FCMs in Asia: What has changed during the last 10 years?

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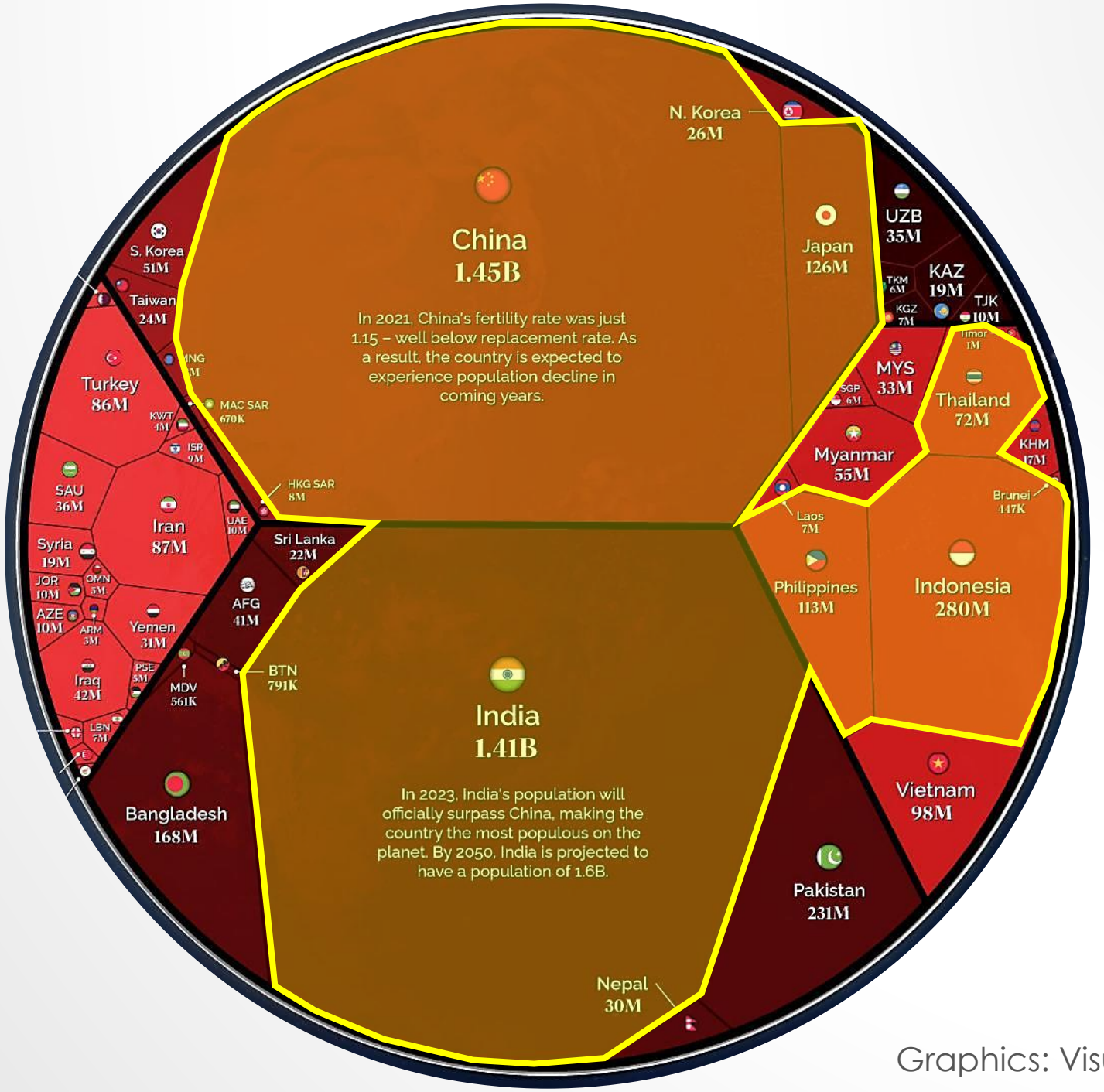
ASIA

- 48 Countries
- Home to 4.7 billion people



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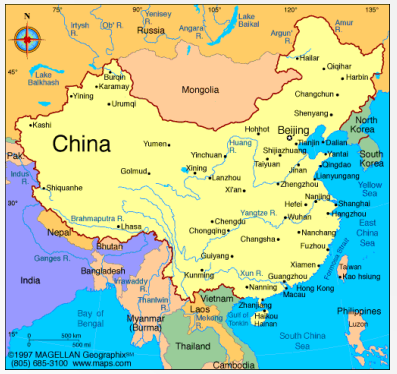
CHINA



