

Guideline for manufacturers on reduction of plasticizers in food

October 2011

I. Introduction

1. Phthalic acid esters (PAEs) are common plasticizers with good dispersibility and adhesiveness, which can increase the ductility and softness of polymer materials. Thus, they are widely used in plastic products. However, studies have shown that some PAEs interfere with the endocrine system of animals, resulting in reproductive, developmental and behavioral abnormalities. Long-term accumulation of them may affect health.
2. The small amount of plasticizer in food is usually caused by environmental contamination of raw materials or migrating from plastic materials such as equipment, container or packaging, but not by additives used in the manufacturing.
3. The management of this kind of contamination should focus on prevention rather than post-treatment. Control measures should be targeted at the current situation and the source of pollution while food manufacturers play a crucial role in maintaining food safety.

II. Purpose

This guideline is intended to provide the manufacturers with monitoring indicators and standards for the prevention of plasticizer contamination and improvement of quality control, so as to fulfill the spirit of independent management, ensure food safety and boost development of industry.

III. Foreign regulatory status

1. The treatment principle of Codex Alimentarius Commission (Codex) for the detection of contaminated substances in food is to compare the content of pollutants with the normal background value in the environment or food. If there is a high risk to public health that is confirmed by scientific assessment, the appropriate measures will be designed based on the assessment results, including:
 - a. Take control measures (e.g. recall of contaminated food, improvement of processing and storage conditions, etc.)
 - b. Consider the need for limitation of the quantity.
 - c. Dietary recommendations must be given when measures are not

sufficient enough to eliminate the health hazards of the pollutant.

2. In the Directive 2007/19/EC, published on 30 March 2007 by the European Union, the specific migration limits (SML) for six plasticizers, including DEHP, are set for all plastic food packaging, kitchen utensils, tableware, machinery and equipment used to make food.
3. Japan has banned the use of PVC gloves for food processing and the contact of PVC products containing DEHP with fatty food, while the DEHP content of plastic food packaging should be less than 0.1%
4. The FDA regulated that DEHP can be used as a plasticizer only for the packaging materials of high-moisture food in the United States because high fat food is more likely to lead to the dissolution of plasticizer.

IV. Domestic regulatory status

1. If plasticizer is confirmed to be added in food on purpose, it is in violation of Subparagraph 3, Paragraph 1, Article 11 of the Act Governing Food Safety and Sanitation, which regulates that foods or food additives that are toxic or harmful to human health shall not be manufactured, processed, prepared, packaged, transported, stored, sold, imported, exported, presented as a gift or publicly displayed.
2. According to Article 10 of the Act Governing Food Safety and Sanitation, the Sanitation Standard for Food Utensils, Containers and Packages is set. For the plasticizers DEHP and DBP, with n-Heptane as the solvent, and under the dissolution test conditions of 25 ° C for 1 hour, there are 1.5 ppm and 0.3 ppm dissolution limits respectively. The standards are the same as the EU and will be revised according to the domestic and international regulatory status. All plastic equipment, utensils, containers and packaging materials that are in direct contact with food should meet the above sanitary standards
3. According to Section 3 and Section 8 of the Food Good Hygienic Practices, “Good Hygienic Practices of Food Manufacturers” and “Food manufacturers process and quality control”, the food manufacturing process plan shall comply with the safety and hygiene principles to avoid food contamination. The equipment, utensils and containers used in the manufacturing process should be protected from food contamination during operation, use and maintenance.

V. Tolerable Daily Intake (TDI)

The tolerable daily intake (TDI) of the plasticizers announced by the FDA is shown in Table 1.

Notes: Tolerable daily intake (TDI) refers to the daily amount of an inedible pollutant that has been assessed safe for human being during the whole lifetime, expressed in mg/kg body weight/day.

VI. Background values of plasticizers in food

The FDA has compiled the monitoring results for the plasticizer content in general foods, as shown in the Table 2.

VII. Index value of plasticizer for enterprises monitoring

According to the tolerable daily intake (TDI) and background value of plasticizer in food, the Ministry of Health and Welfare proposes that enterprises monitor the index value of plasticizer, as shown in Table 3.

