



Infant formula: A comparison of legislation in the United States and Taiwan

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Infant Formula:

A Comparison of Legislation in the
United States and Taiwan

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The paper is submitted in satisfaction of the course requirement.

Abstract

This paper examines and contrasts the legal framework in the United States and comparable legislation in Taiwan. Prompted by the Syntex incident, the U.S. Congress passed the Infant Formula Act of 1980, and delegated the Food and Drug Administration (FDA) the authority to establish the regulations in order to safeguard the health of infant children. In contrast to the legislation history in the United States, Taiwan enacted the comparable law and established relevant regulations late in 2008. A comparison of these two legal systems reveals that the United States has a more comprehensive regulatory scheme for infant formula, while Taiwan focuses only on the sanitary conditions for infant formula manufacture. Besides, U.S. infant formula regulations have expanded and become more stringent while Taiwan's FDA (TFDA) only requires manufacturers to meet certain sanitary requirements, without mandating how to achieve them. Another difference is that the U.S. FDA does not require infant formula manufacturers to note that breastfeeding is more nutritious than infant formula on their product labels, but TFDA takes a firm stance and requires formula manufacturers to state on product labels that breast milk is more nutritious than formula.

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Infant Formula:

A Comparison of Legislation in the United States and Taiwan

Introduction

The first year of human life is marked by rapid development — cognitive, physical, social, and emotional. Infants double their weight between birth and four months and triple it by the age of one.¹ Thus, infants' nourishment, whether it is breast milk or infant formula, plays an important role in their development, and thus, the quality of infant formula on the market can greatly influence the long-term health and welfare of a nation's populace. While technological development has improved living conditions worldwide, it has also changed basic, traditional, healthy practices such as breast feeding. Over the past half century, increasing numbers of women have entered the workplace, which has subsequently decreased breastfeeding practices.²

For bottle-fed infants, infant formula is the sole source of nutrition to support their growth and development up to six months of age because their gastrointestinal and renal systems have not matured enough to digest other foods and fully absorb their nutrition. As a result, infant formula needs to be specially formulated so as to match the nutrients and qualities of mothers' milk to enable infants to receive

¹ Sue Ann Anderson et al., History and Current Status of Infant Formulas, 35 The American Society for Clinical Nutrition, 381, 387(1982).

² Martha A. Toll, Spilled "Milk": A Rebuttal to the United States Vote against the International Code of Marketing of Breast-Milk Substitutes, 2 B.U. Int'l L. J. 103, 105(1983-1984).

adequate nutrition. Based on this unique status, in 1981, the Codex Alimentarius Commission, part of both the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization, developed standards on infant formula.³ Therefore, more and more countries have realized that they need to regulate the manufacture, quality and sale of infant formula to protect their future generation.

This paper compares and contrasts the legal framework in the United States, which enacted the Infant Formula Act in 1980, and comparable legislation in Taiwan, which did not implement a similar act until 2008. Besides, this paper also examines the regulations established by the U.S. the Food and Drug Administration (FDA) and Taiwan's FDA (TFDA), and analyzes how it influences the practice of infant feeding in two countries. Based on the Center of Disease Control National Immunization Survey, in 2004, 42.1% of six month old infants in the United States were breastfed, and in 2008, 44.3% were breast fed⁴. The practice of infant feeding in the United States seems static. In contrast, in Taiwan, breastfeeding largely increased during the recent years; in 2004, only 19.82% of six month old infants were breastfed, but by 2011, 50.4% were breastfed⁵. It implies that the recent legislation and regulation in

³ Berthold Koletzko, *Standards for Infant Formula Milk*, 332 British Medical Journal 621, 622 (2006) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1403284/>

⁴ Centers for Disease Control and Prevention, *Breastfeeding Among U.S. Children Born 2000—2008*, CDC National Immunization Survey, CENTERS FOR DISEASE CONTROL AND PREVENTION http://www.cdc.gov/breastfeeding/data/NIS_data/index.htm (last updated: August 1, 2011)

⁵ Bureau of Health Promotion, *Breastfeeding Statistics*, BUREAU OF HEALTH PROMOTION (Mar. 15 2012) http://www.bhp.doh.gov.tw/breastfeeding/02qna_01.htm

Taiwan may have a strong impact on this change. This paper also examines the political forces that led to the enactment of these two different frameworks.

The forms of legislation and regulations that insure the nutrition and safety of infant formula reflect not only the attitude of a nation toward its “most precious resource – infant children”⁶, but also its distinctive national values. A comparison of these two legal systems reveals that the United States has a more comprehensive regulatory scheme for infant formula, while Taiwan’s falls short and focuses only on the sanitary conditions for infant formula manufacture. Furthermore, U.S. infant formula regulations have expanded and become more stringent since 1980, while TFDA, which suppresses infant formula sales, only requires manufacturers to meet certain sanitary requirements, without mandating how to achieve them. Another difference is that the U.S. FDA does not require infant formula manufacturers to note that breastfeeding is more nutritious than infant formula on their product labels, but TFDA takes a firm stance and requires formula manufacturers to state on product labels that breast milk is more nutritious than formula.

⁶ Infant Formula: Hearing before the Subcomm. on Oversight and Investigations of the Comm. on Interstate and Foreign Commerce, 96th Cong. 1 (1979).

