

Standard Infant Formula

Introduction

Welcome to Minnesota WIC's training module on Standard Infant Formula. This training was adapted with permission from the Wisconsin WIC program.

Objectives

After completing this module, you will be able to:

- Identify Minnesota WIC standard contract formulas.
- Distinguish between standard contract formulas and standard non-contract formulas.
- Identify and differentiate between the nutrition components of milk-based and soy-based formulas.
- And state differences in composition between standard formulas and potential benefits for each formula.

Nutrition Regulation of Formula

In 1980 Congress passed the Infant Formula Act, which established nutrient requirements for all infant formulas. Formulas can vary somewhat in the amount and type of a particular nutrient, but all must meet the basic requirements.

Standards for infant formulas are developed by the American Academy of Pediatrics Committee on Nutrition and are used by the Food and Drug Administration to develop infant formula regulations. According to federal regulations, all WIC contract formulas must contain at least 10 mg of iron per liter and 20 kilocalories per ounce.

Standard Contract Formulas

Federal WIC regulations require that State WIC Programs maintain a contract with a formula company to provide a specific brand of a standard infant formula. These are called standard contract formulas and can be milk-based or soy-based. The current milk-based formula contract for Minnesota WIC is with Mead Johnson and the soy-based formula contract is with Abbott Nutrition.

Alternate Contract Formulas

Under the current WIC formula contract, additional standard contract formulas are available as well.

The Formula Aisle

Next time you are grocery shopping, take a detour and visit the formula aisle. While there, imagine you are a new mom, trying to choose the correct WIC formula. Not only does she need to choose the correct



brand and type of formula, but she will need to choose the correct size as well. This can be very confusing.

Size Matters

Size of container matters. Remind WIC participants to look at the ounces listed on their WIC benefits because this is the only size of container that they can get. Formula containers with "bonus" ounces are not allowed.

Participants may want to buy the larger container of the formula, because it's cheaper per ounce, and they think they will save WIC money. This is not allowed. Sometimes moms will come from the hospital with prefilled bottles of standard ready-to-feed formula or powder formula packets. These are also not allowed. Make sure to carefully go over this information with the participant when formula is issued.

Enfamil Variations

Enfamil makes powdered Organic and NeuroPro products that are not allowed. We will talk more about these particular formulas later in the module.

Non-Contract Formula

Non-contract formula refers to standard formulas manufactured by other companies for which Minnesota WIC does not have a contract. Each state contracts with a different formula manufacturer based on a bidding process. Infants transferring from another state may be receiving a different formula brand. However, in Minnesota, we are only able to provide the Enfamil brand of milk-based standard formula manufactured by Mead Johnson and the Similac soy-based formula, Isomil, manufactured by Abbott Nutrition. There are no exceptions that allow Minnesota WIC to provide non-contract standard formulas.

Beyond large manufacturers, there are several store brand formulas that are usually less expensive and are made with the same FDA standards. Minnesota WIC is also not able to provide these. Store brand formulas can be an alternative for participants when additional formula must be purchased.

This module will give you the basics about the different kinds of standard formula. Infants with a diagnosed medical condition can receive a medical formula with medical documentation from their Health Care Provider; you can find more information about this in the Medical Formula module.

Transitioning to a New Standard Formula

Most infants grow appropriately with a standard milk-based formula. If a caregiver is currently giving or requesting a non-contract standard formula, reassure the caregiver that all standard formulas are nutritionally equivalent. Although all formulas must meet the requirements of the Infant Formula Act, the composition of both branded and store brand formulas may differ slightly in both source and quantity of nutrients within allowed ranges.



Most infants can transition from one formula to another without any problem. However, sometimes older infants may notice the taste difference. Also, parents may be anxious about changing to a different formula. In these cases, a gradual transition may help with both infant and parent acceptance.

Instruct caregivers to mix three parts current formula and one part new formula together for about two days, then mix equal parts of current and new formula for two days or until the supply of current formula is exhausted, then provide only the new formula. This transition schedule can be accomplished with less than a can of the current formula.

If the caregiver refuses to accept the contract formulas, encourage them to address any concerns with the infant's Health Care Provider. Provide nutrition education and issue infant foods if appropriate.

Macronutrients in Infant Formula

Let's explore the macronutrients in infant formulas. Understanding the major nutrients in infant formulas can help WIC staff understand the possible cause of an adverse reaction to a formula and can guide the decision process in determining a formula that may resolve mild intolerances.

Although all formulas meet the same nutrition regulations, formulas differ in the type of carbohydrate, protein, and fat they contain and can vary in composition depending on whether they are powdered, concentrate, or ready-to-use.

