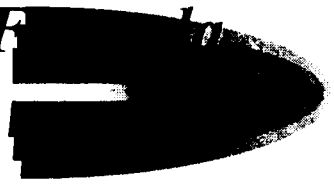
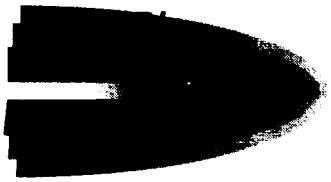
영유아식의 안전성

Safety of Infant F



이화여자대학교
오 상석



1. Introduction
2. cGMP
3. Inspection Procedures
4. cGMP of Infant Formula
5. Summary

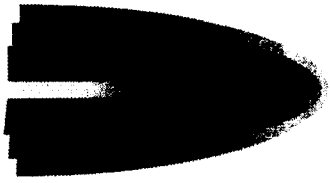
Infa[redacted]mula

- Product intended for use by infants that simulates human milk or is suitable as a complete or partial substitute for human milk

- Persons not more than 12 months of age

doubling by 4 months of age

tripling by 1 year



"There is simply no margin for error in the production of baby formula."

Introducti[redacted]arket

- Powder—late 1800s
- Liquid Concentrate—early 1950s
- Liquid Ready-to-Feed—about 1960

Marketshare Powdered In[redacted]mulas

- Half of U.S. marketshare (d[redacted])

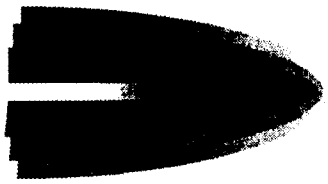
(Source: Information Resources, Inc., 1999)

The Infant For  ***1980***

1978 chloride deficiency.
1980 greater regulatory control
Infant Formula Act of 1980 -recall
1982 recall procedures
infant formula quality control procedures
1985 labeling of infant formula,
exempt infant formulas nutrient
requirements for infant formula

The 1986 Amendments to the In  ***Act***

quality control testing
cGMP
recordkeeping
recall requirements



1989 recalls

1991 infant formula record

record retention requirements

1996 A[redacted]MENT

General Provisions.....Ge[redacted]

Quality Control Procedures for Assuring Current Good Nutrient Content of Infant Formulas Manufacturing Practice

Records and Reports.....Quality Control Procedures.

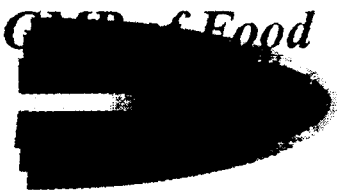
Notification Requirements..... Conduct of Audits.

None.....Quality Factors for Infant Formulas.

None.....Records and Reports.

None.....Registration, Submission, Notification Requirements.

cG[redacted]f Food



- Personnel
- Building and Facility
- Equipment
- Production and Process controls
- Sanitation
- Defect Action Levels, Recall

General Sanitatio[redacted]ions

- Covered by 21 CFR 110, Food
- Compliance Program 7303.803, Domestic Food Safety
- Compliance Program 7303.037, Domestic and Import Cheese Products
- Compliance Program 7303.030, Pathogen Monitoring of Selected High Risk Foods

(L. Stringer, FDA)

Specialized [redacted]tions

- Covered by Specific Regulation
- 21 CFR 108 & 113, Low-Acid Canned Foods (CPG 7303.803A)
- 21 CFR 108 & 114, Acidified Low-Acid Canned Foods (CPG 7303.803A)
- 21 CFR 123, Fish & Fishery Products (CPG 7303.842)
- 21 CFR 106 & 107, Infant Formula (CPG 7321.006)

High Risk Food [redacted]tions

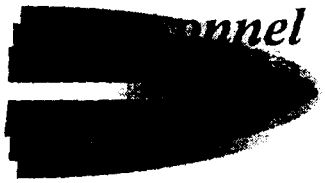
- General Sanitation
- Microbial Risk
  - Soft Cheeses
  - Prepared Foods/Salads
  - Milk and Egg Products
- Microbial Routes of Contamination
  - Water
  - Employees

Low Acid and Acidified Foo[redacted]ions

- Must Follow a "Scheduled Process"
- Records

Seafoo[redacted]ions

- HACCP Required
- Write and Follow a HACCP Plan
- HACCP Plan Must Address all Significant Hazards
- Special Requirements
  - Smoked Fish
  - Shellfish



- Management
  - Who runs this joint anyway?
- Employees
  - Do they know what they're doing?
  - Are they healthy?
  - Do they have health certificates?
  - No Smoking or Eating

- Environment
  - Proximity to creeks, dump sites, etc.
- Construction, Design and Maintenance
  - Is the building falling apart?
- Waste Disposal
  - Is it controlled?