The U.S. Infant Formula Act of 1980

Motivation for Its Enactment: The Syntex Incident

In 1979, two infant formulas, Neo-Mull-Soy and Cho-Free, both manufactured by Syntex Laboratories of California, were found to be greatly deficient in chloride, a chemical nutrient vital to infant development. According to a Committee on Labor and Human Resources report, although no infants died from consuming these two infant formulas, “over 130 infants who had consumed the formula suffered injury from potentially lethal and rare chemical imbalance in the blood known as hypochloremic metabolic alkalosis.”⁷

This tragedy was brought to light by pediatric nephrologist Dr. Shane Roy of the University of Tennessee.⁸ In 1979, Dr. Roy discovered that three infants he was treating for failure to develop normally were fed Neo-Mull Soy, a synthetic soy-based infant formula manufactured by Syntex Corporation of Palo Alto California. He called Syntex to check if they had any reported problems and was told they had none. He had the formula assayed, which showed that the chloride component was two milliequivalents per liter, only one-third of what the production information showed it should contain.⁹ Besides notifying Syntex, Dr. Roy also informed the county public

⁷ Comm. On Labor and Human Resources, Infant Formula Act of 1980, S. REP. No. 96-916, at 5 (1980)

⁸ Randal D. Shields, Food and Drug Law: The Infant Formula Act of 1980, 15 Akron L. Rev. 752, 753 (1981-1982).

⁹ The Subcomm. on Oversight and Investigations of the Comm. on Interstate and Foreign Commerce,

health department, which reported this to the Centers for Disease Control (CDC) in Atlanta.¹⁰ The CDC then conducted a national review and found that among 27 reported metabolic alkalosis cases in which a feeding history was available, 26 infants were on Neo-Mull-Soy (made by Syntex Laboratories of Palo Alto, California), the same formula consumed by babies in the three index cases reported by Dr. Roy (CDC). The CDC then reported this to the FDA.¹¹ During a subsequent hearing before the subcommittee of the Oversight and Investigations Committee in the summer of 1979, Dr. Roy testified that he had treated three infants, all of whom had failed to develop at normal rates. On August 1st, Syntex Corporation of Palo Alto, California, at the request of the FDA, initiated a voluntary and low-key recall of Neo-Mull-Soy infant formula.¹²

Subsequent investigations carried out by the U.S. Senate's Subcommittee on Oversight and Investigation of the Comm. on Interstate and Foreign Commerce, and the Subcommittee on Health and Scientific Research of the Committee on Labor, concluded that multiple factors led to this tragedy:¹³

- Syntex Cooperation failed to establish an adequate quality-control procedure to assure that the infant formulas contained necessary nutrients as

supra note 5, at 6-7.

¹⁰ Id. at 7.

¹¹ Id. at 9.

¹² Id. at 2.

¹³ Comm. On Labor and Human Resource, supra note 6, at 3-4.

recommended by the American Pediatric Association.

- The FDA had not listed chloride in its catalog of vital nutrients for infant formula, ignoring the 1976 recommendation of the American Academy Pediatrics.
- The FDA failed to implement and monitor an immediate and complete recall of Neo-Mull-Soy and Cho-Free infant formulas, which were still on the market three months after the start of the voluntary recall.
- Syntex did not fully cooperate with the FDA to fully recall and oversee the recall of Neo-Mull-Soy and Cho-Free formulas.

Actually, Neo-Mull-Soy and Cho-Free were not the only two infant formulas that were recalled by manufacturers in 1979. In the same year, four infant formulas were recalled — Neo-Mull-Soy, Cho-Free and Soyalac, manufactured by Loma Linda Foods, were recalled because of lack of adequate amounts of chloride, and SMA, manufactured by Wyeth Laboratories, was recalled due to the poor processing which caused many infants sick.¹⁴ As a result, parents' confidence in commercial infant formulas was severely shaken, and the need for legislation to safeguard the quality and safety of infant formulas prompted the U.S. House of Representatives

¹⁴ Infant Formula Act of 1980: Hearing before the Subcomm. on Health and Scientific Research of the Comm. On Labor and Human Resources, 96th Cong. 1 (1980).

Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, in November 1979 to immediately enact legislation to:¹⁵

- Create a separate category of food designated as “infant formula”, to include products intended to provide a nutritionally adequate diet to infants.
- Require that infant formulas contain all nutrients recognized as essential by the American Pediatric Association.
- Require that all products labeled “infant formula” contain the essential nutrients.
- Require that all infant formulas be tested for their nutritional adequacy before marketing and after any changes made in the formula or manufacturing process.
- Require that recalls of infant formula be conducted as FDA Class I recalls, which indicate a potential for serious adverse health consequences or death.
- Grant the FDA the authority in infant formula recall situations to inspect a manufacturer’s records and to enforce compliance with recall directives.
- Require that 100 percent of consignees be contacted during infant formula recalls, a procedure that the FDA defines as a “Level A effectiveness check”.

¹⁵ Id. at 5.