Milk-Based Carbohydrate

Lactose is the major carbohydrate found in both human milk and standard milk-based infant formulas. Lactose is naturally found only in the milks of mammals, such as cows, goats, and humans. Milk-based formula is derived from cow's milk, which has lower lactose content than human milk. During the manufacturing process, additional lactose is added to milk-based formulas to bring the amount closer to that of human milk.

Lactose aids in the absorption of minerals, such as calcium, magnesium, and zinc, and helps promote the growth of good bacteria in the gut.

Milk-Based Protein

The protein in standard milk-based infant formula is derived from cow's milk protein. Milk contains two major kinds of protein: casein and whey. Cow's milk is about 80 percent casein and 20 percent whey, while human milk is 20 to 40 percent casein and 60 to 80 percent whey. Casein proteins form larger curds in the infant's stomach and are harder to digest. Some formulas have been manufactured to be higher in whey protein. Although this produces a formula that is similar to human milk, the whey proteins in human milk are very different from the whey proteins in cow's milk.

Lactalbumin is the major whey protein found in human milk, whereas lactoglobulin is the major whey protein of cow's milk. Lactoglobulin has a greater potential for causing protein allergy than lactalbumin.



Milk-Based Fat

The fat sources between human milk and cow's milk also differ. Cow's milk contains butterfat, which is difficult for the infant to digest. When cow's milk-based infant formulas are produced, manufacturers remove the butterfat and replace it with vegetable oils, which are easier to digest. Vegetable oils are added in a specific amount to create a formula that is similar to human milk. Standard milk-based infant formulas may include various combinations of fats including soy, coconut, safflower, and essential omega-3 and omega-6 fatty acids.

Standard Milk-Based Formula

Here you can see Minnesota's contract milk-based formulas. Let's discuss them further.

Enfamil Infant

The standard milk-based contract formula is Enfamil Infant. This formula contains an intact protein, consisting of 60% whey and 40% casein. Most infants will tolerate this formula very well.

This formula is contraindicated for any baby with a diagnosed milk allergy or who has galactosemia.

Enfamil Reguline

Enfamil Reguline uses a partially hydrolyzed whey protein, consisting of 60% whey and 40% casein. This formula contains 50% lactose. Designed to support digestive health, Reguline contains easy to digest fiber and proteins to support soft stools for infants with constipation.

Constipation may be a sign that the infant is having difficulty digesting formula. It is very important to further explore with parents what they are labeling as constipation, because many times, they may not recognize what is normal. When a baby is fed formula, stools are more solid than breastfed babies and require more work. For example, it is normal for babies to wrinkle up their faces and get all red when they are having a bowel movement. Hard "rabbit pellet" infrequent bowel movements are not normal, and a Health Care Provider should be consulted about trying a partially hydrolyzed formula.

This formula is contraindicated for infants diagnosed with a milk allergy or galactosemia.

Enfamil Gentlease

Enfamil Gentlease uses a partially hydrolyzed whey protein, consisting of 60% whey and 40% casein as its protein source. This formula contains 20% lactose. Designed to reduce fussiness, gas, and crying, Gentlease may be appropriate for infants that require a lower lactose formula.

It is good to note that true lactose intolerance is thought to be rare in infants. Perceived symptoms may be due to improper formula preparation, other formula ingredients, and/or feeding behaviors such as over-feeding, or a lack of understanding of normal baby behavior.

This formula is contraindicated for infants diagnosed with a milk allergy or with galactosemia.



Enfamil A.R. Spit-Up

Enfamil A.R. for Spit-Up contains intact proteins with 20% whey and 80% casein. This formula has added rice starch resulting in a thicker formula. It is indicated for reduction of frequent spit up and volume of regurgitation.

It is contraindicated for infants with a milk allergy and galactosemia.

Enfamil A.R. for Spit-Up cont.

It's important to note that Enfamil A.R. for Spit-Up only works if the infant is not on reflux medications (ranitidine, prevacid, etc.) because stomach acid is needed for the rice starch to work, and these medications reduce stomach acids.

The rice starch makes the formula look grainier than other formulas. The grains are small and should not cause issues with feeding through a nipple. Discourage parents from enlarging the hole in the nipple. This formula mixes a little more slowly with water than other formulas. Mead Johnson recommends mixing the powder and water, waiting five minutes, then shaking again before serving.

This formula is a better option than adding rice cereal to formula. No evidence-based research shows that adding rice cereal to the bottle helps with spit up or sleeping longer stretches. Adding rice cereal to bottles is no longer generally recommended since it alters the nutrient profile. Rice cereals add calories, extra carbohydrates, and displaces other necessary nutrients, such as protein, in the feeding.

