

Infant & Pediatric Nutrition Training Program

Infant Formula: A History of Innovation



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Infant Formula: A History of Innovation

Learning Objectives

- Acquire a basic understanding of the history of the infant formula industry
- Summarize the current standards for infant formula when babies are not breastfed
- Demonstrate knowledge of how cow's milk is modified to produce infant formula
- Describe the major quality control elements of the infant formula manufacturing process

A Brief History of Infant Formula

Sucrose: A disaccharide consisting of glucose and fructose.

Lactose: A disaccharide consisting of one molecule of glucose and one molecule of galactose, found only in milk.

Casein: A class of proteins in milk that form hard curds when precipitated by enzymes or acid in the stomach.

Curd: The insoluble solid portion of milk protein, consisting mainly of casein, which forms when milk is coagulated (see also whey).

Lactic acid: A compound that forms in the cells as the end product of glucose metabolism in the absence of oxygen.

For centuries, humankind has sought an acceptable substitute for nature's ideal infant food – breast milk.¹ During the 18th century, mothers who were unable or unwilling to breastfeed often sought the services of a “wet nurse” to nourish infants.² In the 19th century, as wet nursing fell out of favor, attention turned to feeding infants milk from animals such as goats, cows, mares, and donkeys. Cow's milk became the most commonly used because of its wide availability.²

As early as the beginning of the 19th century, it was recognized that infants fed unaltered cow's milk had a higher mortality rate and incidence of indigestion and dehydration compared with infants who were breastfed. Scientists and physicians began to search for an adequate breast milk substitute. In 1838, Johann Franz Simon published a chemical analysis that showed cow's milk to have a higher protein and lower carbohydrate content than human milk.² A few chemists attempted to overcome these deficiencies by adding water, sugar, and cream to cow's milk to make it more digestible, but these cow's milk modifiers gained little popularity.²

Despite numerous attempts to satisfactorily modify cow's milk, by the late 19th century most physicians still believed that the available commercial formulations were nutritionally inadequate for young infants.² They began to take matters into their own hands, proposing many different infant formula compositions at pediatric meetings. Authorities recommended various additions to diluted milk, including **sucrose**, **lactose**, corn syrups, **casein curds**, cereals, flour, butter, cream, **lactic acid**, and lime water. Some advocated formulas with high protein content or formulas low in sugar, others urged acidified formulas, and still others made a case for formulas with raw rather than boiled milk.³

By the turn of the century, the most commonly used formula was prepared according to the “percentage” method developed by Dr. Thomas Morgan Rotch. Rotch advocated that proportions of milk, cream, lactose, and lime water be varied at regular intervals to suit the changing needs of the infant. Since variations as small as 0.1% were

considered significant in influencing digestibility, complex calculations were required and preparation was time-consuming.³ Although some commercial laboratories began to compound customized formulas based on physician prescription, the expense, limited availability, and the complexity of it all doomed the Rotch method.² Most infants who were not breastfed still received formulas made in the home from whole milk or “top milk” (milk with 7%–10% fat).⁴



Dr. Henry John Gerstenberger

The proper feeding of infants who were not breastfed was a major concern of Dr. Henry John Gerstenberger, a pediatrician who had an interest in nutritional deficiencies and diseases. Dr. Gerstenberger, a professor at a prestigious midwestern US medical school, foresaw the need for an infant formula that could be easily prepared in the hospital or at home and that required minimal supplementation to fully meet the nutritional requirements of the infant.³

In 1910, Dr. Gerstenberger began his quest for a nutritionally complete formula to be patterned after the complex mixture of nutrients in human milk. Much of his work focused on the formula's fat component. Eventually his efforts yielded a formulation that replaced poorly tolerated cow's milk butterfat with a blend of fats and oils that approximated the physical and chemical characteristics of fat in human milk.³ With the aid of colleague Dr. Harold Ruh, Dr. Gerstenberger began clinical evaluation of his formula. By 1915, they were able to report successful results from preliminary trials at the annual meeting of the American Pediatric Society.³

The new formula replaced poorly tolerated cow's milk butterfat with a blend of fats and oils that approximated the physical and chemical characteristics of fat in human milk.

In 1918, extensive clinical trials with more than 300 babies were completed.³ These trials confirmed that Dr. Gerstenberger's formulation, now christened Synthetic Milk Adapted – or SMA™ for short – was a successful feeding alternative for non-breastfed infants. Although many companies would later claim “bragging rights” to making the first truly physiologic infant formula, historical accounts acknowledge Dr. Gerstenberger's SMA™ as the original.^{3,5}

SMA™, the first formula patterned after human milk, was received favorably by the pediatric community.³ In 1919, commercial production of SMA™ began at the Telling-Belle Vernon Company, a dairy company in the United States.³ Bolstered by

Beta-carotene: A precursor of vitamin A and an antioxidant important for healthy tissue growth.

Whey: The soluble protein in milk; a class of proteins in milk that are found in the liquid remaining after casein is precipitated by enzymes or stomach acid (see also curd and casein).

Arachidonic acid (AA): A type of long-chain fatty acid that assists in brain growth and development. It can be synthesized from the precursor linoleic acid. AA is a precursor of prostaglandins and is a component of cell membranes.

Docosahexaenoic acid (DHA): A type of long-chain fatty acid that assists in brain growth and development. It can be synthesized from the precursor linolenic acid. DHA is an important component of cell membranes and plays a role in neural and retinal development.

Alpha-lactalbumin: A whey protein present in milk from cows and many other mammalian species at a lower concentration than casein.

Lutein: A yellow pigment found in some green leaves and vegetables. It is one of two carotenoids that belongs to the xanthophyll class and is used by the organism as an antioxidant. It is found in high concentrations in the retina of the eye and helps protect the eye from damage by filtering blue light.

Oxidative damage: The effect of oxidation when an abnormal level of oxygen free radicals leads to damage to specific molecules with consequential injury or disease to cells or tissue.

practicing physicians' high regard for SMA™, sales grew. In 1921, Telling-Belle Vernon formed a subsidiary, the Laboratory Products Company, to begin distribution of SMA™ across the United States. This event marked the birth of the modern infant formula industry.³ In 1925, SMA™ was distributed internationally for the first time, with shipments to England and the Philippines.³



The Laboratory Products Company, later renamed the SMA Corporation, was eventually acquired by American Home Products Corporation, and later would become part of the pharmaceutical company known as Wyeth, where many of the scientific advancements to our infant formula occurred. In October 2009, Pfizer acquired Wyeth. At this time, Wyeth Nutrition became Pfizer Nutrition, an independent business unit within Pfizer.³ Throughout the company's eventful history, its infant formulas continuously evolved, guided by Dr. Gerstenberger's original premise – that infant formula should duplicate the nutritional properties of human milk.³ The corporation's commitment to science yielded a number of major innovations:^{3,6}

- The first formula fortified with breast milk–like levels of **beta-carotene**, a source of vitamin A
- The world's first infant formula with a 60:40 **whey**-to-casein ratio, similar to that in mature human milk
- A patented fat blend whose composition of saturated, monounsaturated, and polyunsaturated fats was very similar to that found in human milk
- Formulas fortified with balanced, human milk–like levels of **arachidonic acid (AA)** and **docosahexaenoic acid (DHA)** from a highly purified all-vegetable source
- The first infant formula rich in **alpha-lactalbumin**, the predominant whey protein in human milk, to produce a protein and amino acid profile comparable to that of breast milk
- The first infant formula fortified with **lutein** to help protect developing eyes from harmful blue light and **oxidative damage**

Infant formula should duplicate the nutritional properties of human milk.

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