The Content of the 1980 Infant Formula Act

Pushed by the urgent need of legislation following the Syntex case, the U.S. House passed the bill on 20th May 1980, which the Senate subsequently amended and passed on 8th September, 1980; the House immediately concurred on the Senate's amendment on 9th September 1980, which resulted in the Infant Formula Act (HR 6940, Public Law 96-359), signed into the law by President Jimmy Carter on 26th September 1980.¹⁶ In signing the Act, President Carter said, "This legislation recognizes that our most important resource for the future — our children — should be afforded safe and nutritionally adequate formulas during a critical period of development."¹⁷

The Infant Formula Act creates a unique legal category of food designated as "infant formula". According to 21 U.S.C §321 (aa), the term *infant formula* is "a food which purports to be or is represented for special dietary use solely as food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." It specifies minimums, and some maximums, of the amount of protein, fat, essential fatty acids, vitamins, and minerals and their

¹⁶ Infant Formula Act of 1980, Pub. L. No. 96-359, 94 Stat. 1190, 1195 (1980) (codified as amended at 21 U.S.C 301).

¹⁷ Jimmy Carter, *Infant Formula Act of 1980 Statement on Signing H.R. 6940 Into Law*, THE AMERICAN PRESIDENCY PROJECT, <http://www.presidency.ucsb.edu/ws/index.php?pid=45151#axzz1pPvkngBM> (last visited: Mar. 17, 2012) Read more at the American Presidency Project: [www.presidency.ucsb.edu http://www.presidency.ucsb.edu/ws/index.php?pid=45151#ixzz1pPxW6qU0](http://www.presidency.ucsb.edu/ws/index.php?pid=45151#ixzz1pPxW6qU0)

densities.¹⁸ In view of development of knowledge of nutrients and health, it also grants the Secretary of Health and Human Services Dept. authority to revise the list of nutrients and their required densities and levels for infant formula when necessary.¹⁹ In addition, to assure the safety of infant formulas, the Secretary is empowered to establish quality factors²⁰, quality control procedures²¹, recall requirements²², record keeping²³ and any infant formula exemptions for special types of infant formulas²⁴ under the Infant Formula Act. If an infant formula fails to contain the required nutrients or meet the quality requirements, or if a company fails to process the formula in compliance with the quality control requirements, it will be deemed adulterated.²⁵

The U.S. Congress set definite nutrient requirements for infant formulas, rather than grant the FDA comprehensive authority to make these rules, apparently responding to the urgent need to set clear criteria for the FDA's implementation.²⁶ The Committee on Labor and Human Resources persuaded Congress that "it would be an irresponsible public policy to permit the effective establishment of formula safety

¹⁸ Infant Formula Act of 1980, *supra* note 17 Sec. 412. (a)(1)(A), (g).

¹⁹ *Id.* Sec. 412. (a)(2)(A), (B).

²⁰ *Id.* Sec. 412. (a)(2)(C).

²¹ *Id.* Sec. 412. (a)(2)(D).

²² *Id.* Sec. 412. (d)(2).

²³ *Id.* Sec. 412. (e)(2).

²⁴ *Id.* Sec. 412. (f)(2).

²⁵ *Id.* Sec. 412. (a)(1).

²⁶ Toby Milgrom Levin, *The Infant Formula Act of 1980: A Case Study of Congressional Delegation to the Food and Drug Administration*, 42 Food Drug Cosm. L. J. 101,114(1987.)

and quality standards to be delayed one or two years due to the procedural requirements of the rule making process.”²⁷ Thus, Congress accepted the 1976 recommendation of the American Academy of Pediatrics to list all required nutrients in the nutrient table in the Act, and ask the Secretary of Health and Human Services to work in concert with the Committee on Nutrition of the American Academy of Pediatrics (CON/AAP), the infant formula industry, the Codex Alimentarius Commission and others to update the nutrient table in the Act regularly. Later, in October 1985, referring to the 1983 recommendation of CON/AAP and the Codex Alimentarius Commission’s International Standard of Infant Formula, the FDA updated the nutrient requirements of infant formula.²⁸

- Under subsection (c)(1) of the Act, infant formula manufacturers must promptly notify the Secretary of HHS if they have reasonable knowledge that their formula does not contain nutrients in compliance with those required under the FDA, or may be otherwise adulterated or misbranded, and could jeopardize human health.²⁹ Further, under subsection (b)(3), after a manufacturer changes a formula’s ingredients or percentage of ingredients, or processing, changes that the manufacturer can reasonably determine

²⁷ The Subcomm. on Health and Scientific Research of the Comm. on Labor and Human Resources, *supra* note 13, at 21.

²⁸ Nutrient Requirements for Infant Formulas, 50 Fed. Reg. 45,106, 108(Oct. 30, 1985)(to be codified at 21 C.F.R Pt. 107)

²⁹ Infant Formula Act of 1980, *supra* note 15, Sec. 412. (c)(1).

could influence whether the formula is adulterated, the manufacturer should notify the Secretary that:

- The nutrients in the infant formula meet the standards in the nutrient table in the Act.
- The infant formula complies with the FDA's quality factor requirements.
- The infant formula processing conforms to the FDA's quality control procedure.³⁰

The addition of these notification provisions could be Congress's response to the Syntex incident, which many people believed was caused by the FDA's failure to monitor the nutrient levels in infant formula, which led to the 1979 tragedy.³¹

However, under the Infant Formula Act, the FDA does not have the power to mandate infant formula recalls. The initiation of a recall remains up to the manufacturer's discretion. Nonetheless, the FDA can establish the scope and extent of the recall.³²

There is a time limit of days after the beginning of a recall and every 15 days afterwards until the recall is completed³³, allowing FDA to review whether the manufacturer conforms to the regulations.

³⁰ Id. Sec. 412. (b)(3).

³¹ Randal D. Shields, Food and Drug Law: the Infant Formula Act of 1980, 15 Akron L. Rev. 752, 755(1981-1982).

