Food Contact in South Korea
(and comparison with Japan)

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DECERNIS

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PRODUCTS:
- Reference
- Formulation Compliance Analysis
  - Red light/Green Light
- Certification Letter Automation
- Questionnaire Automation

16 May 2013
Pira Food Contact Barcelona
Presentation Plan

• Governmental Structure
• Statutary Structure
• Details
• New and Exciting!!
• Comparison: Korea vs. Japan
Governmental Responsibilities

- The **Ministry of Health & Welfare** → Pharmaceutical & Food Policy Division → Health Policy Bureau is responsible for promulgation and revision of the Food Sanitation Act.

- **Korea Food and Drug Administration (KFDA)** is responsible for enforcement and implementation of the Food Sanitation Act and establishing specific standards and specifications for food and food additives.

- The **Food Safety Bureau of KFDA** is responsible for, undertaking monitoring and surveillance for illegal and adulterated food and supervising import food control, including food packaging.

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Korea

**Governmental Responsibilities (2)**

- The **Food Safety Evaluation Department** within KFDA is responsible for the evaluation of microbiological and chemical contamination of foods.

- The **Containers and Package Team** in the Food Safety Evaluation Department is responsible for apparatus, containers and packages i.e. food contact.

- There are also **six regional KFDA offices** responsible for inspection, implementation and investigation of food manufacturing facilities and other related facilities (Busan, Daegul, Daejeon, Gwangju Gyeongin and Seoul).
Korea

• Governmental Responsibilities (3)
  – The **National Institute of Food & Drug Safety Evaluation** created 1 May 2009
    – Risk assessment organization for KFDA
    – Provides scientific risk evaluation for food, food supplement and other regulated products
  – **National Food Safety Information Service** created 14 July 2009
    – Risk communication organization
    – Provides food safety information in English
Relationships

KFDA

Inquiry

Notice

NIFDS

Inquiry

Report

Local authorities
(Provinces, Counties, Cities etc.)

Response to the inquiries from public or industries

Legal actions against violation

-Risk assessment
-Research
Korea

Legal System

- Framework Act on Food Safety
- Food Sanitation Act
- Food Code
  - **KFDA Rule**: Standards & Specifications for Food Utensils, Containers & Packaging
  - **Enforcement Rule of FSA**
Relevant chapters for food contact:

- Chapter I Definitions for “Apparatus” and for “Containers and Packages.”
- Chapter III – Apparatus, Containers and Packages
- Chapter V Korean Food Code
- Chapter VI Inspection Requirements
Art. 2 (Definitions)

“Apparatus” means machines or utensils which come into direct contact with foods or food additives, or other goods.

“Containers and Packages.” means goods used for packing or wrapping foods or food additives, which are delivered with foods and food additives.
Article 19

Reporting on Imports 
Inspections

→ Enforcement Rule of FSA, 1986

• FCS not controlled by premarket system such as Positive List
• Domestic Goods required to be tested
• Imports: Inspections of finished products
Requirements for imported food contact articles

1. Submission
2. Inspection
3. Compliance with Food Code:
   - Certification by KFDA → Import
4. Non-compliance with Food Code:
   - Notification of the violation → Destruction or Turn-back

Source: Gangneung-Wonju National University, Korea
Chapter 7 (21 pages)

Standards & Specifications for Equipment, Containers and Packages

- Prohibitions and restrictions for food contact
- Material specifications for food contact substances
- Establishes General Standards and Material Specifications for apparatus, containers and packages
- Similar to KFDA Rule: Specifications and Standards except lists 41 substances.
Chapter 7  (21 pages)

1. General Standard
2. Common Manufacturing Standards
3. Standards for End Use
4. Specification for Materials (41)
5. Test Methods
<table>
<thead>
<tr>
<th>Type of plastic Details</th>
<th>PVC</th>
<th>PE /PP</th>
<th>PS</th>
<th>PVDC</th>
<th>PET</th>
<th>PF</th>
<th>MF</th>
<th>UF</th>
<th>POM</th>
<th>Acrylic Resin</th>
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<td>(19) Melamine</td>
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<td>(20) Methylmethacrylate</td>
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</table>

16 MAY 2013  
Source: Gangneung-Wonju National University, Korea
Material Specifications

Summary

• Specifications do not generally identify substances which can be used

• Instead identify End Tests which must be performed

• Tests include:
  - Heavy metal limits
  - Total residue after evaporation under specified migration conditions
  - Residue limits from specified materials
1. General Standards:

- **Rules**
  - **Colorants** = only KFDA approved food additives
  - **Printing Inks** must be completely dried after printing. No printing on FC surface.

