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Food Contact in South Korea

(and comparison with Japan)

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- **70,000 Regulations, 163 Countries, 14 Economic Areas**
- **30 languages, 5 million synonyms & identifiers**

PRODUCTS:

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

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Presentation Plan

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- **Governmental Structure**
- **Statutory Structure**
- **Details**
- **New and Exciting!!**
- **Comparison: Korea vs. Japan**

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(South) Korea



- **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



Korea



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- **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, Daegu, Daejeon, Gwangju Gyeongin and Seoul)



Korea



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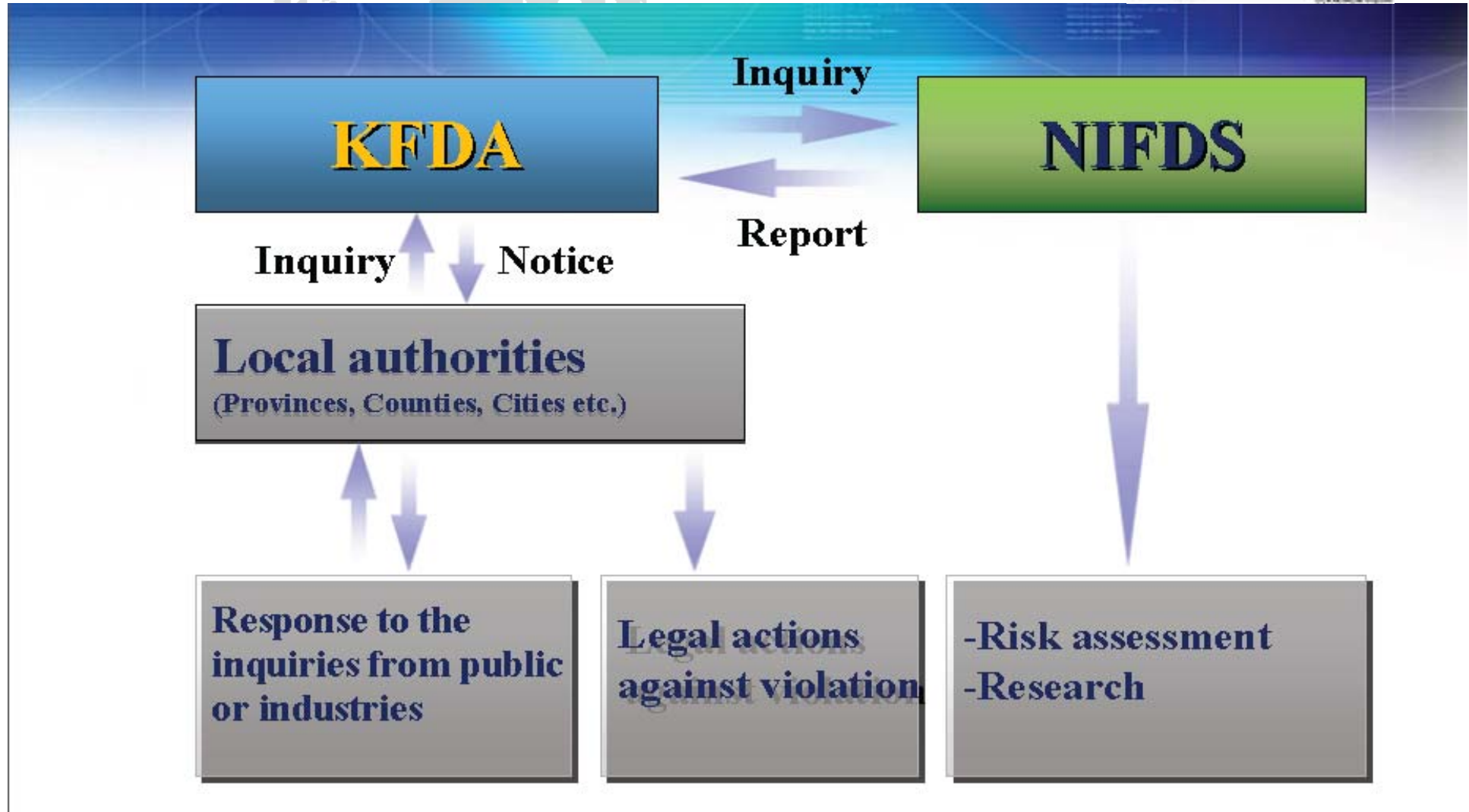
- **Governmental Responsibilities (3)**
 - The **National Institute of Food & Drug Safety Evaluation** created 1 May 2009
 - Risk assessment organization for **KFDA**
 - Provides scientific risk evaluation for food, food supplement and other regulated products
 - **National Food Safety Information Service**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