³² Infant Formula Act of 1980, *supra* note 15 Sec. (d)(2).

³³ Id. Sec. 412. (d)(1).

The 1986 Amendment to the Infant Formula Act

Although the U.S. Congress, in establishing the Infant Formula Act of 1980, granted the FDA authority to establish regulations relating to infant formula nutrient requirements, quality control procedures, labeling requirements, exemption status, and recalls, it was not satisfied with the consequent regulations set by the FDA. Moreover, in early 1982 a vitamin B6-deficient Nursoy concentrated liquid and Nursoy ready-to-feed infant formula, manufactured by Wyeth Laboratories, shattered the public's already fragile confidence in infant formula.³⁴ Thus, Congress took another step to specify the level of the FDA's regulatory control so as to better protect the public health.³⁵ Consequently, the 1986 Amendment was passed by both the House and the Senate and signed by President Ronald Reagan on 27th October 1986.

The 1986 amendment modified the Infant Formula Act of 1980, by:³⁶

- Deeming an infant formula to be adulterated unless it provides certain required nutrients, meets the quality requirements established by the Secretary of Health and Human Services and is manufactured in accordance with Current Good

³⁴ Infant Formula: the Present Danger: Hearing before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce , 97th Cong. 10-11 (1982).

³⁵ Toby Milgrom Levin, *supra* note 24 ,118.

³⁶ Infant Formula Act Amendment of 1986, Pub. L. No. 99-570, 100 Stat. 3207- 116, (1980) (codified as amended at 21 U.S.C 301)

Manufacturing Processes (CGMP) and quality control procedures established by the Secretary of Health and Human Services;

- Requiring that the Secretary issue regulations establishing requirements for quality factors and CGMP, including quality control procedures;
- Requiring that infant formula manufacturers regularly audit and examine their operations to ensure that they comply with CGMP and quality control regulations;
- Expanding the circumstances in which manufacturers must make a submission to notify the FDA to include when a manufacturer makes major changes in an infant formula, and when a manufacturer makes changes that may affect whether the formula is adulterated;
- Specifying the nutrient quality control testing required on each batch of infant formula;
- Modifying the infant formula recall requirements; and
- Giving the Secretary authority to establish requirements for retention of records, including records necessary to demonstrate compliance with CGMP and quality control procedures.³⁷

³⁷ Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula, 61 Fed. Reg.

FDA regulations relating to infant formula

In 1982, the FDA delegated through the Infant Formula Act adopted Infant Formula Recall Procedures in subpart D of 21 CFR part 107 of its regulations³⁸ and Infant Formula Quality Control Procedures in subpart B of 21 CFR part 106³⁹. In 1985, the FDA further implemented the Infant Formula Act by establishing subparts B⁴⁰, C⁴¹, and D⁴² in 21 CFR part 107 regarding the labeling of infant formula, exempt infant formulas, and nutrient requirements for infant formula respectively. Prompted by the 1986 Amendment, in 1989, the FDA established subpart E in 21 CFR part 107⁴³; in 1991 the FDA implemented the provisions on record and record retention requirements by revising 21 CFR 106.100⁴⁴, as detailed below.

However, the FDA to date has not fully responded to the 1986 Amendment in terms of establishing good manufacturing practices. The FDA proposed a set of regulations relating to “Current Good Manufacturing Practices, Quality Control

36154-01(1996)

³⁸ Infant Formula Recall Procedures, 47 Fed. Reg. 18,832 (Apr. 30, 1982)(to be codified at 21 C.F.R. Pt. 106)

³⁹ Infant Formula Quality Control Procedures, 47 Fed. Reg. 17,016 (Apr. 20, 1982)(to be codified at 21 C.F.R Pt. 106)

⁴⁰ Infant Formula: Labeling Requirements, 50 Fed. Reg. 1,833 (Jan. 14, 1985)(to be codified at 21 C.F.R Pt. 105, 107)

⁴¹ Exempt Infant Formula, 50 Fed. Reg. 48,183, (Nov. 22, 1985)(to be codified at 21 C.F.R. Pt. 107)

⁴² Nutrient Requirements for Infant Formulas, 50 Fed. Reg. 45,106, (Oct. 30, 1985)(to be codified at 21 C.F.R Pt. 107)

⁴³ Infant Formula Recall Requirements, 54 Fed. Reg. 4,006, (Jan. 27, 1989)(to be codified at 21 C.F.R Pt. 107)

⁴⁴ Infant Formula Record and Record Retention Requirement, 56 Fed. Reg. 66,566,(Dec. 24, 1991) (to be codified at 21 C.F.R Pt.106)

Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula” in 1996⁴⁵, but incredibly, it has not yet announced the final rules. Because of the complexity of infant formula manufacturing procedures and the continually advancing knowledge on best nutrients for infant formulas, the FDA has received abundant comments on the proposed regulations and has indicated that integrating all of these recommendations is quite cumbersome. Thus, after publishing the proposed regulations in 1996, the FDA reopened the comment period twice, and the last which ended 15th September 2006. Earlier 2012 the FDA had announced that it had planned to announce the final rules of “Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula.”⁴⁶

As of end of February 2012, the FDA’s regulations on “infant formula quality control procedures” were still primarily based on the content of the Infant Formula Act of 1980, without being revised; Besides the FDA deferred to the infant formula industry’s comments to a great extent by revising the proposal to remove “unnecessary details” and to eliminate “unnecessary” sampling and testing requirements.⁴⁷ With regards to ingredient controls, if an ingredient is considered

⁴⁵ Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula, *supra* note 36.