VIII. Enterprise monitoring measures

1. Food equipment, containers and packaging materials:

For plastic equipment, utensils, containers and packaging materials that are in direct contact with food, it should be confirmed that they meet the hygienic standards and have relevant certificates for reference. Factors such as the risk of plasticizer dissolution caused by long-term use or storage shall be taken into consideration in the determination of the useful life of plastic material equipment, utensils and containers. The appropriate frequency of maintenance or replacement shall be set while the alternative materials shall be taken into account.

2. Producers/suppliers of food materials, food additives and other sources shall first carry out plasticizer assessment tests, and set quality control indicators according to the independent assessment results for different products (i.e. the range of normal plasticizer content for raw materials or additives). The frequency and quality control index values of such assessments shall be kept for reference by downstream companies or health authorities for confirmation and examination.

3. When purchasing food materials, food additives, semi-finished products and finished products, the food manufacturer may require the supplier to provide information such as quality control index values to prove that there is no contamination except for normal background

value, which shall serve as the basis for the acceptance of the products. Relevant certificates shall be retained for reference.

4. The food company shall independently manage the manufacture, processing, distribution, packaging, transportation, storage, sale, import or export of food products to avoid the possibility of indirect contamination of food products due to the dissolution of plasticizer, and shall confirm that the products produced or sold are in accordance with the relevant food monitoring indicators in this guideline.
5. The food companies shall formulate control measures to prevent plasticizer from being added in the products on purpose.

IX. Exception handling

1. If the content of plasticizer in processed food exceeds the monitoring index indicated in this guideline, the company shall take the following exception handling procedures immediately.
 - a. Check the scope and quantity of abnormal products and control the delivery/sale of abnormal products. When necessary, recall the products.
 - b. Examine the raw materials and manufacturing process of the abnormal products thoroughly to clarify the possible contamination causes.
 - c. Propose improvement plan for pollution cause and carry out test to confirm that the plan is able to eliminate abnormality or to make the plasticizer content lower than the monitoring target index.
 - d. Keep a complete record of the exception handling process for reference.
 - e. Review and tighten up the sampling inspection of quality control.
2. Inform the health authorities: When the content of plasticizer in processed food exceeds the monitoring indicators ruled in this guideline, in addition to the exception handling measures mentioned in the previous chapter, the company shall notify the local health authority and the Ministry of Health and Welfare immediately. After the whole process ends, the comprehensive report shall be submitted to the health authorities for future reference.
 - a. For products with TDI that is more than 100 g (mL), the amount of plasticizer detected is more than 50% of TDI; or

- b. For products with TDI that is less than 100 g (mL), the amount of plasticizer detected is more than 10% of TDI.
3. If the manufacturer finds that the plasticizer content in food, food ingredients or food additives is abnormally high or seems to be added on purpose, in addition to the abnormal notification mentioned in the previous paragraph, a recall plan shall be proposed and carried out immediately. Only after the health authorities confirm that the product is harmless can it be sold again.
4. The health authorities shall make a list of the abnormal notification for control and check purpose and release news to remind the public when necessary.

X. Conclusion

For food that may be contaminated by plasticizer, the Ministry of Health and Welfare not only includes content of plasticizer in the routine inspection and implement the monitoring plan on background value of food but also continues to modify the regulations on the specifications, health standards of plastic food packaging and food containers in order to reduce the chance of contamination.

At the same time, it is expected that domestic companies can take the social responsibility of keeping food hygienic and safe and reduce the content of plasticizer in food by managing, assessing materials, manufacturing processes, possible pollution channels and formulating quality improvement plans. Through efforts of the public and private sectors, the food safety of the people can be protected.