- **Prohibitions**
  - **DEHP** not allowed in utensils, containers and packaging.
  - **DEHA** not permitted in cling wraps.
  - **DBP/BBP/BPA** not permitted in feeding bottles (including nipples).

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KFDA RULE: Standards and Specifications for Utensils, Containers and Packaging for Food Products, October 2011

2. Material-Specific Standards:

- **Plastics**
- Cellophane, regenerated cellulose
- Rubber
- Paper and paper board
- Metals (including metal cans)
- Wood
- Glass, ceramics, enamels and pottery
- Starch
KFDA Approved Plastics:

1-1 Poly(vinyl chloride)(PVC)
1-2 Polyethylene(PE) and Polypropylene(PP)
1-3 Polystyrene(PS)
1-4 Poly(vinylidene chloride)(PVDC)
1-5 Poly(ethyleneterephthalate)(PET)
1-6 Phenol-formaldehyde resin(PF)
1-7 Melamine-formaldehyde resin(MF)
1-8 Urea-formaldehyde resin(UF)
1-9 Polyacetal(polyoxymethylene(POM))
1-10 Acrylic Resin
1-11 Polyamide(PA)
1-12 Polymethylpentene(PMP)
1-13 Polycarbonate(PC)
KFDA Approved Plastics:

1-14 Poly(vinylalcohol) (PVA)
1-15 Polyurethane (PU)
1-16 Polybutene-1 (PB-1)
1-17 Acrylonitrile-butadiene-styrene copolymer (ABS) and Acrylonitrile-styrene copolymer (AS)
1-18 Polymethacryl styrene (MS)
1-19 Poly(butylene terephthalate) (PBT)
1-20 Polyyarylsulfone (PASF)
1-21 Polyarylate (PAR)
1-22 Hydroxybutyl polyester (HBP)
1-23 Polyacrylonitrile (PAN)
1-24 Fluorocarbon resin (FR)
1-25 Poly(phenylene ether) (PPE)
1-26 Ionomer resin
Korea

KFDA Approved Plastics:

1-27 Ethylene-vinylacetate copolymer (EVA)
1-28 Methylmethacrylate-acrylonitrile-butadiene-styrene copolymer (MABS)
1-29 Poly(ethylenenaphthalate) (PEN)
1-30 Epoxy Resin
1-31 Poly(phenylenesulfide) (PPS)
1-32 Poly(ethersulfone) (PES)
1-33 Poly(cyclohexane-1,4-dimethylene terephthalate) (PCT)
1-34 Polyimide (PI)
1-35 Polyetheretherketone (PEEK)
1-36 Polylactide (poly(lactic acid), PLA)
1-37 Butylenesuccinate-adipate copolymer (PBSA)
1-38 Cross-linked polyester resin
• On 23 March 2013, New president Park Geun-Hye announced the passage of a contentious “Government Restructure Bill”.

<table>
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<tr>
<th>OLD</th>
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<td>Ministry for Food, Agriculture, Forestry and Fisheries</td>
<td>Ministry of Agriculture, Food and Rural Affairs (MAFRA)</td>
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<tr>
<td>Korea Food and Drug Administration (KFDA)</td>
<td>Ministry of Food and Drug Safety (MFDS)</td>
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</table>
Recent Changes

- MFDS Reorganization – 25 Mar 2013
  - Expected to be “Control Tower” for Food Safety
  - “Modern Means of Management”
  - No longer sub-Agency of Ministry of Health and Welfare
  - Upgraded from an Agency to Ministry
  - Many new responsibilities transferred from e.g., Ministry of Agriculture to MFDS
  - Regional Food and Drug Administration – intact
  - National Institute of Food and Drug Safety Evaluation (NIFDS) = more staff.
Recent Changes

“Modern Means of Management” (Cont.)

• Separation of Duties:
  - **MFDS:** Policy making and development
  - **Regional FDA:**
    • Enforcement – new on site inspection teams
    • Surveillance
    • Monitoring
    • Evaluation
Main Task

“The Food Safety Bureau of the KFDA is responsible for all food safety activities regarding policy, enforcement, inspection and surveillance, nationwide monitoring of contaminants in food, to protect the health of the consumers by ensuring the safety of foods from farm to table.”

Mission

Protect and promote the health of consumers by ensuring the safety of foods.