⁴⁶ Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions, 77 Fed. Reg. 7664-01(2012)

⁴⁷ Infant Formula Quality Control Procedures, *supra* note 38, at 17020.

generally stable on shipping and storage, or if a supplier guarantees that the nutrient composition has been analyzed, or if the formula is labeled as having a certificated nutrient composition, then there is no need for the manufacturer to analyze the ingredients before manufacture.⁴⁸ Thus, “a manufacturer may handle raw materials in any reasonable manner.”⁴⁹ Regarding in-process controls, the current regulations require the infant formula manufacturer to implement a quality control system to verify the addition of each ingredient⁵⁰, but the manufacturer maintains the flexibility to design a system most suitable to its needs.⁵¹ Concerning product evaluation, the manufacturer has the authority to establish the criteria for sampling and testing each batch of infant formula prior to distribution.⁵²

Under subpart C of 21 CFR part 106, the manufacturer should maintain all records pertaining to “food-packaging material,”⁵³ “nutrient premix testing,”⁵⁴ “compliance with proper quality control procedure,”⁵⁵ “required nutrients at the final product stage,”⁵⁶ “distribution of infant formula,”⁵⁷ “the microbiological quality and purity of raw materials and finished powdered infant formula,”⁵⁸ “audit plans and

⁴⁸ Infant Formula Quality Control Procedures, 21 C.F.R Pt. 106.20(a)(2011).

⁴⁹ Infant Formula Quality Control Procedures, *supra* note 38, at 17020

⁵⁰ Infant Formula Quality Control Procedures, *supra* note 47, 106.25(a).

⁵¹ Infant Formula Quality Control Procedures, *supra* note 38, at 17021.

⁵² Infant Formula Quality Control Procedures, *supra* note 47, 106.30(a).

⁵³ *Id.* 106.100(b).

⁵⁴ *Id.* 106.100(c).

⁵⁵ *Id.* 106.100(e).

⁵⁶ *Id.* 106.100(f).

⁵⁷ *Id.* 106.100(g).

⁵⁸ *Id.* 106.100(h).

procedures,”⁵⁹ and a file regarding “infant formula complaints”⁶⁰. This subpart was a response to the 1986 Amendment aimed to ensure a safe, wholesome and sanitary source of nutrients for infants. On the other hand, in an effort not to unduly burden the manufacturers, the FDA specified that “infant formula manufacturers need not obtain from upstream companies and that infant formula manufacturer cannot be expected to obtain all premix testing records.”⁶¹ In effect, the premix supplier holds the obligation to retain all records necessary to confirm the accuracy of premix certifications and guarantees of analysis.⁶²

Under subpart B of 21 CFR part 107, the FDA specified that infant formula labels should contain: 1) a table nutrients; 2) a “use by” date; 3) a warning statement of improper preparation and use of infant formula; 4) a statement that the infant formula should be used as directed by physicians; and 5) directions for preparation and use.⁶³ The FDA does not require manufacturers to include bilingual directions for formula preparation and use, but requires manufacturers to use proper symbols and pictograms to illustrate the boiling, measuring, and mixing of water with a measured amount of concentrated or powered infant formula, which should also be understandable for consumers who do not speak English. As for ready-to-feed infant

⁵⁹ Id. 106.100(i).

⁶⁰ Id. 106.100(k).

⁶¹ Infant Formula Record and Record Retention Requirement, *supra* note 43.

⁶² Infant Formula Quality Control Procedures, *supra* note 47, 106.100(d).

⁶³ Infant Formula, 21 C.F.R Pt. 107.10, 107.20(2011)

formulas (those that do not require mixing with water), only more essential information necessary for preparation and use is required on the individual containers, but the rest of information can appear on the outer label of the multiunit packages.⁶⁴

In addition, the FDA established terms and conditions in the subpart C of 21 CFR part 107 under which formulas geared for infants with special medical and dietary needs can be exempted from the requirements set by FDA. The FDA sorted exempted infant formulas by their availability at the retail level: manufacturers of exempt infant formula generally available at the retail level should comply with the requirements for nutrients, quality control procedures and labeling for regular infant formulas established by the FDA, unless specific deviations are justified; manufacturers of exempted infant formulas generally not available at the retail level should establish an appropriate quality control procedure to ensure infant formula meets applicable nutrients, including any special nutritional needs for the specific disorders or conditions for which the formula is intended.⁶⁵

In order to comply with the 1986 amendment, the FDA revised its recall requirement for infant formula in the subpart E of 21 CFR part 107 to:

- Specify recall procedures that should be used by manufacturers in removing from the marketplace adulterated and misbranded infant formula

⁶⁴ Id. 107.30.

⁶⁵ Id. 107.50.

that the FDA had determined may present a risk to human health;

- Require a manufacturer recalling an infant formula that presents a risk to human health to request that each retail establishment at which infant formula is sold or available for sale post a notice of such recall; and
- Establish infant formula distribution records retention requirements.⁶⁶

In sum, with respect to the administrative policy for infant formula, the FDA has become stricter; its infant formula regulations have become more detailed and stringent. Along with this trend, the upcoming regulations on “Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula” stand a good chance of containing more particulars.