Table 1-Tolerable Daily Intake (TDI)

Plasticizer		Tolerable daily intake (mg/kg bw/day)
Chinese name	English name (Abbreviation)	
鄰苯二甲酸二(2-乙基己基)酯	Di(2-ethylhexyl)phthalate (DEHP)	0.05
鄰苯二甲酸二丁酯	Di-n-butyl phthalate (DBP)	0.01
鄰苯二甲酸二異壬酯	Di-isononyl phthalate (DINP)	0.15
鄰苯二甲酸二異癸酯	Di-isodecyl phthalate (DIDP)	0.15
鄰苯二甲酸丁基苯甲酯	Benzyl butyl phthalate (BBP)	0.5

Table 2- Background values of plasticizers in food

Product type	Total number of samples	Plasticizer type	Test result (Screen level : 1 ppm)	Number of samples	Percentile of detected result (Screen level : 1 ppm)(ppm)	
					90th percentile	98th percentile
Juice, tea, sports drink	307	DEHP	Not detected	307	<1	<1
		DINP	Not detected	307	<1	<1
		DBP	Not detected	307	<1	<1
Jam, fruit preserves, jelly (Desserts)	74	DEHP	Not detected	73	<1	<1
			Detected	1		
		DINP	Not detected	72	<1	<1
			Detected	2		
		DBP	Not detected	74	<1	<1
			Detected			
Products in form of capsule, ingot or powder	417	DEHP	Not detected	362	2.5-3.5	11.5-12.5
			Detected	55		
		DINP	Not detected	406	<1	2.5-3.5
			Detected	11		
		DBP	Not detected	408	<1	1.5-2.5
			Detected	9		
High fat food (oil, cream, etc.)	38	DEHP	Not detected	35	<1	7.5-8.5
			Detected	3		
		DINP	Not detected	38	<1	<1
		DBP	Not detected	38	<1	<1
Rice, flour products	76	DEHP	Not detected	69	<1	1.5-2.5

(Cookies, instant noodles)			Detected	7		
		DINP	Not detected	72	<1	3.5-4.5
			Detected	4		
		DBP	Not detected	76	<1	<1
Food for infant and young child	16	DEHP	Not detected	16	<1	<1
		DINP	Not detected	16	<1	<1
		DBP	Not detected	16	<1	<1
Dairy products	63	DEHP	Not detected	63	<1	<1
		DINP	Not detected	63	<1	<1
		DBP	Not detected	63	<1	<1

※Sources: Division of Research and Analysis, Food and Drug Administration,
Executive Yuan.

※Screen level: 1 ppm.

Table 3- Index value of plasticizer for enterprises monitoring

(Unit: ppm)

Food type \ Plasticizer		DEHP	DBP	DINP	BBP	DIDP
Beverage		1	0.5	3	10	3
Food for infant and young child	Infant formula	0.5	0.1	1.5	5	1.5
	Follow-up infant formula and complementary foods for infant	0.5	0.1	1.5	5	1.5
	Probiotics powder	1	0.2	3	10	3
	Vitamin	1	0.2	3	10	3
Capsule and ingot food		5	0.6	9	30	9
Oils		3	0.6	9	30	9
Staple food	Rice, flour products	1	0.3	3	10	3
Desserts and other processed food		3	1	9	30	9

Notes:

1. For the food categories not listed in this table, there is no recommended index value currently. However, food businesses shall implement self-management and set quality control indicators according to the management principles mentioned in Chapter 8 of this guideline to strengthen the prevention of plasticizer contamination.
2. The scope of foods in this table is as follows.
 - 1) Beverage: Products to drink, which are mainly made of water.
 - 2) Food for infant and young child: Food for children under 3 years old.
 - 3) Capsule and ingot food: All foods that are in the form of capsule and ingot.
 - 4) Oils: Vegetable and animal oils, butter that are mainly consisted of fats.
 - 5) Staple food: Rice and flour products.
 - 6) Desserts and other processed food: Processed food that contains Jam, fruit preserves or jelly.

Appendix 1- PAEs restrictions and SML standards specified in the EU Directive 2007/19/EC

PAEs	Restrictions	Maximum use level in plastic materials	SML (mg/kg)
DEHP	Plasticizer used in reusing materials in contact with non-fatty foods	0.1%	1.5
DBP		0.05%	0.3
BBzP	1. Plasticizer used in reusing materials. 2. Plasticizer in single-use materials and articles contacting non-fatty foods except for infant and follow-up infant formula as defined by Directive 91/321/EEC and cereal based foods for infant and young child according to Directive 96/5/EC.	0.1%	30
DINP		0.1%	9
DIDP		0.1%	9
DNOP+DNDP	-	-	5