R[redacted]ials

- Source
  - Where are they from?
- Handling
  - How are they received?
- Condition
  - Is any salvaged?
  - Morgue area
- Food Chemicals Codex

Equipment [redacted]nsils

- Clean
  - Is it clean before use?
- Cleanable/Sanitary
  - Can it be cleaned?
- Adequate for Use
  - Are they cutting with a spoon?
- Shovels on floor???
  - Coal - Okay
  - Ice - Not so good

Manufactu[redacted]ocess

- Process Diagrams
- Floor Diagrams
- Reprocess/Rework
- Cross-Contamination Routes
  - Microorganisms

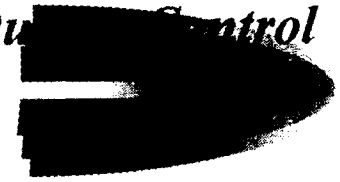
Manufacturing Process Ingredi[redacted]dling

- How are ingredients added to the process?
- Are bags cleaned before opening?
- Tailings?
- Process Delays
  - Does product wait for a long time between steps?

Manufacturing Proce[redacted]ulas

- No requirements to provide them
  - Coke, secret sauce
- Especially important for allergens
- Is the labeling adequate?

Manufacturing Process Qu[redacted]ntrol



- Inspection System
  - Is product actually rejected?
- Laboratory Tests
  - What kind?
  - Why?
- Manufacturing Codes
  - For recall/complaints

[redacted]ation

- "Conditions whereby food may become contaminated with filth"
  - Filthy conditions
- "Whereby it may be rendered injurious to health"
  - Microorganisms

Sanitation Routes of Co[redacted]ation

- Insects - Tailings
- Rodents - Egress points
- Pesticides - Storage
  - Use
  - Exterminators
- Birds

Sanitation Microbiologi[redacted]erns

- Cross-contamination?
- Temperature/time abuses
- Cleaning

Sanit[redacted]orage

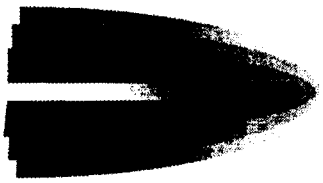
- Warehouse conditions
  - Temperature
  - First In/First Out (FIFO)
- Transportation Vehicles
  - Trucks
  - Trains
  - Barges

...ibution

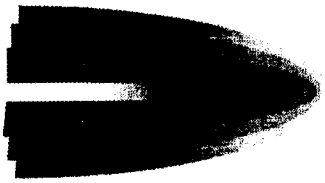
- Shipping
  - How?
  - Where?
- Promotion and Advertising
- Recall Procedure
- Complaints

cGMP of Inf...rmula

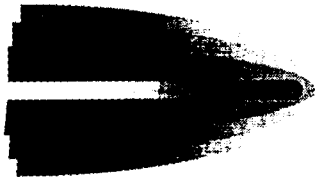
1. Manufacturing practices required of drug manufacturers



2. cGMP and quality control procedures:
   in-process controls
   sufficient personnel
   recordkeeping
   processing,
   packing
   holding of each infant formula
   nutrient stability testing



3. Controls to Prevent Adulteration by Workers
4. Controls to Prevent Adulteration Caused by Facilities
5. Controls to Prevent Adulteration Caused by Equipment or Utensil
6. Controls to Prevent Adulteration Due to Automatic (Mechanical or Electronic) Equipment
7. Controls to Prevent Adulteration Caused by Ingredients, Containers, and Closures



8. Controls to Prevent Adulteration During Manufacturing
9. Controls to Prevent Adulteration from Microorganisms
10. Controls to Prevent Adulteration During Packaging and Labeling of Infant Formula
11. Controls on the Release of Finished Infant Formula
12. Traceability
13. Audits of CGMP regularly scheduled audits

Quality Contro[illegible]dures

1. Introduction

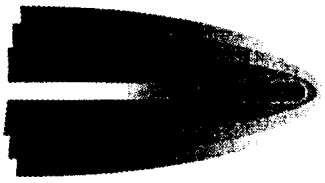
INGREDIENT CONTROL
IN-PROCESS CONTROL
FINISHED PRODUCT EVALUATION

2. Nutrient Testing

3. Stability Testing

4. Quality Control Records

5. Audits of Quality Control Procedures

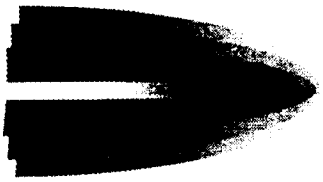


Conduct of Audits

Quality Factors for Infant Formulas

Records and Reports

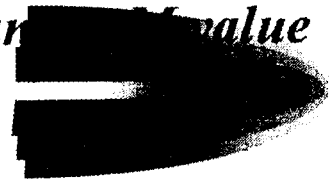
Registration, Submission, and Notification Requirements