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Relationships

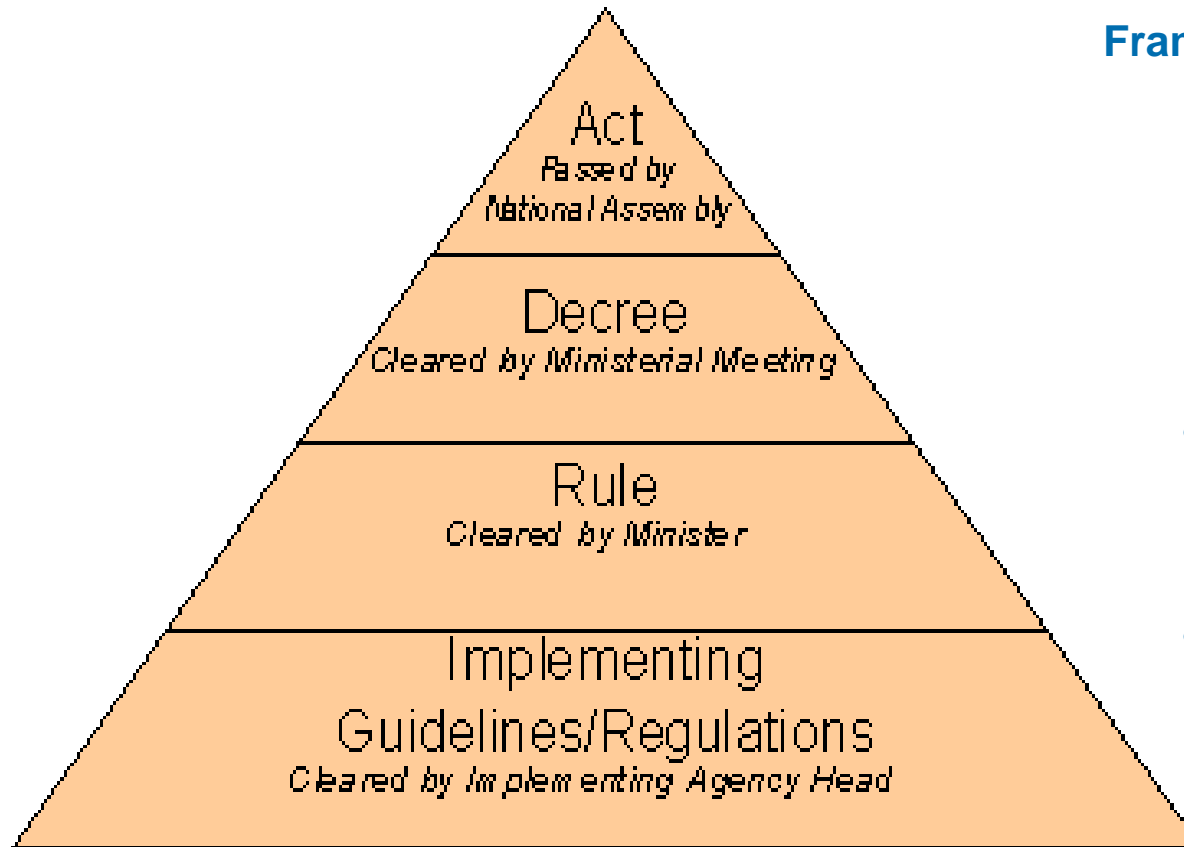




Korea



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**

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Food Sanitation Act (1962)



