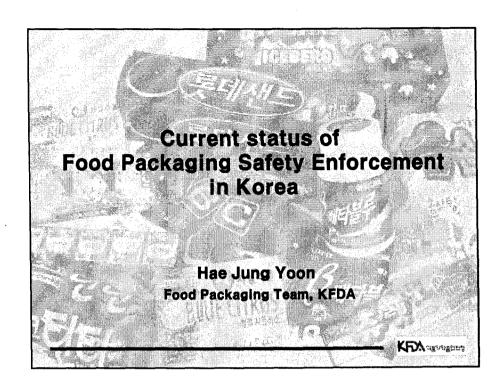
## Current Trends in Safety Supervision for Domestic Food Container Materials "국내 식품용기 포장재의 안전관리현황"

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#### KOREA FOOD AND DRUG ADMINISTRATION

#### 1996 April

The Korea Food and Drug Safety Headquarter was inaugurated.

- Containers and Package Division was made a new start

#### 1998 February

The Korea Food and Drug Safety Headquarter was raised to the status of administration (Korea Food and Drug Administration)

#### Vision in Food area

- Promoting public health by ensuing food safety
- Strengthening food law enforcements
- Promoting participation and improving public services



Set in A7 Countries Standards

KFX agreement

#### **Promulgation of the Food Sanitation Act**

#### 1962 Jan Law -1007

- Established the Food Sanitation Act
- Granted the responsibility on establishing food packaging standards

#### 1968 July Ordinance - 249

Announced the first 4 food packaging standards

- Plastics, Metals, Ceramics & Feeding apparatus

KFDA = good grows

#### Chapter I. General Provisions

Article 1.Purpose

The purpose of this Act is to contribute to the improvement of national health by preventing sanitary dangers and harm caused by food and improving the quality of food nutrition.

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#### **FOOD SANITATION ACT**

#### Chapter I. General Provisions

#### Article 2. Definitions

- 4. the term "apparatus" means utensils, such as tableware, cookware, etc., and machines, implements and other things used for collecting, manufacturing, processing, preparing, storing, transporting, displaying, delivering or taking food or food additives, which come in contact directly with food or food additives, excluding such machines, implements and other things used for collecting food in agriculture and fishery
- 5. the term "containers and packages" means articles which are used for containing or packaging food or food additives, and offered with them at the time of their delivery

KEDA PARTEREZES

#### Chapter III. Apparatus, Containers and Packages

Article 8. Prohibition of Sale and Use of Poisonous Apparatus, etc

The apparatus, containers or packages which contain or are stained with poisonous and detrimental materials, and may thereby injure the health of the human body, or which are in contact with food or food additives and exert influence on them so that they might injure the health of the human body, shall not be sold, or manufactured, imported, stored, transported or displayed for the purpose of sale, or used for business.

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#### **FOOD SANITATION ACT**

#### Chapter III. Apparatus. Containers and Packages

#### Article 9. Criteria and Standards

With respect to those the criteria and standards of which are not notified publicly under paragraph ①, the Administrator of the Korea Food and Drug Administration may have manufacturers and processors thereof present the criteria for the manufacturing method of such apparatus, containers and packages, and the standards for such apparatus, containers and packages and raw materials thereof, and for a limited time recognize the criteria and standards for such apparatus, containers and packages and raw materials, through an examination of the food sanitation inspection agency designated under Article 18.

KDA DERESES

#### Chapter IV. Labels

#### Article 10. Criteria for Labels

- ① The Administrator of the Korea Food and Drug Administration may, if deemed especially necessary for the national health, determine and publicly notify the criteria necessary for labels of food or food additives for sale and those of apparatus, containers and packages whose criteria and standards are determined under Article 9 ①
- ② Food, etc. for which criteria for labeling are determined under paragraph ①, shall not be sold, displayed or transported for the purpose of sale, or used for business without labels as conforming with such criteria.

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#### **FOOD SANITATION ACT**

#### Chapter VI. Inspection, etc

#### Article 19. Obligation of Self-Quality Inspection

① Any person who carries on the business of manufacturing or processing food, etc., shall inspect whether or not his manufactured or processed food, etc., conforms to the criteria and standards as prescribed in Article 7 ① and ② or 9 ① and ② under the conditions as prescribed by the Ordinance of the Ministry of Health and Welfare.