With the United States’ regulatory system outlined, we now examine Taiwan’s regulatory scheme on infant formula.

⁶⁶ Infant Formula Recall Requirements, *supra* note 42.

Taiwan's Food Sanitation Act and Regulations on Infant Formula

Taiwan's Food Sanitation Act

Compared to the legislative history of infant formula in the United States, Taiwan recognized the specific characteristics of infant formula relatively later. While Taiwan's Congress passed the Food Sanitation Act in 17th January 1973, it does not apply to infant formula. It took until May 2008 for Taiwan's Congress to revise the Food Sanitation Act and add two clauses that give infant formula legal standing.⁶⁷

However, the Food Sanitation Act defines “infant formula” only as a “special dietary food” that is nutritionally balanced or has added nutrients, to be consumed by people with special nutrient requirements⁶⁸; it delegates Taiwan's Department of Health to prescribe restrictions on the scope, methods and venues of advertising for special dietary foods.⁶⁹ The Food Sanitation Act, the only statute concerning infant formula, does not specify any nutrient or processing requirements. In other words, Taiwan still does not regard infant formula as a special category of food, as does the United States. Taiwan's Food Sanitation Act treats infant formula as other food by

⁶⁷ Legislative Yuan, Legislative history of the Food Sanitation Act in Taiwan (2008), available at [http://lis.ly.gov.tw/lcggi/lglaw?@6:1804289383:f:NO%3DE02513*%20OR%20NO%3DB02513\\$\\$10\\$ \\$\\$NO-PD](http://lis.ly.gov.tw/lcggi/lglaw?@6:1804289383:f:NO%3DE02513*%20OR%20NO%3DB02513$$10$ $$NO-PD).

⁶⁸ Food Sanitation Act of Taiwan §2, available at <http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0040001>.

⁶⁹ Id. §19.

authorizing Taiwan's Department of Health to establish regulations on the sanitation, safety and quality standards of infant formulas.

Taiwan's Infant Formula Sanitation Criterion Regulation

Based on Food Sanitation Act, TFDA was authorized by Department of Health to establish Infant Formula Sanitation Criterion Regulation on 2nd July 2009.⁷⁰ This regulation does not specify sanitation criteria in detail. Instead it solely sets a brief standard for the sanitation of infant formula, including the total number of bacteria allowed in the standard plate count procedure, and no *Escherichia coli*, no *Enterobacter sakazakii*, no hormones, no antibiotics, no radioactive substances, no pesticides or pesticide residues, no aflatoxin, or any other foreign substances.

TFDA ordinances

On 27th December 2001, Taiwan's Department of Health issued an ordinance requiring that all manufacturers of foods that are considered special dietary foods, including infant formula, register their products with TFDA. Under the regulation,

⁷⁰ Infant Formula Sanitation Criterion Regulation, Dep. of Health of Executive Yuan of Taiwan (2009), available at <http://law.moj.gov.tw/LawClass/LawAll.aspx?PCode=L0040087>.

infant formula manufacturers, among other manufacturers of dietary supplements, such as vitamins, must acquire TFDA approval to register a new infant formula. To register, a manufacturer must submit the following documents: 1) an ingredient list; 2) a product specification report, 3) a nutrient analysis report; 4) an official certificate that shows the product is being sold or used by other countries, or related clinical trial reports of the product; 5) a copy of summarized diagram on manufacturing process; 6) a summary and diagram of the manufacturing process; 7) an official certificate issued by Ministry of Economic Affairs, R.O.C. that verifies the legitimacy of the original manufacturer; 8) two copies of the label, outer package, inserted instruction and Chinese label of the product; 9) a copy of the applicant's [the manufacturer's] business license ; 10) a sample of the intact product.⁷¹

TFDA has created an online database that enables the public to look up whether an infant formula is approved by TFDA. As of February 23, 2012, 95 types of infant formula had been approved by TFDA, most of which are manufactured by foreign manufacturers.⁷² As to the labeling of infant formula, TFDA designed a logo as Fig.1 and ordered that all manufacturers of approved infant formulas place this logo, which contains two sentences — “Breastfeeding is healthier for infants” and “The

⁷¹ No. 0900080575 Ordinances of Dep. of Health of Executive Yuan of Taiwan (2001).

⁷² Food and Drug Administration of Taiwan, Infant Formula Database, (Feb. 23 2012), <http://consumer.fda.gov.tw/Food/BabyFood.aspx?nodeID=291#>

Department of Health cares about you” — on all packages and containers.⁷³ In 2003 TFDA issued another ordinance prohibiting any retailer or manufacturer or wholesaler from advertising and promoting infant formula; it explained that this policy is aimed to encourage breastfeeding.⁷⁴

Taiwan’s National Standards on Infant Formula

In contrast to the U.S.’s FDA, TFDA does not have the authority to establish standards for infant formulas. In Taiwan, the Bureau of Standards (BOS) has the power to set the standards (e.g., purity, nutrient content, manufacturing processes, and labeling) on infant formula. First, the BOS promulgated standards on infant formula in 1980 by establishing mandatory infant formula criteria including “essential ingredients and quality factors,” “food additives,” “contaminants,” “packaging,” “container,” and “labeling”.⁷⁵ Over the past three decades, the BOS, referring to Codex Standard, put forth by the Codex Alimentarius Commission, revised its standards in March 1984, March 1988, September 1988, August 1993, and November 2008.