- **Food Safety Law – enacted in 2009**

- **Amended in 2015, 2018, and 2021**
- **2015:** Framework for FCMs

Horizontal Standards	Commodity Standards	Test Method	Manufacturing Practice
• General safety requirement of FCM • Additive and usage requirement (GB 9685) • General Practice of FCM • General requirement on migration test	• Plastic • Ceramic • Glass • Coating • Rubber • Metal and Alloy • Paper and paperboard • Etc.	• Test method for commodity material • Test method on migration of individual substances	• Individual GMP requirement

CHINA

- **2016**: China had 53 mandatory GB standards related to FCMs

GB 9685	Standard for Uses of Additives in FCM and food contact articles
GB 4806.1	General Safety Requirements for FCM: OML 10 mg/dm^2 or 60 mg/kg, usage requirements, labelling requirements, traceability requirements
	Appendix A: Positive List of Food Additives and use restrictions
GB 4806.2	Nipples
GB 4806.3	Enameled articles
GB 4806.4	Ceramic Articles
GB 4806.5	Glass Articles
GB 4806.6	Resins Used to Make Plastics in Contact with Foodstuffs
GB 4806.7	Plastic Materials and Articles in Contact with Foodstuffs
GB 4806.8	Paper and Paperboard in Contact with Foodstuffs
GB 4806.9	Metal Materials and Articles in Contact with Foodstuffs
GB 4806.10	Paints and Coatings in Contact with Foodstuffs

- **2019**: National Health Commission (NHC) announced plans to enact or revise 81 food safety standards including FCM standards
- **Recent years to present**: NHC has been proposing and approving new FCMs or expanded scope for FCMs

INDIA

- **Food Safety and Standards Act– enacted in 2006**
  - Established the Food Safety and Standards Authority of India (FSSAI)

- **2016-2017: Study by FSSAI and Indian Institute of Packaging**
  - All samples of packaging material failed to meet Indian standards
  - Cases of contamination due to substandard materials
- **2018: FSSAI announced new regulations**
  - Overall migration level 10 mg/dm^2 or 60 mg/kg, no visible color migration
  - Specified requirements for direct contact and compatibility with intended use, and also specified Indian Standard
  - Specific migration limits focused on 7 heavy metals
  - Requires all manufacturers to obtain Certificate of Conformity from a lab
- **2022: latest version of Food Safety and Standard (Packaging) rules**

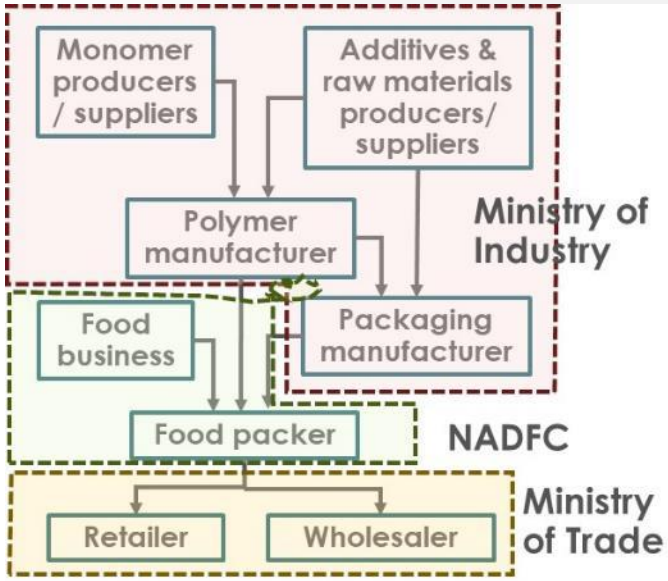
INDIA

- **Some Issues**
  - Some Indian standards are old and need upgrading
  - Some confusion on definitions
  - No labelling requirements
  - No traceability and documentation requirements
  - SMLs for metals only

- **Recent Issue: Use of recycled plastic for FCM**
  - 2018 regulations banned use of recycled plastic
  - 2019: ban was rescinded and FSSAI allowed recycled plastic in FCMs
  - 2022: FSSAI issued stricter standards governing use of recycled plastic due to pushback
    - Conventional recycling of PET without removal of contaminants cannot be used for FCM
    - Processes that decontaminate (high heat and/or vacuum, chemical distillation and vacuum degassing, chemical purification) can be used to make food grade rPET
    - Testing required: challenge test, extraction test, migration test
    - Recyclers for food grade rPET must apply and register