Approaches

- Higher level of consumer health protection
- Enhanced food safety control and traceability from Farm to Table
- Internationally harmonized risk-based decision making
- Enhanced Risk Communication with public participation and transparency

Strategy

Science based Food safety Control Scheme → Global Harmonization → Consumer Oriented Policy Enforcement → Promotion of Food Industry
Korea vs. Japan
Structure: Korea vs. Japan

Japanese Legislation for Food Contact Articles

Food Safety Basic Law

Food Sanitation Law

Compositional Standards for Milk and Milk Products

- Annex 4. Specifications and Standards of Utensils and Packages of Milk etc. and Their Materials
- Normal liquid milk
- Certified milk
- Goat milk
- Skimmed milk
- Liquid milk recombinant

- Fermented milks
- Lactic acid drinks
- Milk drinks
- PE, PP, PET or PS packages
- PE-processed paper package
- PE, PP, PS or PET packages with aluminum foil

Formulated milk powder
- Plastic-laminated packages
- Metal can with sealing of PE or PET

Specifications and Standards of Food, Food Additives, etc

- Section 1 Food
- Section 2 Food Additives
- Section 3 Utensils and Packages
- Section 4 Toys
- Section 5 Detergents

A. Specification of utensils, packages, and their materials
B. General test methods of utensils and packages
C. Reagents, test solutions, etc
D. Specifications of utensils and packages and their raw materials by material
  1. Glass, ceramic and enameled ware
  2. Plastics
  3. Rubber
  4. Metal can
E. Specifications of utensils or packages by applications
F. Standards of manufacture of utensils and packages

Source: Japanese NIHS
Structure: Korea vs. Japan

- Structure of Laws
- Both have separated:
  - Executive Agencies (MFDS vs MHLW)
  - Assessment Agencies (NIFDS vs. NIHS)
- Japan relies on Industry Associations such as JHOSPA.
  - JHOSPA does FC certifications. No equivalent in Korea.
Korea vs. Japan

- Neither regime uses Positive list approach. Both are considering moving in that direction
- Substantial differences in specifications.
# Resins Covered by JHOSPA

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<td>Polyehtylene-terephthalate (PET)</td>
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<td>Polycarbonate (PC)</td>
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<td>Polyvinylalcohol (PVA)</td>
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<td>Polyacetal(polyoxyethylene) (POM)</td>
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<td>Polyphenylene ether (PPE)</td>
<td>Polyphencylene-ether (PPE)</td>
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<td>Polyacrylonitrile (PAN)</td>
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<td>Fluorocarbon resin (FR)</td>
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<td>Polybutylene terephthalate (PBT)</td>
<td>Polybutylene-terephthalate (PBT)</td>
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<td>Polymethacrilystyrene (MS)</td>
<td>Methylmethacrylate- Styrene Resin (MS)</td>
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<td>Polyarylsulfone (PASF)</td>
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<td>Polyarylate (PAR)</td>
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<td>Poly[cyclohexane-1,4-dimethylene terephthalate)(PCT)</td>
<td>Polyhydroxybenzoic-acid (HBP)</td>
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<td>Polyetherimide (PEI)</td>
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<tr>
<td>Korea</td>
<td>Japan</td>
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<td>Polyethylenenaphthalate (PEN)</td>
<td>Polyethylene-naphthalate (PEN)</td>
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<td>Polyester-carbonate (PPC)</td>
<td>Ethylene-tetracyclododecene copolymer (E/TD)</td>
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<td>Polylactide (poly(lactic acid) (PLA)</td>
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<td>Polybutylenesuccinate (PBS)</td>
<td>Ethylene-2-norbornene copolymer(E/NB)</td>
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<td>1-1 Poly(vinyl chloride) (PVC)</td>
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<td>Poly(vinylidene chloride)(PVDC)</td>
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<td>Melamine-formaldehyde resin (MF)</td>
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<td>Urea-formaldehyde resin (UF)</td>
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<td>Acrylic Resin</td>
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<td>Polyurethane (PU)</td>
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<td>Hydroxybutyl polyester (HBP)</td>
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<td>Ionomer Resin</td>
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<td>Ethylene-vinylacetate copolymer (EVA)</td>
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<td>MethyImethacrylate-acrylonitrile-butadiene-styrene copolymer (MABS)</td>
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<td>Silicone Resins</td>
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<td>Epoxy resin</td>
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<td>Poly(phenylenesulfide)(PPS)</td>
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<td>Poly(ethersulfone)(PES)</td>
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<td>Polyimide (PI)</td>
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<td>Polyetheretherketone (PEEK)</td>
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<tr>
<td>Butylenesuccinate-adipate copolymer (PBSA)</td>
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<tr>
<td>Cross-linked polyester resin</td>
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Thank you!