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

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Food Sanitation Act



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

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Food Sanitation Act



Article 19

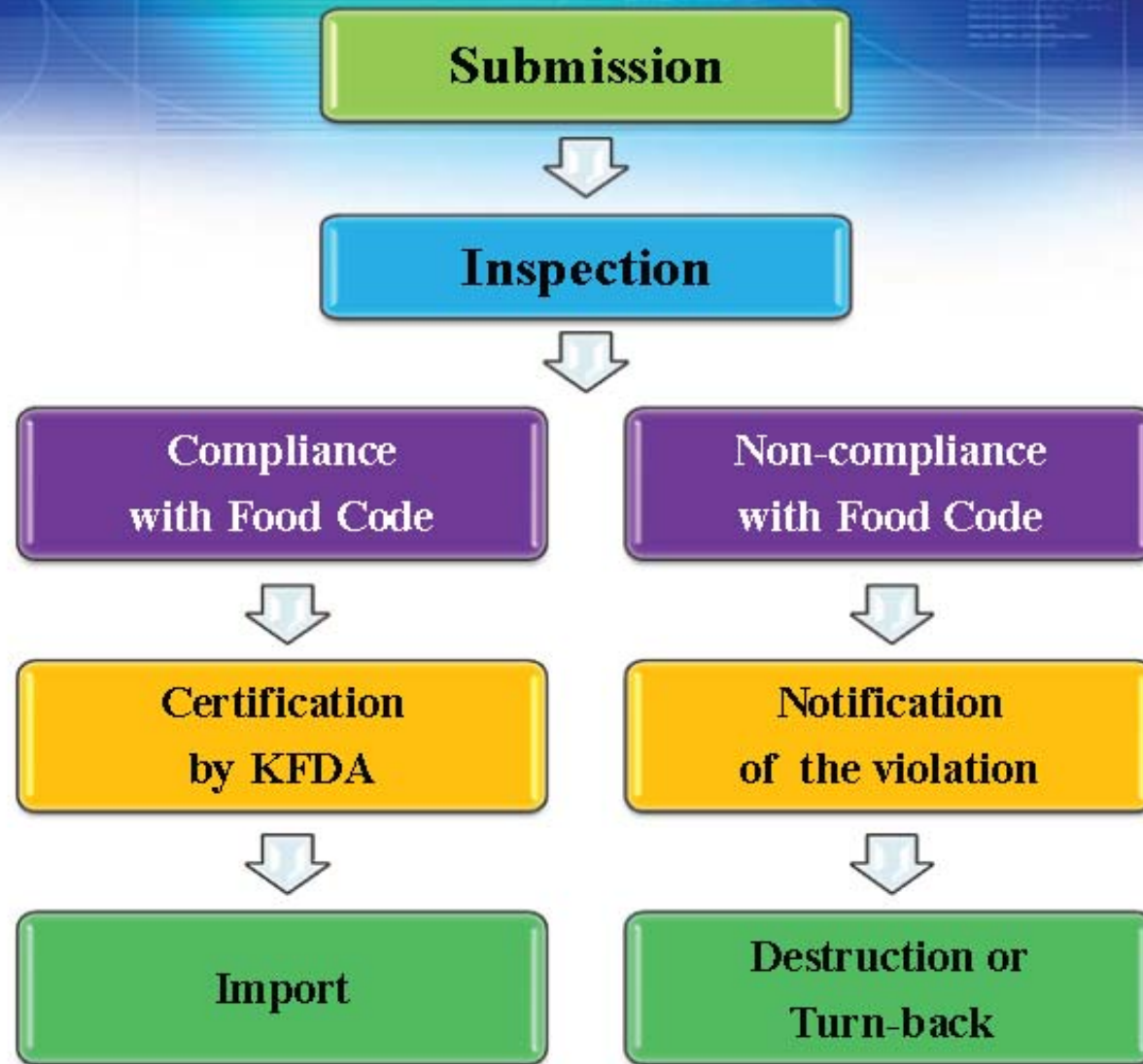
Reporting on Imports Inspections

→ 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

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Requirements for imported food contact articles





Korean Food Code

1000+ pages, Apr 2012



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.