⁷³ No. 0900011671 Ordinances of Dep. of Health of Executive Yuan of Taiwan (2001).

⁷⁴ No. 0920313122 Ordinances of Dep. of Health of Executive Yuan of Taiwan (2003).

⁷⁵ National Standards of the Republic of China (CNS) no. 6849, Bureau of Standards, Metrology and Inspection of Executive Yuan of Taiwan (Promulgated in 1980, and revised in March 14th 1984, March 22nd 1988, 14th Sep 1988, Aug 23th 1993, Nov 21st 2008).

Comparison of the U.S. and Taiwan's Legal framework of Infant

Formula

Generally speaking, the United States has a comprehensive scheme of regulating infant formula, and Taiwan divides its regulations between TFDA and BOS.

When the U.S. Congress enacted the Infant Formula Act of 1980, the U.S. FDA was assigned comprehensive authority to regulate the manufacture of infant formula, while TFDA and BOS share the authority of regulating the manufacture of infant formula. Under the U.S. regulatory model, infant formula manufacturers know who regulates what aspects of infant formula, and if they have questions about the regulations or want to make suggestions to improve the infant formula industry, they clearly know with whom to communicate.

In contrast, in Taiwan, manufacturers and distributors of infant formula face a bit more confusion with both the BOS and TFDA sharing the authority over the manufacture, purity and safety of infant formula. On the one hand, Taiwan's BOS borrows indiscriminately from the Codex Alimentarius Commission's experience to establish standards for infant formula, and on the other hand, TFDA has the duty not

only to implement the standards set by Taiwan's BOS and to supervise manufacturers' compliance with these standards, but also the duty to oversee compliance with the Infant Formula Sanitation Criterion Regulation and issue the ordinances relating to labeling and promotion of infant formulas. However, the scope of TFDA's authority is not well-defined. Sometimes infant formula manufacturers are not sure as to which authority regulates their products and to whom they should direct specific questions or complaints. On Nov. 26, 2010 TFDA announced on its official website that if the standards set by BOS are in conflict with any ordinances issued by TFDA, the ordinances issued by TFDA should applied. Nonetheless, this announcement is not backed up or confirmed by BOS or any other government body so far.

Moreover, since the U.S. FDA is the only agency with the power to establish regulations and to implement its policy, it is easier for the FDA to identify and remedy the pitfalls of its regulations and close any loopholes. However, while Taiwan's BOS enjoys the power to set the standards of "essential ingredients and quality factors of infant formula", "food additives," "contaminants," "packaging," "container," and "labeling," TFDA is charged with carrying out the standards in practice. Hence, when TFDA discovers loopholes in the regulations and assumes the costs and endures the public pressure in executing the regulations, it has no authority

to revise the standards. Consequently, TFDA must assume the burden of persuading the BOS to revise its standards, which though time-consuming and burdensome, is part of its official responsibilities.

Further, in the United States infant formula enjoys a unique status of food. In this context, the U.S. FDA has a well-established, clear, and systematic framework to regulate all aspects of infant formula. Under 21 CFR part 106 and 107, the U.S. FDA specifies required quality control procedures, records and reporting systems, notification requirements, formula labeling, exemption, nutrient requirements and recall processes and regulations. At the same time, infant formula has not yet become an independent category of food in Taiwan, but is classified under “special dietary foods”. In terms of establishing regulations and issuing ordinances, TFDA gives great weight to infant formula production sanitation standards, labeling and promotion of infant formula, but it fails to systematize all its regulations and ordinances.

In sum, the United States has a relatively comprehensive, clear and efficient framework to govern infant formula production, distribution, and marketing based on its legal authority and set of regulations. Taiwan’s regulatory system, in contrast, does not classify infant formula as a unique food category, though it does consider it a dietary supplement. In effect, Taiwan’s infant formula regulatory system is quite confusing for manufacturers. Furthermore, since Taiwan has two legal authorities that

regulate infant formula, and scattered regulations, even more confusion results for manufacturers.

Over several decades, the U.S. FDA transformed its regulatory policy from relatively loose, or weak control to stricter regulations that mandate compliance in all areas of formula manufacturing, marketing and labeling, while TFDA has chosen to address only a few major areas of infant formula.

In 1982, while establishing 21 CFR part 106, TFDA repudiated its own originally proposed regulations by eliminating some details in order to “permit each manufacturer to adopt the system that is best suited to its needs.”⁷⁶ In its proposed rules, the FDA expatiated on the sampling, testing, analysis, operations control, and recordkeeping for in-process and completed formulas, and required manufacturers to establish an acceptance protocol for ingredients, an in-process operational control program, and a finished product evaluation system.⁷⁷ After receiving several comments from the infant formula manufacturers during the public comment period, the FDA agreed that the proposed rules required unnecessary details. Hence, the FDA revised the proposed rules by stating only the objectives without specifying how they should be achieved.

The 1986 Amendment was a turning point in the U.S. FDA’s regulatory

⁷⁶ Infant Formula Quality Control Procedures, *supra* note 38.