KDA PERFECTS

#### Chapter VII. Business

#### Article 21. Criteria for Facilities

- ① Any person who intends to operate the following businesses, shall provide facilities suitable for such criteria as prescribed by the Ordinance of the Ministry of Health and Welfare
  - 2. Business of manufacturing apparatus, containers or packages

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#### **FOOD SANITATION ACT**

#### Chapter III. Apparatus. Containers and Packages

#### Article 9. Criteria and Standards

① If it is deemed necessary for national health, the Administrator of the Korea
Food and Drug Administration may determine and notify publicly the criteria
for the manufacturing method of apparatus, containers and packages as
designed to sell, or used for business, and the standards for such apparatus,
containers and packages and raw materials thereof.

#### → Korea Food Code

6. Criteria and Standards for apparatus, Containers and Packages

KFX = B P B C C T

#### **FOOD CODE**

#### 6. Standards and Specifications for apparatus, containers and packages

#### 1. General Standards

- Article 1. Prohibit the shapes that may lead to food contamination physically and chemically
- Article 2 Exclude Non-volatile extractives from criteria of packaging materials
- **Article 3** Prohibit the soldering in manufacturing and repairing
- **Article 4** Electrode is limited to Fe, Al, Pt, Ti and stainless
- Article 5 Hygienic treatment of packaging materials made of copper on the side directly contacted with food
- **Article 5** Use only the colorants permitted in Food Sanitation Act
- Article 7 Prohibit printing on the side directly contacted with food
- Article 8 Prohibit the use of DEHP in all food packaging articles
- **Article 9** Prohibit the use of DEHA in wrap, feeding milk bottles

KEN APPRECIA

#### FOOD CODE - 6. Criteria and standards for apparatus, containers and packages 2. Criteria for Individual Packaging Materials Potvarvisulfon(PASF) Polychylchlorida(PVC) Polyethylene(PF), Polypropylene(PP) polyarylate(PAR) 23 Hydroxybutylpolyester(HBP) Polystyrene(PS) Polychlorovinylidene(PVDC) 24 Polyacrylonitrile(PAN) Polyethyleneterephthalate(PET) Fluoro resins(FR) **Plastics** Phenoiformaldehyde(PF) Polyphenyleneether(PPE) 26 Ethylenevinylacetate(EVA) 1-7. Melamineformaldehyde (MF) 28. 1) Definition 29 30 Polyethylenenaphthalate(PEN) Melamineformaldehyde resins are manufactured

by the condensation of melamine and formaldehyde.

- 2) Criteria for Material (mg/kg)
- (1) Lead and Cadmium: below 100, respectively
- 3) Criteria for Migration (mg/l)
- (1) Heavy Metal: below 1.0 as lead
- (2) Non-volatile Extractives : below 30
- (3) Formaldehyde: below 4.0
- (4) Phenol: below 30
- (5) Melamine : below 30

- Methylmothaetylate-acrylesatrile-butadiene-styrene(MABS)
- Silicone

- polyetherimide 33
- Polyphenylensulfide(PPS) polyethersulfone(PES)
- Polycyclohegane-L4-dimethylterphthalate(PCT) 36
  - Ethylenevinylalcohol(EVOH)
- Polylmide(PI) Polyetheretherketon(PEEK)
- Polylactide(PLA)
- Polybutylenesuccinate-co-adipate(PBSA)

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#### **FOOD CODE**

- 6. Standards and Specifications for apparatus, containers and packages

#### 3. Test Methods

#### Material Tost vs. Migration Tost

#### ex) Migration Test Conditions

✓ Simulants according to various food types

Food T	vpes	Simulants	
	According to the con-		
Fatt		n-Heptane	
Table Seam State was 1915 of		valvani talvaniy planeti ili 1999-94	
Alcoho	olic	20% Ethanol	
Kingadi Milijad Mahabah Miliy		Sylvation (Association)	
	< pH 5	4% Acetic acid	
Others	aana iso <mark>- maana san</mark>	Andrew Commence of the Commenc	
	> pH 5	Distilled Water	

✓ Test Cell



- ✓ Test conditions
  - 25°C, 60min for n-heptane
  - 60°C, 30min for other simulants
  - > Especially, 95°C, 30min for materials used at 100°C above

KEN ARRESTER

#### **FOOD CODE**

6. Standards and Specifications for apparatus, containers and packages

#### Chemical Substances Restricted in Food Packaging Materials

- Heavy Metal
- **Raw Materials**
- **Additives and Byproducts**

- Lead
- Vinyl chloride
- DEHP

- Cadmium
- Styrene
- DEHA

- Antimony
- Phenol

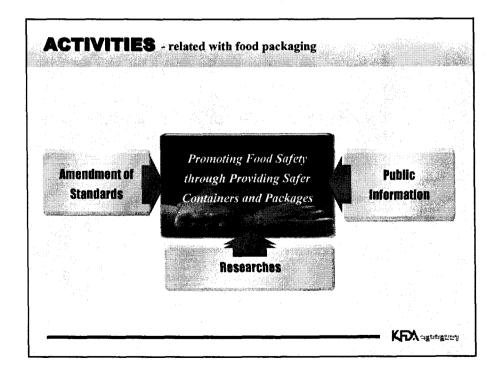
- Arsenic
- **PCBs**
- √ Formaldehyde

- Melamine
- Fluorescence Whitening Agent
- Methylmethacrylate
- Toluene
- Caprolactam
- Bisphenol-A
- Isocyanate
- Acrylonitrile
- BADGE, BFDGE