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Korean Food Code

1000+ pages, Apr 2012



Chapter 7 (21 pages)

1. General Standard
2. Common Manufacturing Standards
3. Standards for End Use
4. Specification for Materials (41)
5. Test Methods

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Food Code Material Specifications



Type of plastic Details	PVC	PE /PP	PS	PVDC	PET	PF	MF	UF	POM	Acrylic Resin
(1) Pb, Cd, Hg, Cr ⁺⁶ (as the sum)	100	100	100	100	100	100	100	100	100	100
(2) Vinyl chloride	1.0	-	-	-	-	-	-	-	-	-
(3) Dibutyl tin compounds	50	-	-	-	-	-	-	-	-	-
(4) Cresol phosphoric esters	1000	-	-	-	-	-	-	-	-	-
(5) Volatile substances (including styrene, toluene, ethylbenzene, Isopropyl benzene and n-propylvenzene)	-	-	5000 ¹⁾	-	-	-	-	-	-	-
(6) Vinylidene chloride	-	-	-	6.0	-	-	-	-	-	-
(7) Barium	-	-	-	100	-	-	-	-	-	-
(8) BPA (including phenol, bisphenol A and <i>p-t</i> -butylphenol)	-	-	-	-	-	-	-	-	-	-
(9) Diphenyl carbonate	-	-	-	-	-	-	-	-	-	-
(10) Amines(triethylamine and tributylamine)	-	-	-	-	-	-	-	-	-	-
(11) 1,3-Butadiene	-	-	-	-	-	-	-	-	-	-

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Source: Gangneung-Wonju National University, Korea



Food Code: Material Specifications



Type of plastic Details	PVC	PE/PP	PS	PVDC	PET	PF	MF	UF	POM	Acryl resin
(1) Heavy metals(Pb)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(2) Consumption of KMno ₄	10	10	10	10	10	-	-	-	10	10
(3) Residues after evaporation	30 ¹⁾	30 ²⁾	30 ³⁾	30	30	30	30	30	30	30
(4) Dibutyl phthalate	0.3	-	-	-	-	-	-	-	-	-
(5) Benzylbutyl phthalate	30	-	-	-	-	-	-	-	-	-
(6) Di-(2-ethylhexyl) phthalate	1.5	-	-	-	-	-	-	-	-	-
(7) Di-n-octyl Phthalate	5	-	-	-	-	-	-	-	-	-
(8) Diisononyl phthalate	9	-	-	-	-	-	-	-	-	-
(9) Diisodecyl phthalate	9	-	-	-	-	-	-	-	-	-
(10) Di-(2-ethylhexyl) adipate	18	-	-	-	-	-	-	-	-	-
(11) 1-Hexene	-	3(PE)	-	-	-	-	-	-	-	-
(12) 1-Octene	-	15(PE)	-	-	-	-	-	-	-	-
(13) Antimony	-	-	-	-	0.04	-	-	-	-	-
(14) Germanium	-	-	-	-	0.1	-	-	-	-	-
(15) Terephthalic acid	-	-	-	-	7.5	-	-	-	-	-
(16) Iso-phthalic acid	-	-	-	-	5.0	-	-	-	-	-
(17) Phenol	-	-	-	-	-	5	5	5	-	-
(18) Formaldehyde	-	-	-	-	-	4.0	4.0	4.0	4.0	-
(19) Melamine	-	-	-	-	-	-	30	-	-	-
(20) Methylmethacrylate	-	-	-	-	-	-	-	-	-	6 ⁴⁾



Material Specifications Summary



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- **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



KFDA RULE



Standards and Specifications for Utensils, Containers and Packaging for Food Products, October 2011- 230 pages

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).