Assessing Infant Spit Up

Again, exploring with parents about feeding is very important if a parent perceives their baby "spits up all the time." Asking parents to describe what the spit up is like, including the amount and frequency, can help determine whether the spit up is normal or not. How is the formula prepared and stored? Are they holding the baby in a semi-upright position when feeding and following the Paced Feeding method? How long is the feed? What happens after the feed? What are their expectations for their baby's behavior? These questions can all help with determining whether a formula switch may be helpful or whether adjustments to the feeding process may resolve some of the perceived problem. Assure parents that things get easier, and fussy or colicky babies usually outgrow their symptoms as their gastrointestinal tract matures, usually around three months of age.

Soy-Based Formula

The standard contract soy-based formula for Minnesota is Similac Soy Isomil. The carbohydrate source of soy formula may be corn maltodextrin, corn syrup solids, or sucrose, making it lactose free. The protein source is soy protein isolate with certain amino acids added to improve the quality of the protein. Soy formula is free of cow's milk proteins.

There are additional nutrient requirements for soy-based formulas because they are plant-based. These nutrients are biotin, choline, and inositol.



Soy Isomil is lactose free and is completely plant-based, making it appropriate for caregivers who do not want to feed their infants animal products.

Soy-Based Formula cont.

Soy formulas have been used since 1929 for infants. The American Academy of Pediatrics has issued recommendations for the use of soy formulas in full-term infants in the following situations:

- For infants with galactosemia and hereditary lactase deficiency
- Documented short-term lactose intolerance from acute gastroenteritis
- And when a vegan diet is preferred.

Soy formulas may be recommended following episodes of diarrhea with symptoms of significant lactose intolerance. Generally, after symptoms have subsided, the infant can retry a lactose-containing formula.

Soy-Based Formula cont.

The American Academy of Pediatrics contraindicates the use of soy formulas for conditions that include prematurity and low birth weight (LBW) infants. Soy-based formulas are not designed or recommended for preterm infants. Data on the effects of current soy formulas on bone mineralization in preterm infants is scarce, but there is a significant risk of osteopenia in premature and LBW infants even with calcium and vitamin D supplementation. Therefore, the use of soy formulas with premature infants should be avoided.

It is also not recommended for infants with a documented cow's milk protein allergy because 10 to 14 percent of these infants will also have a soy protein allergy. This includes infants with documented cow's milk protein-induced enteropathy or enterocolitis. They should be provided formula with extensively hydrolyzed protein or an elemental formula. More information about these formulas is in the Medical Formula training module.

The routine use of soy-based formula has no proven value in the prevention or management of infant colic or fussiness. It also has no proven value in the prevention of atopic dermatitis in healthy or high-risk infants.

Soy Isoflavones

Participants and physicians may voice concerns about the use of soy formulas because soy contains isoflavones, which are naturally occurring plant estrogens or phytoestrogens.

In 2008, the American Academy of Pediatrics stated: "there is no conclusive evidence from animal, adult human, or infant populations that dietary soy isoflavones may adversely affect human development, reproduction, or endocrine function."

In 2013, the National Toxicology Program of the National Institute of Health's Institute of Environmental Health Sciences concluded there was "minimal concern for adverse effects on development in infants



who consume soy infant formula."

If parents inquire about using soy formula, encourage them to talk with their Health Care Provider about appropriate use.

Nutrients

As new research emerges about the composition and qualities of human milk, formula manufacturers strive to incorporate these ingredients and qualities into their products and market this to consumers. The Infant Formula Act of 1980, amended in 1986, established minimum levels of 29 nutrients and the maximum levels of nine nutrients.

Other nutrients not required by the Infant Formula Act have been added by manufacturers to various formulas since the 1980s. Clinical studies of safety and possible efficacy are conducted when the ingredient is added to formula, and the new or modified formula is reported to the FDA. Some examples of these additions include taurine, nucleotides, DHA, ARA, prebiotics, and probiotics.

Probiotics and Prebiotics

Some formula manufacturers add prebiotics and probiotics to formulas in order to try to mimic the effects of those naturally occurring in human milk. There are no standard current recommendations about the use of probiotics or prebiotics for infants.

A baby's intestines continue to be colonized with bacteria soon after birth and with the first feeding. Two main factors that determine the types of bacteria are the baby's diet and whether the baby is born vaginally or by cesarean section. Studies have shown that the intestines of babies born vaginally and fed colostrum or breast milk as the first feeding contain greater quantities and varieties of beneficial bacteria than the intestines of babies born by cesarean section and/or who were never fed colostrum or breast milk. A complex mix of prebiotics and probiotics are transferred to the infant through breast milk. They act to promote the growth of beneficial bacteria early in life.

Beneficial bacteria, also known as probiotics, serve many health protective functions. They ferment carbohydrates in the colon to produce acids, making the gut environment more acidic, which inhibits the growth of potentially harmful bacteria. This is thought to be one of the reasons why breastfed infants experience fewer occurrences of diarrhea and other types of infections than do formula-fed infants. In addition, these helpful bacteria line the intestinal wall, acting as a barrier to help prevent disease-causing bacteria and potential allergens from entering the body. Other beneficial effects include better mineral absorption and the use of vitamins, such as vitamin K and folic acid. They also boost immunity to fight disease by stimulating anti-inflammatory agents. Common types of probiotics you may read on formula labels include lactobacillus and bifidobacterium. The image on the slide is of lactobacillus bacteria viewed under a microscope.