INDONESIA

- **Reg. No. 28 Food Safety, Quality & Nutrition, 2004**
  - Art. 16-20: General requirements for FCMs
  - Three national authorities
- **2010: Ministry of Industry Reg. No. 24/M...**
  - Label "safe for food contact"
- ➢ **2011: National Agency for Drug & Food Control**
  - ➢ Reg. No. HK…6664 – Food Packaging Control



- **2014: Amendment to NADFC No. HK…6664**
  - Broad list of FCMs
  - Negative List of prohibited substances
  - Positive List of substances with and without migration limits
  - Approval process for new substances or expanded functions
  - Regular sampling and analysis by NADFC inspectors

INDONESIA

- **2014: Indonesian Standards (SNI) for PVC, phthalates**
- **2015: Indonesian Standard for melamine, styrene in polystyrene, paper and paperboard**
- Etc.
- **2019: NADFC Reg. No. 20 replaced HK…6664 and its 2014 amendment**
  - More stringent legal framework
  - Compulsory for all types of food packaging
  - Manufacturers had to comply by July 2020
  - Broad scope:
    - New and recycled plastics: inks and dyes, paper and board, resins and polymer coatings, metals, ceramics, glass plus single-layer plastic, multi-layer plastic, rubber and elastomer, cover/gasket/seal
  - Prohibited substances, permitted substances with or without migration limits
  - Production requirements for recycled materials in food packaging
  - Compliance with Good Manufacturing Practices for FCMs

JAPAN

- **Food Sanitation Law – enacted in 1947**
- **Food Safety Basic Law – enacted in 2003**

➢ Safety of food-contact utensils, containers and packaging (UCP) by
  - ❖ Government regulation
  - ❖ Voluntary standards by trade associations

- **2016-2017: Study by the Committee on Regulation of Food UCP**
  - Substances not allowed in EU or USA could be used in Japan
  - Businesses not members of trade associations fall outside regulatory framework
  - No Positive List
  - No mechanism to share information among businesses to ensure product is compliant
  - No mechanism to ensure uniform Good Manufacturing Practices

JAPAN

- **2018: Amendment of the Food Sanitation Law**
  - Introduction of a Positive List
  - New Article 18 Paragraph 3:
    - Substances cannot be used if not in Positive List and if no UCP standards exist
    - Ministry of Health, Labor and Welfare (MHLW) shall provide a "Quantity that is unlikely to harm public health"
  - New Article 52: MHLW shall publish criteria for sanitary management of facilities and GMP
  - New Article 53: Information sharing among Food UCP manufacturer, food manufacturer, vendors, importers, etc.
- **April 2020**: "Quantity that is unlikely to harm public health" = 0.01 mg/kg
- **June 2020**: Positive List issued, 5-year grade period for unlisted substances
- **October 2022**: Positive List being amended to include unlisted substances, provisional list available

THAILAND

- **Qualities or Standard of Containers Made of Plastic, 1988**
- **Modified by the Ministry of Public Health (MOPH), 2003**

- MOPH conducted a survey of FCMs on the market and their users
- **June 2022: MOPH issued "Prescribed Quality or Standard of Plastic Containers"**
  - New requirements enter into force in January 2023
  - ➢ Expanded scope including multilayer plastic, multi-materials, and plastic coated packaging
  - ➢ Updated migration limits
  - ➢ List of permitted FCMs, overall migration limits, specific migration limits for metals, limits related to primary aromatic amines, etc.
  - ➢ Thai Food and Drug Administration must approve any new plastic not in the list
  - ➢ Stricter standards for use of recycled plastics including proof of reduced or eliminated contaminants
  - Mandator standards by Thai Industrial Standards Institute replace voluntary standards

PHILIPPINES

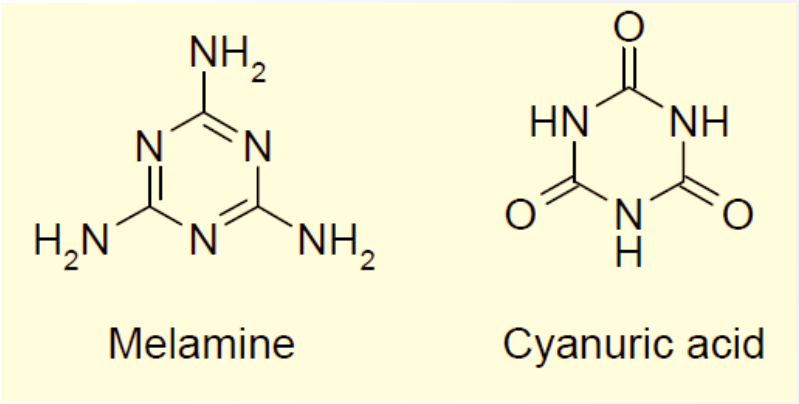
- **Food, Drug and Cosmetics Act of 1963**
- **Food and Drug Administration Act of 2009**