Korea



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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



Korea



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)

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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 Polymethacrylstyrene (MS)
- 1-19 Poly(butylene terephthalate) (PBT)
- 1-20 Polyarylsulfone (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

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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

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Recent Changes



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- On 23 March 2013, New president Park Geun-Hye announced the passage of a contentious “Government Restructure Bill”.

OLD	NEW
Ministry for Food, Agriculture, Forestry and Fisheries	Ministry of Agriculture, Food and Rural Affairs (MAFRA)
Korea Food and Drug Administration (KFDA)	Ministry of Food and Drug Safety (MFDS)



Recent Changes



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- **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



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“Modern Means of Management” (Cont.)

• Separation of Duties:

- **MFDS:** Policy making and development
- **Regional FDA:**
 - Enforcement – new on site inspection teams
 - Surveillance
 - Monitoring
 - Evaluation



<http://www.kfda.go.kr/eng/index.do>



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- [DRUG](#)
- [BIO](#)
- [MEDICAL DEVICES](#)
- [ABOUT MFDS](#)
- [MFDS NEWS](#)

MINISTRY OF FOOD AND DRUG SAFETY

New Beginning, Bigger Hope, Brighter Future towards a strong nation for food and drugs



Vision

Safe Food and Drugs, Healthy Nation, Well-being of Society

1

Ensuring safety of the people to improve quality of life

2

Consumer-based safety management from Farm to Table

Purpose

3

Realization of safer and healthier lives of the people

4

Beyond safety, providing assurance to the people

Number of medical devices is on the rise due to ageing population and increasing interests in personal health. -The KFDA released 2012 status report on medical devices approval.- Apr 4, 2013

□ According to an analysis of the 2012 current status on medical devices approvals by the Ko... [more](#)

- Mar 28, 2013 MFDS Reforms and Takes a New Step Forward
- Dec 13, 2012 Memorandum of Understanding between the Gyeongin R...
- Dec 13, 2012 'Makgeolli' Exporting to China made easy.
- Dec 12, 2012 Revised Food Classification Facilitates smooth exp...
- Dec 5, 2012 Presentation Materials for Foreign Embassies' Unde...
- Nov 30, 2012 Notice No. 2012-260 of the Korea Food & Drug Admin...
- Oct 23, 2012 The 2nd International Symposium on Quality Assuran...
- Oct 5, 2012 Notice No. 2012-209 of the Korea Food & Drug Admin...
- Sep 7, 2012 Notice No. 2012-174 of the Korea Food & Drug Admin...



ABOUT MFDS
Vision



ABOUT MFDS
History



ABOUT MFDS
Video Clip



ABOUT MFDS
Commissioners



INFORMATION FOR
MULTICULTURAL FAMILY

Foreign Official Laboratory



<http://www.kfda.go.kr/eng/index.do>



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FOOD DRUG BIO MEDICAL DEVICES ABOUT MFDS MFDS NEWS

FOOD

Food Safety Bureau
- Safe food, Healthier Future -

Home > FOOD > Main Task

FOOD

[Main Task](#)

Introduction

Topics & Activities

- Ensuring Food Safety
- Foodborne Disease Surveillance and Prevention Activities
- Food Standards
- Food Additives
- Health Functional Foods
- The Special Act on the Safety Management of Children's Dietary Life
- Imported food Safety
- International Cooperation

Food Safety Information

- National Food Safety Information Service
- Foodborne Disease

News

- MFDS NEWS
- Upcoming CODEX meetings

Main Task

"The Food Safety Bureau of the KFDA is responsible for all the 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

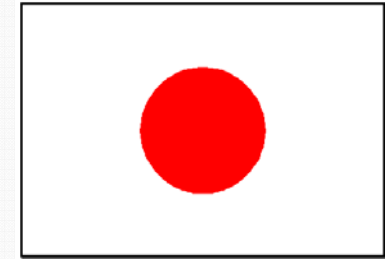
- › Higher level of consumer health protection
- › Enhanced food safety control and traceability from Farm to Table
- › Internationally harmonized risk-based decision making
- › Enhanced Risk Communication with public participation and transparency

