O.C. 9: 394-396.
19. Kao, Y. M., Jao, M. L. and Shy, R. J. *et al.* 1997. Survey on the hygienic safety status of polystyrene food containers for instant noodles. 1997 Res. Rept. NLFD Taiwan R.O.C.
20. Liao, M. I., Huang, C. T. and Cheng, C. C. *et al.* 2000. Survey on sanitary status of polystyrene paper and polystyrene food utensils. Ann. Rept. NLFD Taiwan R.O.C. 18: 143-152.
21. Agency for Toxic Substances and Disease Registry. 2006. Toxicological profile for vinyl chloride. U.S. Department of Health and Human Services, Public Health Service. Atlanta, GA.
22. Agency for Toxic Substances and Disease Registry. 2005. Toxicological profile for tin and tin compounds. U.S. Department of Health and Human Services, Public

Health Service. Atlanta, GA.

23. Loh, H. L., Lee, S. C. and Chou, S. S. 1988. Survey on residue of vinyl chloride monomer in polyvinylchloride-made products of lunch box. Ann. Rept. FDB Taiwan R.O.C. 6: 106-108.
24. Chu, H., Huang, C. T. and Bai, M. J. *et al.* 1993. Survey on safety status of polyvinyl chloride food containers. Ann. Rept. NLFD Taiwan R.O.C. 11: 246-256.
25. Chang, M. H., Liao, M. I. and Cheng, C. C. 1996. Survey on safety status of polyvinyl chloride food containers. Ann. Rept. NLFD Taiwan R.O.C. 14: 274-279.
26. Agency for Toxic Substances and Disease Registry. 2002. Toxicological profile for di(2-ethylhexyl)phthalate. U.S. Department of Health and Human Services, Public Health Service. Atlanta, GA.
27. Kao, Y. M., Wang, C. W. and Cheng, C. C. *et al.* 2002. Study on the analytical method of phthalate esters plasticizers in polyvinylchloride wrapping films. Ann. Rept. NLFD Taiwan R.O.C. 20: 349.
28. Kao, Y. M., Yang, Y. J. and Cheng, C. C. *et al.* 2004. Studies on the analysis of phthalate esters plasticizers in polyvinylchloride-made food utensils, containers and packages. Ann. Rept. BFDA Taiwan R.O.C. 22: 339.
29. Huang, C. T. and Lee, S. C. 1989. Survey on the sanitary status of thermos cup. Ann. Rept. NLFD Taiwan R.O.C. 7: 233-235.
30. Kao, Y. M., Liao, M. I. and Huang, C. T. *et al.* 2001. Studies on the residue and migration of bisphenol A from polycarbonate baby bottles and investigation on their hygienic and safety status. Ann. Rept. NLFD Taiwan R.O.C. 19: 322.
31. Krishnan, A. V., Stathis, P. and Permuth, S. F. *et al.* 1993. Bisphenol-A: an estrogenic substance is released from polycarbonate flasks during autoclaving. Endocrinology 132: 2279-2286.
32. Chang, M. H., Yan, W. L. and Tsou, C. S. *et al.* 2011. Survey of endocrine disruptor bisphenol A leaching from food utensils, containers and packages. Ann. Rept. Food Drug Res. 2: 192-200.
33. Agency for Toxic Substances and Disease Registry. 1999. Toxicological profile for formaldehyde. U.S. Department of Health and Human Services, Public Health Service. Atlanta, GA.
34. Agency for Toxic Substances and Disease Registry. 2008. Toxicological profile for phenol. U.S. Department of Health and Human Services, Public Health Service. Atlanta, GA.
35. Loh, H. L., Lee, S. C. and Chou, S. S. 1989. Survey on sanitation status of formaldehyde-made table service food utensils. Ann. Rept. NLFD Taiwan R.O.C. 7: 82-88.
36. Chang, M. H., Yan, W. L. and Kao, Y. M. *et al.* 2010. Studies on the migration of melamine from melamine tablewares. Ann. Rept. Food Drug Res. 1: 77-86.
37. Vazquez-Duhalt, R., Marquez-Rocha, F. and Ponce, E. *et al.* 2005. Nonylphenol, an integrated vision of a pollutant. Appl. Ecol. Environ. Res. 4: 1-25.
38. White, R., Jobling, S. and Hoare, S. A. *et al.* 1994. Environmentally persistent alkylphenolic compounds are estrogenic. Endocrinology 135: 175-182.
39. Chang, M. H., Lee, H. C. and Yan, W. L. *et al.* 2007. Determination of nonylphenol from plastic food utensils, containers and packages. 2007 Res. Rept. BFDA Taiwan R.O.C.
40. Votavova, L., Dobias, J. and Voldrich, M. *et al.* 2009. Migration of nonylphenols from polymer packaging materials into food simulants. Czech J. Food Sci. 27: 293-299.
41. U.S. Environmental Protection Agency. 2009. Screening-level hazard characterization: alkylphenols category. Hazard Characterization Document.