⁷⁷ Proposed Infant Formula Quality Control Procedures, 45 Fed. Reg. 86,362 (Dec. 30, 1980).

approach to infant formula. Dissatisfied with the FDA's regulations and implementation of the Infant Formula Act, Congress explicitly required that the FDA issue regulations establishing requirements for quality factors and CGMP, including quality control procedures, and it also tightened its infant formula recall requirements. Consequently, the subsequent rules established by the FDA contained more details and were more stringent. The proposed rules of "Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula" in 1996 is a good example of the tightened requirements for manufacturing infant formulas. Consequently, this change of regulatory policy reduced the industry's freedom to design its own manufacturing, quality control and labeling regime and forced it to comply with stricter standards.

In contrast to the U.S.'s regulatory tightening, TFDA embraced a skeleton method of addressing its rules. Infant Formula Sanitation Criterion Regulation set only sanitation goals without mandating any manufacturing best practices or quality control procedures. In addition, all the ordinances do no more than tell manufacturers what the standards are, rather than how to achieve those standards and they do not provide for the enforcement of these standards. Perhaps this outcome is due to the fact that Taiwan's Congress and TFDA have chosen not to recognize infant formulas as a

special food or unique food category as the United States has done.

Although Taiwan has a weak infant formula regulatory system, it does not mean that the administration has decided to completely rely on industry self-regulation. For example, despite the slim rules, TFDA mandates that no infant formula can be marketed without TFDA analysis and approval of such infant formula. Thus, if a manufacturer wants to enter Taiwan's infant formula market, it holds the burden of persuading TFDA that its infant formula meets all the standards set by TFDA. In contrast, in the United States, infant formula manufacturers are required to notify the FDA 90 days prior to marketing a new formula and submit written verifications that summarize test results demonstrating that its infant formula complies with specific FDA requirements after its first production batch and before its introduction into interstate commerce.

Following this analysis of infant formula regulatory systems in the United States and Taiwan, which approach is better for the welfare of infants remains inconclusive. On one hand, systematic and detailed regulations require manufacturers to meet the standards, ensuring the nutrient quality, safety and sanitation of infant formulas. On the other hand, it takes a longer time and more resources to collect comments; analyze the feasibility of the regulations; integrate different opinions and establish the rules. For instance, after the U.S. Congress passed the 1986 Amendment, it took the FDA

almost ten years to propose the “Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula”. And since the proposed rules was published in the Federal Registrar in 1996, the FDA reopened the comment period twice and so far the final rules have not yet been announced.

In comparing the two nations’ approaches to regulating the manufacture of infant formula, it is evident that the United States assumes that people know what is best for their children and is careful not to intrude on manufacturers’ right to expression, but TFDA prioritizes public policy and to some extent restricts manufacturers’ right to express themselves.

First, in the United States, the FDA does not require infant formula manufacturers to place labels on formula stating that breastfeeding provides more health benefits than infant formula. During the comment period of 21 CFR Part 107 Subpart B, some suggested that there should be a label on formula containers informing consumers that breastfeeding is recommended by physicians and offers the most healthy form of nourishment for infants. The U.S. FDA responded that no studies or data unequivocally find that infant formula labeling that states benefits of breastfeeding encourages the practice of breastfeeding or deters women from using formula. In addition, requiring a statement encouraging breastfeeding may cause

mothers who have decided not to breastfeed their infants to feel guilty or inferior because of their decision to use formula⁷⁸

Although the fact that breast-milk contains the most suitable nutrients for infants prevailed in the U.S. when the Infant Formula Act was first established in 1980, the U.S. FDA was reluctant to mandate that such public information be required on infant formula containers sold in the United States. In strong contrast, in 2001, the TFDA issued an ordinance requiring formula manufacturers not only to put a logo (Fig. 1) containing an image of a mother nursing a baby, but also to include “Breastfeeding makes infants healthier” and “The Department of Health cares about you” on the labels of every container of formula. In addition, TFDA in 2003 took a further step to promote breastfeeding by restricting the promotion or advertisements of infant formulas in a drugstores or and retail shops. TFDA thus reflects an attitude of paternalism to safeguard the nutrition for all infants. In comparison the U.S. seems more interested in protecting the infant formula industry.

Conclusion

U.S. regulation of infant formula manufacturing and sale has its unique history

⁷⁸ Infant Formula: Labeling Requirements, *supra* note 39, at 1838.

and background, as does Taiwan's case. Learning from the Syntex case, the U.S. Congress moved to acknowledge the unique characteristics of infant formulas, and gave formula a separate designation than other foods. And responding to public opinion, Congress enacted the Infant Formula Act of 1980 and empowered the FDA to make and implement regulations to ensure that infant formula manufactured and sold in the United States is nutritious, safe and manufactured under hygienic conditions. However, despite its wide ranging regulations and rules, the U.S. FDA appears to have confidence in the self-regulation of the infant formula industry and allows them to exercise their rights to expression.

Without a tragedy like Syntex to prompt Taiwan to regulate infant formula, Taiwan began promulgating regulations later compared to 1980 for the United States. Although it is hard to assess whether establishing rules in details is a necessary and efficient way to safeguard the quality of infant formula, Taiwan can learn some lessons from the United States, as the United States can also learn some lessons from Taiwan. In terms of Taiwan's future challenges, constructing a more comprehensive and systematic framework of rules and having only one regulatory authority could help Taiwan to better address how best to safeguard infant formula through regulations. On the other hands, the United States may rethink about its gradually decreased breastfeeding rate and ask the infant formula industry to inform the public

that breast-milk contains the most suitable nutrients for infants, because the public entrusts the government with the power and even the duty to tell people what is best for them.



字體大小 8 號字體

(Fig. 1)