Strategy





Korea vs. Japan



DECE
NIS

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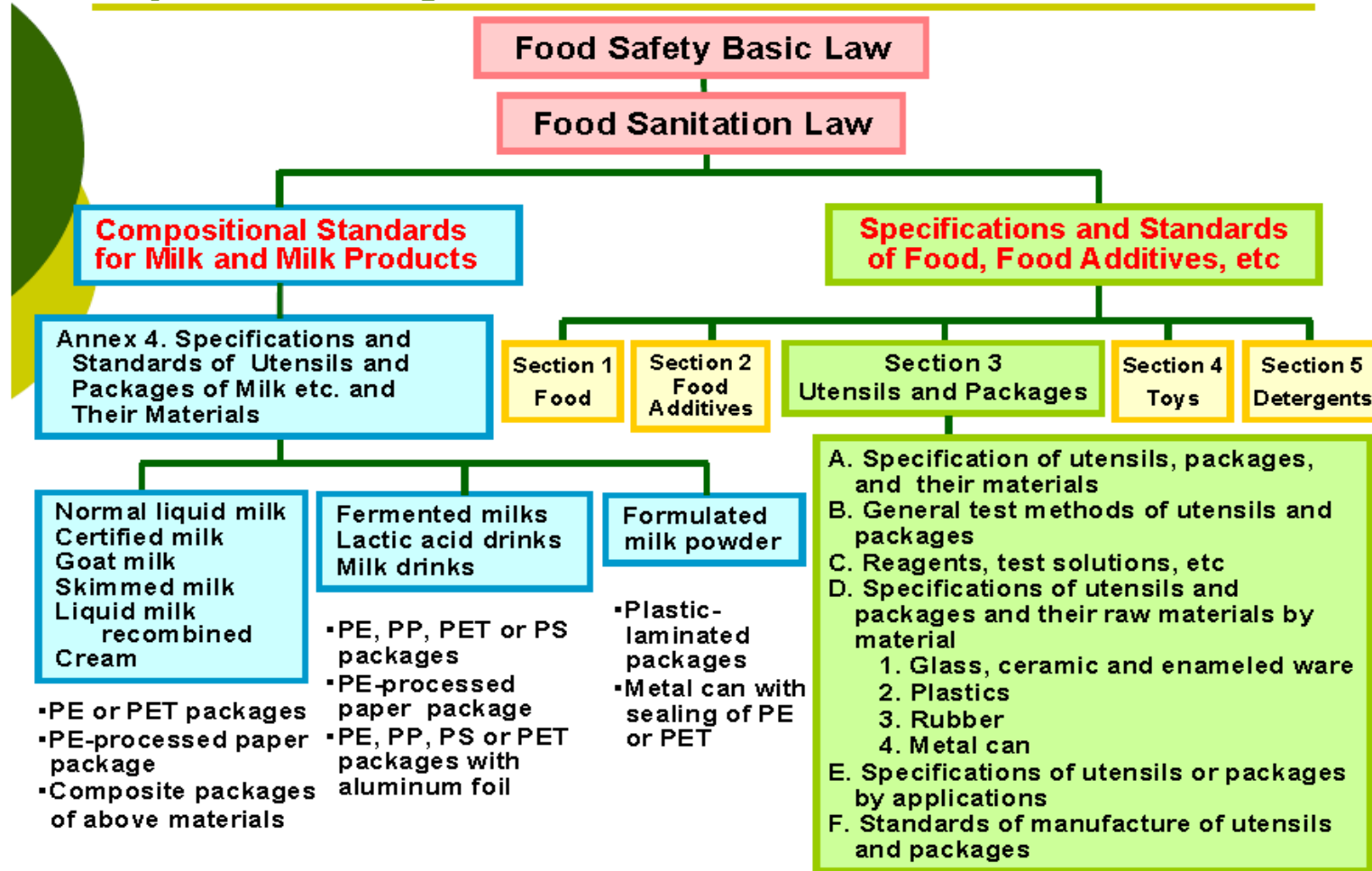
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Structure: Korea vs. Japan