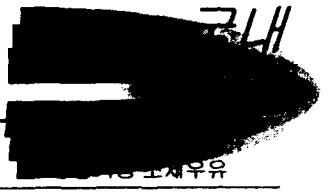
PART 106--INFANT FORMULA—

Requirements Pertaining to cGMP, Quality Control procedures, Quality Factores, Records and Reports, and Notifications

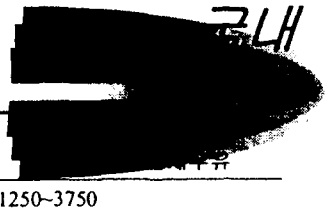
Microorgan[redacted]alue



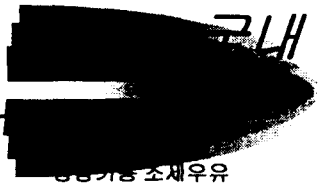
Aerobic Plate Count(APC).... 10,000CFU/gram (g)
Coliforms ..... 3.05 MPN/g.
Salmonella..... 0
Listeria monocytogenes..... 0
Staphylococcus aureus..... 3.05 MPN/g.
Bacillus cereus ..... 100 MPN/g or CFU/g.



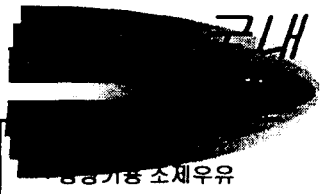
항목 \ 유형	조제분유·조제우유	[redacted] 조제우유
성상	고유의 색택과 향미를 가지고 이미·이취가 없어야 한다.	고유의 색택과 향미를 가지고 이미·이취가 없어야 한다
수분(%)	5.0 이하 (단, 액상제품 제외)	5.0 이하 (단, 액상제품 제외)
조단백질(%)	9.0~20.0	12.0~27.5
조지방(%)	15.0~30.0 (리놀렌산은 조지방 함량의 9.0% 이상이어야 한다)	15.0~30.0 (리놀렌산은 조지방 함량의 9.0% 이상이어야 한다)
유성분(%)	60.0 이상	60.0 이상



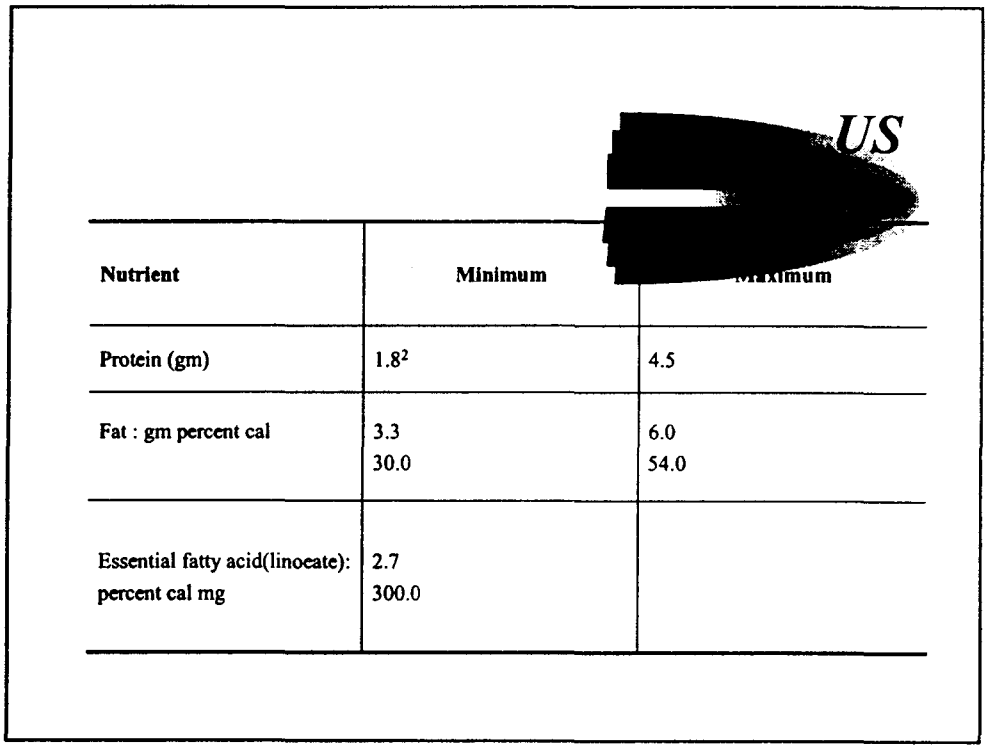
항목 \ 유형	조제분유·조제우유	[redacted] 조제우유
비타민A (IU/100g)	1250~2500	1250~3750
비타민D (IU/100g)	200~400	200~600
비타민C (mg/100g)	40 이상	40 이상
비타민B_1 (mg/100g)	0.20 이상	0.20 이상
비타민B_2 (mg/100g)	0.30 이상	0.30 이상
니코틴산 (μg/100g)	1250 이상	1250 이상
비타민B_6 (μg/100g)	175 이상	225 이상
엽산 (μg/100g)	20 이상	20 이상
판토텐산 (μg/100g)	1500 이상	1500 이상
비타민B_{12} (μg/100g)	0.5 이상	0.75 이상
비타민K_1 (μg/100g)	20 이상	20 이상
비타민E (IU/100g)	3.5 이상	3.5 이상



