

COMPARISON BETWEEN CHINA'S NATIONAL STANDARD AND U.S. REGULATION IN INFANT FORMULA

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Introduction

- 2008 China's infant formula incident
 - Melamine
 - Six baby deaths and an estimated 300,000 babies physical ailments and other physical harms (Chen, 2009).
- China's national infant formula standard GB 10765-2010
- United States Code of Federal Regulations Part 107 in Title 21 regulation
- A Policy Design component from the Social Construction framework



Literature Review

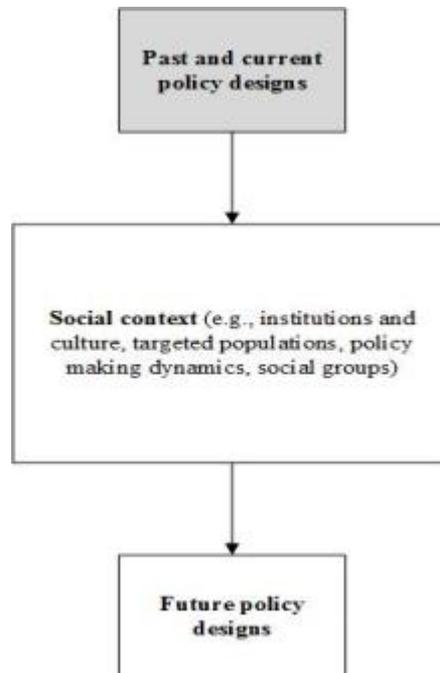
- The existence of China's infant formula industry safety problems
 - Expansion
 - Food safety problems (2004, 2008, 2011, 2012)
 - The current status

- China's 2008 melamine infant formula incident and reform
 - An estimated financial loss of \$2.8 billion (Lu & Tao, 2009)
 - In 2009, Food Safety Law of the People's Republic of China
 - In 2010, National Food Safety Standard Infant Formula (GB 10765- 2010) & National Food Safety Standard Good Manufacturing Practice for Powdered Formulae for Infants and Young Children (GB – 23790 -2010)
 - In 2012, National Food Safety Standards of Special Medical Use Infant Formula Rules

- United States dairy industry and infant formula regulation
 - The United States dairy industry is a mature industry compared to China.
 - Infant formula industry is a very important sector in the dairy industry.
 - Highly concentrated.

Methodology

- “Social Construction” developed by Ingram et al. (2007)
- “Policy Design” provides a framework for analyzing policy standards. (Ingram & Schneider, 1990)
- The characteristics of the policy design include: problem definition, allocation of benefits and burdens, rules, tools, rationales, causal logic (Ingram et al., 2007, p. 96)



Analysis and Results

- Problem definition: China's national standard and U.S. regulation both addressed the problem of regulating the infant formula safety.
- Allocation of benefits and burdens

Stakeholders	China GB 10765-2010	United States CFR Part 107 in Title 21 regulation
Suppliers	Burden	NA
Manufacturers	Burden	Benefit/Burden
Distributors	Benefited	Benefited
Retailers	Benefited	Benefited
Consumers	Benefited	Benefited
FDA	NA	Benefit

- Rule

China GB 10765-2010	United States CFR Part 107 in Title 21 regulation
Requirements for raw materials	NA
Sensory requirement (e.g., color, taste, odor, structural state, dissolvability)	NA
Nutrition requirements (essential and optional)	Nutrition requirements
Labels	Labels
Directions for proper preparation and application	Directions for proper preparation and application
Direction for improper preparation and application	Direction for improper preparation and application
Packaging	NA
Limits contaminants, mycotoxin, and microorganisms	NA
Food additives and nutrition fortifiers	NA
NA	Exemptions
NA	Infant formula recalls



Analysis and Results

□ Tools

- Tools described by Ingram and Schneider (1990) as instruments “intends to motivate implementing agencies and target populations to make decision and take actions consistent with policy objectives” (p. 72).
- The Chinese national standard did not provide any tools, but the standard itself.
- The U.S. regulation introduced two tools necessary for the implementation of the regulation, which includes the Federal Food, Drug, and Cosmetic Act and the Federal Food and Drug Administration food regulation (Infant formula, 2014).

□ Rational

China GB 10765-2010	United States CFR Part 107 in Title 21 regulation
Regulate infant formula industry	Regulate infant formula industry
Replace GB 10765-1997	
Replace GB 10766-1997	
Replace GB 10767-1997	

Analysis and Results

□ Causal logic

China GB 10765-2010	Cause	Effect
	Requirements for raw materials	Ensure the infants' safety and meet the nutrition demands, and should not use the substances that may endanger the nutrition and health of infants
	Sensory requirement (e.g., color, taste, odor, structural state, dissolvability)	Suboptimal infant formula indicators to prevent consumption
	Nutrition requirements (essential and optional)	Essential for growth and development
	Labels	Labels with adequate and sufficient information
	Directions for proper preparation and application	Prevent mistakes and harms in preparation and application
	Direction for improper preparation and application	Provide a warning
	Packaging	Adequate storage
	Limits contaminants, mycotoxin, and microorganisms	Avoid health harms
	Food additives and nutrition fortifiers	Safe food additives

United States CFR Part 107 in Title 21 regulation	Cause	Effect
	Nutrition requirements	Nutrition should not be lower than the minimum specified level
	Labels	Labels with adequate and sufficient information
	Directions for proper preparation and application	Prevent mistakes and harms in preparation and application
	Direction for improper preparation and application	Provide a warning and course of action to take
	Exemptions	An exempt infant formula is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.
	Infant formula recalls	Course of action for stakeholders involved

Future Research

- This research explored and provided a perspective and a comprehensive understanding of the differences and similarities of China's national infant formula standard (GB 10765-2010) and United States CFR Part 107 in Title 21 regulation.
- The information obtained will be used for the development of a future survey and interview questions. The survey and interview will be utilized in a manner of collecting government, academia, and industry perspectives for improving China's infant formula policies.

Questions?

- Thank you!