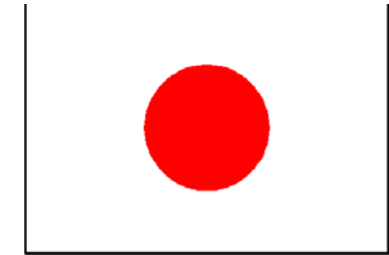
Japanese Legislation for Food Contact Articles



Source: Japanese NIHS



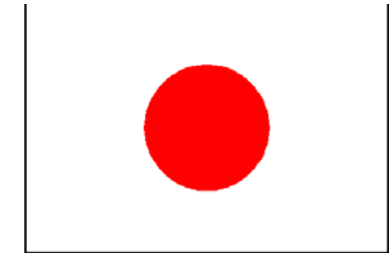
Structure: Korea vs. Japan



- **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.**

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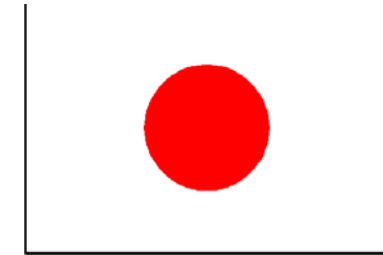
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Resins Covered by JHOSPA

- 
- | | | | |
|----|------------------------------------|----|--------------------------------------------------|
| 1 | Polyethylene | 17 | Polycarbonate |
| 2 | Polypropylene | 18 | Polyvinyl alcohol |
| 3 | Polymethylpentene | 19 | Polyacetal |
| 4 | Polybutene-1 | 20 | Polybutyleneterephthalate |
| 5 | Butadiene resin | 21 | Polyaryl sulfone |
| 6 | Ethylene/tetracyclododecen polymer | 22 | Polyacrylate |
| 7 | Polystyrene | 23 | Polyesters of hydroxybenzoic acid |
| 8 | SAN resin | 24 | Polyether imide |
| 9 | ABS resin | 25 | Polycyclohexylene di-
methylene terephthalate |
| 10 | Polyphenylene ether | 26 | Polyethylene naphthalate |
| 11 | Polyacrylonitrile | 27 | Polyester carbonate |
| 12 | Fluorine resin | 28 | Poly lactic acid |
| 13 | Polymethacryl styrene | 29 | Polybutylene succinic acid |
| 14 | Methacryl resin | 30 | Ethyrene/2-norbornen resin |
| 15 | Nylon resin | | |
| 16 | Polyethylene terephthalate | | |



Korea vs. Japan



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KOREA

Polyethylene and polypropylene (PE/PP)

Polyethylene and polypropylene (PE/PP)

Polystyrene (PS)

Acrylonitrile-butadiene styrene (ABS)/ acrylonitrile styrene (AS)

Acrylonitrile-butadiene styrene (ABS)/ acrylonitrile styrene (AS)

Polymethylpentene (PMP)

Butadiene (BDR)

Polyamide/Nylon (PA)

Polybutene-1 (PB-1)

Poly(ethyleneterephthalate) (PET)

Polycarbonate (PC)

Polyvinylalcohol (PVA)

Polyacetal(polyoxymethylene) (POM)

Polyphenylene ether (PPE)

Polyacrylonitrile (PAN)

Fluorocarbon resin (FR)

Polybutylene terephthalate (PBT)

Polymethacrylstyrene (MS)

Polyarylsulfone (PASF)

Polyarylate (PAR)

Poly(cyclohexane-1,4-dimethylene terephthalate)(PCT)

JAPAN

Polyethylene (PE)

Polypropylene (PP)

Polystyrene (PS)

AS resin (AS)

ABS resin (ABS)

Polymethylmethacrylate (PMMA)

Polymethylpentene (PMP)

Butadiene resin (BDR)

Nylon (PA)

Polybutene-1 (PB-1)

Polyethylene-terephthalate (PET)

Polycarbonate (PC)

Polyvinylalcohol (PVA)

Polyacetal (POM)