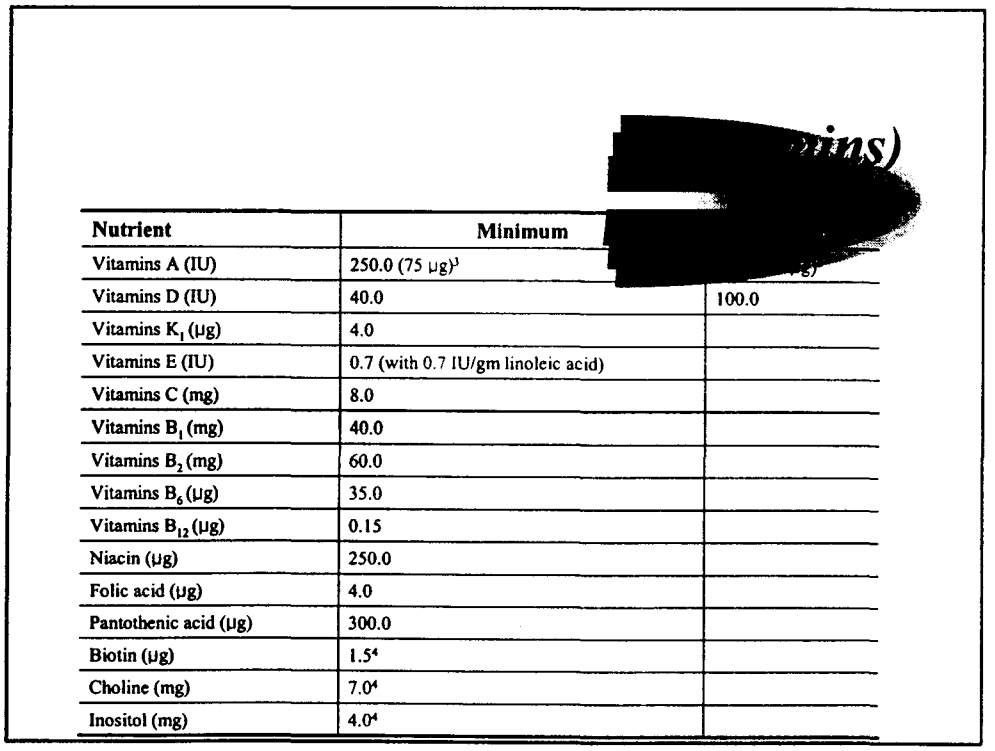
유형 / 항목	조제분유·조제우유	[redacted] 조제우유
나트륨 (mg/100g)	100~300	100~425
칼륨 (mg/100g)	400~1000	400 이상
염소 (mg/100g)	275~750	275 이상
칼슘 (mg/100g)	250 이상	450 이상
인 (mg/100g)	125 이상	300 이상
마그네슘 (mg/100g)	30.0 이상	30.0 이상
철 (mg/100g)	1.25 이상	5.0~10.0
요오드 (μg/100g)	25 이상	-
구리 (μg/100g)	300 이상	1500 이상
아연 (mg/100g)	2.5 이상	2.5 이상
망간 (μg/100g)	25 이상	25 이상



유형 / 항목	조제분유·조제우유	[redacted] 조제우유
인공감미료	검출되어서는 안된다.	검출되어서는 안된다.
타르색소	검출되어서는 안된다.	검출되어서는 안된다.
세균수	1g당 20000 이하 (조제우유는 음성이어야 한다.)	1g당 20000 이하 (조제우유는 음성이어야 한다.)
대장균군	음성이어야 한다.	음성이어야 한다.