### Provisional Approval of Standards and Specification

In case of packaging materials not covered by the regulations, manufacturers must obtain pre-market approval from KFDA. A submission to KFDA must be include the name and contact information for the manufacturer of the material, the product name, identification of the chemical name for the product, a description of its manufacturing process and its intended use, material and migration specification, and test methods that are use to ensure compliance with these specifications.

KDX DEPOSED TO



#### Recent Amendments of Food Packaging Standards

#### √ KFDA Draft Notice 2007 (2007.3.13)

Establishing Analytical methods on dibutyltin compounds &tricresyl phosphate

#### ✓ KFDA Notification 2007-12(2007.2.28)

Establishing migration ML for Epichlorohydrin (0.5 ppm) in Hexane from Epoxy resin

#### ✓ KFDA Draft Notice 2007-17 (2007.1.29)

Prohibiting use of DBP(dibutylphthalate) & BBP(Benzylbutylphthalate) in Baby feeding bottle

#### ✓ KFDA Notification 2006-35 (2006. 8.29)

Revising analytical method for acrylonitrile

#### √ KFDA Notification 2005-73(2005.12.29)

Establishing PBA specification & revising analytical method for glass wares, ceramics wares, enamel wares and potteries

KFDA GENERALITA

#### Researches

#### On going or Planned

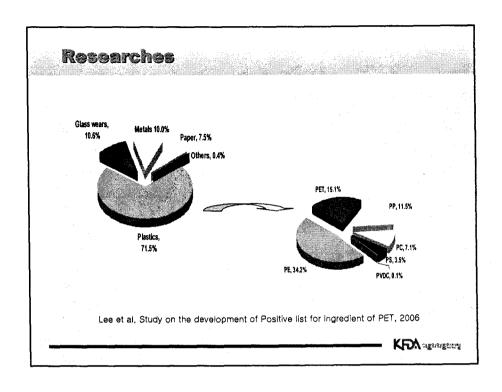
- ✓ Monitoring 4,4-MDA residues from cooking utensils ('07)
- ✓ Monitoring hazardous metal residues from glass wares, ceramic wares and potteries ('07)
- ✓ Monitoring possible hazardous residues originated from polymerization reaction of plastics
- ✓ Building food contact substances database on mostly commercial used plastics in food packaging

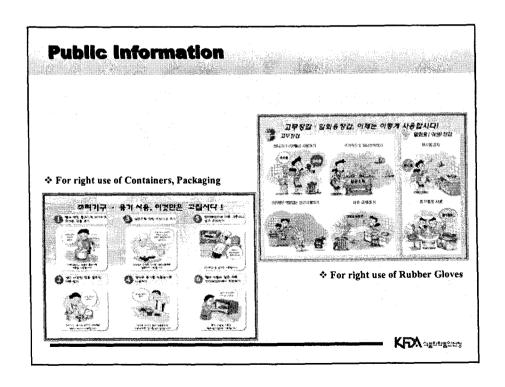
#### ~ 2006

- ✓ Monitoring ITX residues from printed carton in current Korean Market
- ✓ Monitoring PFOA/PFOS residues from cooking utensils
- ✓ Monitoring chemicals classified as Endocrine Disruptors from food packaging
- ✓ Building information on mostly commercial used plastics PET, PVC
- ✓ Developing Risk assessment methodology for food contact substances

References are found in www.kfda.go.kr

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#### विधानिस्य भवस्थ्यव्यक्ताणव्य

- International harmonization of Food Packaging Standards
  - Prior pre-market approval of the food contact articles, build information of food contact substances on most commercially used plastics
  - Continuously update and revise analytical methods
- Assessment of the chemical exposure from food packaging materials
  - Assess the actual state consumption of the hazardous food contact substances
  - Develop Risk assessment methodology for food contact substances
- Induction Effort of autonomous quality controls by manufactures
  - minimizing migrations of hazardous residues from food contact surface

KFDA SHEERINGS

KDA SECUREUR