Prebiotics are carbohydrates that are resistant to digestion by stomach acid and enzymes. They pass intact to the lower gastrointestinal tract and fuel the growth of naturally occurring beneficial bacteria.



Common types of prebiotics you may see on formula labels include galacto-oligosaccharides and fructo-oligosaccharides.

Formula Advertising

Participants may ask about qualities of a formula that they have heard advertised. Each formula brand has its own blend of nutrients, including prebiotics and probiotics, which are added to the formula. These blends are given names, and then are highly advertised as superior to convince parents that a certain brand of formula is better than another or has a certain ingredient that will enhance development. Some examples are illustrated. Note how these tag lines and names imply superior attributes.

As discussed earlier, the nutrient content of formula is regulated, and all standard formula must meet these nutrient requirements. WIC cannot provide a standard non-contract formula because a parent desires an advertised attribute.

Enfamil Sensitive

Some parents may ask about a sensitive formula option. Sensitive formulas have been indicated for infants who may have mild intolerance to the standard milk-based formula.

Sensitive formulas contain a higher percentage of casein than Standard formula, resulting in a formula that has less lactose, although it is not a lactose free formula. As stated earlier, it is good to remember that true lactose intolerance is thought to be rare in infants. A true lactose intolerance should be diagnosed by the appropriate medical professional.

Minnesota WIC does not offer a Sensitive contract formula. For infants that require a less lactose formula, Enfamil Gentlease is an appropriate choice.

Organic and Non-GMO

Organic and non-GMO products are currently popular trends in our food system, and formula companies are manufacturing products to meet these trends.

To be a Certified Organic/USDA Organic formula, 95 percent of the content by weight must be organic. The five percent of remaining ingredients must consist of substances approved on the USDA's National List. GMOs are NOT on this list, so USDA Organic products are also usually GMO-free.

Non-GMO/GMO-free means the product does not contain any ingredients that have been genetically modified through gene splicing techniques in order to induce a desirable trait. An organic product will be labeled with a certified seal. Non-GMO products may or may not be advertised as such on the label.

Mead Johnson makes Enfamil Simply Organic and Neuro-Pro, a non-GMO version of their standard formula.



In general, the Enfamil Organic and Neuro-pro formulas are not Minnesota WIC-allowed formulas. However, the Neuropro RTF formulas will be allowed in limited circumstances per MOM <u>Section 7.5 WIC Formulas</u>.

Standard Formula for Medical Conditions

While standard formula is designed for healthy full-term infants, it may also be given to children with a medical condition. As an example, a premature infant may need formula until 9-12 months adjusted age or longer, depending on the infant's medical needs. In this case, if a child is one year of age or older, medical documentation is required to provide a standard contract formula.

Other prescription-required formulas are available to infants with a diagnosed medical condition. You may hear these formulas called medical, prescription-required, exempt, therapeutic, or specialty formulas. They will be discussed in the Medical Formula module.

Goat's Milk

Some caregivers may think goat's milk is a good alternative if their infant is allergic to cow's milk protein, but goat's milk also contains lactoglobulin just like cow's milk. Goat's milk is not recommended for infants and if fed, can result in major health consequences. Goat's milk contains inadequate quantities of iron, folic acid, vitamins C and D, thiamin, niacin, vitamin B6, and pantothenic acid to meet an infant's nutritional needs. The lack of folate can cause a serious condition called megaloblastic anemia. Some brands of goat's milk are fortified with vitamin D and folate, but other brands may not be fortified.

This milk also has a higher renal solute load compared to cow's milk and can place stress on an infant's kidneys. Goat's milk has also been found to cause a dangerous condition called metabolic acidosis when fed to infants in the first month of life.

The American Academy of Pediatrics recommends only breast milk or infant formula for infant's first year of life. Goat's milk should not be used for infants.

Toddler Formulas

Caregivers may ask about the use of toddler or follow-up formulas. These formulas are marketed by formula companies for infants who are at least nine months of age and are eating solid foods. Toddler formulas are higher in calcium and protein than standard milk-based or soy-based formulas. These formulas are more expensive than standard formulas and are not nutritionally necessary for most older infants and toddlers. It is developmentally normal for the infant to decrease the amount of formula they drink when they begin to eat solid foods.

Minnesota WIC does not currently provide toddler or follow-up formulas.

End

This concludes the Standard Infant Formula training module. If you have additional formula related questions, contact your State WIC Consultant. Thank you for taking the time to view this.