Polyphenylene-ether (PPE)

Polyacrylonitrile (PAN)

Fluorocarbon resins (FR)

Polybutylene-terephthalate (PBT)

Methylmethacrylate- Styrene Resin (MS)

Polyarylsulfone (PASF)

Polyarylate (PAR)

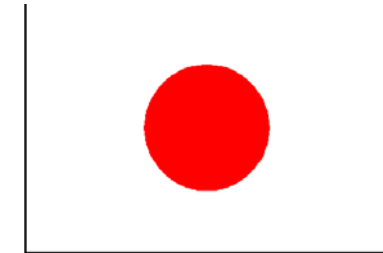
Polyhydroxybenzoic-acid (HBP)

Polyetherimide (PEI)

Polycyclohexylene-di-methylene-terephthalate (PCT)



Korea vs. Japan



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KOREA

Polyethylenephthalate (PEN)



Poly lactide (poly(lactic acid) (PLA)



1-1 Poly(vinyl chloride) (PVC)

Poly(vinylidene chloride)(PVDC)

Phenol-formaldehyde resin (PF)

Melamine-formaldehyde resin (MF)

Urea-formaldehyde resin (UF)

Acrylic Resin

Polyurethane (PU)

Hydroxybutyl polyester (HBP)

Ionomer Resin

Ethylene-vinylacetate copolymer (EVA)

Methylmethacrylate-acrylonitrile-butadiene-styrene copolymer (MABS)

Silicone Resins

Epoxy resin

Poly(phenylenesulfide)(PPS)

Poly(ethersulfone)(PES)

Polyimide (PI)

Polyetheretherketone (PEEK)

Butylenesuccinate-adipate copolymer (PBSA)

Cross-linked polyester resin

JAPAN

Polyethylene-naphthalate (PEN)

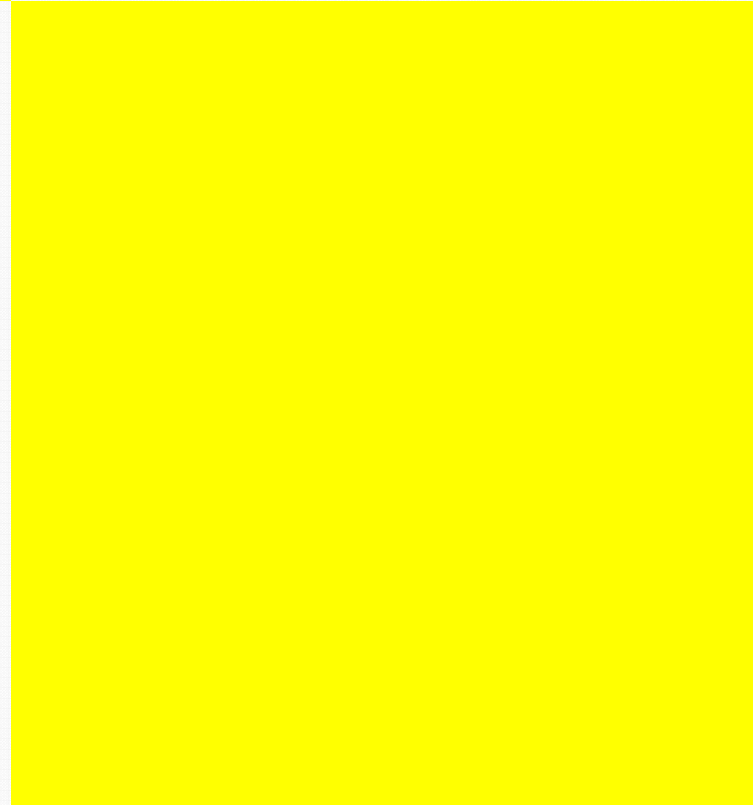
Polyester-carbonate (PPC)

Ethylene-tetracyclododecene copolymer (E/TD)

Poly lactic-acid (PLA)

Polybutylenesuccinate (PBS)

Ethylene-2-norbornene copolymer(E/NB)





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Thank you!

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