- **Food Safety Act of 2013**
  - Mentions risk analysis of hazards from packaging
  - Department of Health's responsibility to ensure safety of food product packaging
  - Food Safety Regulatory Agencies are:
    - Department of Health/Food and Drug Administration
    - Department of Agriculture
- **2022: Guidelines on Voluntary Certification of Food Contact Articles Used for Prepackaged Processed Food Products**
  - Evaluation by FDA's lab re "food grade certification"
  - Standards based on Japan's and US FDA's standards

EXAMPLES OF CHALLENGES:

- MELAMINE TABLEWARE
- SACHETS

MELAMINE TABLEWARE



- **2007-2008: Melamine adulteration of pet food and infant formula powder**
- **Adverse health effects of melamine, especially with cyanuric acid**
  - Kidney damage (renal tubular cell injury, renal dysfunction, risk of kidney stones)
  - Effects on male reproductive system (sperm morphology and count)
  - Neurotoxicity
- **Tolerable Daily Intake (TDI)**
  - WHO (2008): 0.2 mg/kg body weight
  - US FDA (2008): 0.063 mg/kg body weight
- **Migration Limits**
  - China: 0.2 mg/dm^2
  - Ling *et al*. (Taiwan, 2016) suggested 0.07 mg/dm^2 due to impact on children

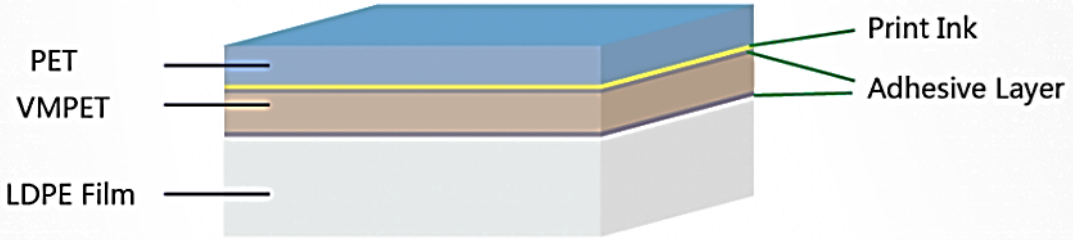
MELAMINE TABLEWARE

- **Sources of melamine exposure**
  - Adhesives, flame retardants, fertilizers, inks, printed textiles, disinfectants, chlorine stabilizer in swimming pools
  - Coatings in food packaging, coatings for canned food
  - Melamine tableware: plates, bowls, cups, utensils, chopsticks
- **Choi *et al.*, *Chemosphere*, August 2022:**
  - More than 60% of pregnant mothers in the US had melamine, cyanuric acid, and other aromatic amines in their urine, especially among Hispanic and Black mothers
- **Common scenario in Asia**
  - Melamine tableware in homes, restaurants, fast food stalls, street food vendors
  - Many Asian foods including hot soups are acidic
  - Many food stalls heat up soups in melamine bowls in microwave ovens
  - Melamine, cyanuric acid and other melamine derivatives migrate to food
  - Multiple sources of melamine exposures

SACHETS

- **Sachets**
  - Typically 45x45 mm up to 100x180 mm
  - For wet foods (soy sauce, cooking oil, condiments, tomato sauce, milk, baby food, drinks, sauce mixes, etc.)
  - For dry foods (coffee powder, sugar, salt, milk powder, chocolate powder, etc.)
  - For personal care products (shampoo, bath soap, lotion, toothpaste, etc.)
  - For household items (cleaning soap, detergent, fabric conditioner, etc.)
- **History in the Philippines**
  - Traditional neighborhood stores sold small quantities of products using reusable containers (usually glass and metal) and a refill system and brought home in traditional natural fiber baskets so low income-families could buy daily needs in small affordable quantities
  - Around the 1960s, multinational companies wanting to expand markets replaced the traditional system with single-use sachets and single-use plastic bags creating a profitable sachet economy.

SACHETS



- **Designs of Sachets**
  - Aluminum foil layer + polyethylene terephthalate (vacuum metalized PET) plus laminated LDPE layer with printing, adhesive layers
  - Several layers of Metallized biaxially oriented polypropylene, LDPE, ethylene-methacrylic acid copolymer coating

- **Health and Environmental Issues**
  - Migration of adhesives and possibly other substances in FCM
  - Filipinos use 164 million pieces of sachets every day
  - 60 billion sachets discarded into the environment every year
  - About 452,000 tons of residual waste every year
  - More and more microplastics found in our fish

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