Nutrient	Minimum	Maximum
Protein (gm)	1.8[2]	4.5
Fat : gm percent cal	3.3 30.0	6.0 54.0
Essential fatty acid(linoeate): percent cal mg	2.7 300.0	



Nutrient	Minimum	
Vitamins A (IU)	250.0 (75 µg)[3]	
Vitamins D (IU)	40.0	100.0
Vitamins K_1 (µg)	4.0	
Vitamins E (IU)	0.7 (with 0.7 IU/gm linoleic acid)	
Vitamins C (mg)	8.0	
Vitamins B_1 (mg)	40.0	
Vitamins B_2 (mg)	60.0	
Vitamins B_6 (µg)	35.0	
Vitamins B_{12} (µg)	0.15	
Niacin (µg)	250.0	
Folic acid (µg)	4.0	
Pantothenic acid (µg)	300.0	
Biotin (µg)	1.5[4]	
Choline (mg)	7.0[4]	
Inositol (mg)	4.0[4]	

...erals)

Nutrient	Minimum	...imum
Calcium (mg)	50.0[5]	
Phosphorus (mg)	25.0[5]	
Magnesium (mg)	6.0	
Iron (mg)	0.15	
Iodine (µg)	5.0	
Zinc (mg)	0.5	
Copper (µg)	60.0	
Magnesium (µg)	5.0	
Sodium (mg)	20.0	60.0
Potassum (mg)	80.0	200.0
Chloride (mg)	55.0	150.0

Regulations for Infant Fo...abels

- Preparation and use instructions include
  - Product storage
  - "Sterilization" of water, bottle, and nipples, when necessary
  - Dilution for powder and liquid concentrates, including pictogram showing major steps for preparation

(Source: Title 21 Code of Federal Regulations 107.20)

(S.A. Anderson, FDA)

Federal Regulations for Infant Fo[redacted]bels

- Other required information
  - "The health of your infant depends on carefully following the directions for preparation and use."
  - "Use as directed by a physician."
  - "Use by" date

(Source: Title 21 Code of Federal Regulations 107.20)

Examples of Manufacturers' Label Instructions for Powd[redacted]ulas

- Water Preparation
  - Bring water to a boil then cool to 100°F(40°C).
  - Boil additional water for formula to a rolling boil (approximately 1 minute), then let cool to lukewarm temperature.
  - Boil water for 5 minutes. Cool to a warm temperature (120° - 130° F)

(Source: Title 21 Code of Federal Regulations 107.20)

Examples of Manufacturers' Label Instructions for Powd[redacted]mulas

- Water Preparation
  - Ask your baby's doctor about infant formula use, including the need to boil water for formula, bottle, and nipple assembly. Pour desired amount of warm water into bottle.
  - Ask your baby's doctor if you need to boil (sterilize) water for formula and bottle preparations. Pour desired amount of warm water into bottle.

Examples of Manufacturers' Label Instructions for Powd[redacted]mulas

- Feeding and storage
  - Feed immediately or cover and refrigerate prepared formula. Use within 48 hours.
  - Cover prepared formula not used immediately. Store in refrigerator and use within 48 hours.

Examples of Manufacturers' Label Instructions for Powd[redacted]mulas

- Feeding and storage
  - Feed immediately or cover and refrigerate bottled formula to be used within 24 hours.
  - Feed immediately, or cover and refrigerate bottled formula until needed. Use within 24 hours.
  - Store in refrigerator until used. Use within 24 hours after mixing.

Examples of Manufacturers' Label Instructions for Powd[redacted]mulas

- Disposal of unused formula after feeding
  - Discard unused formula in bottle after feeding.
  - Throw away prepared formula left in feeding bottle or cup within one hour after feeding begins

Preparation of Formulas for Infants Guidelines for Health [redacted]

Recommendations developed by The American Dietetic Association (ADA)

2002 revised and abbreviated version:

http://www.eatright.org/formulaguide.html

Guidelines for Infant Formula Use for Nip[redacted]nfants

- Feed within 4 hours of preparation
- Cover and refrigerate for up to 24 hours
- If warmed, warming should take less than 15 minutes
- Discard any product remaining in bottle one hour after feeding begins

(Source: The American Dietetic Association, 2002)

Guidelines for Infant Formula Use for Tu[redacted]fants

- Feed within 4 hours of preparation
- Cover and refrigerate for up to 24 hours
- Intermittent (bolus)—Package in amounts for one feeding or for a 4-hour period
- Continuous—Hang time should not exceed 4 hours

(Source: The American Dietetic Association, 2002)

[redacted]mary

- Powders are not sterile products.
- Detailed Infant Formula regulation required.