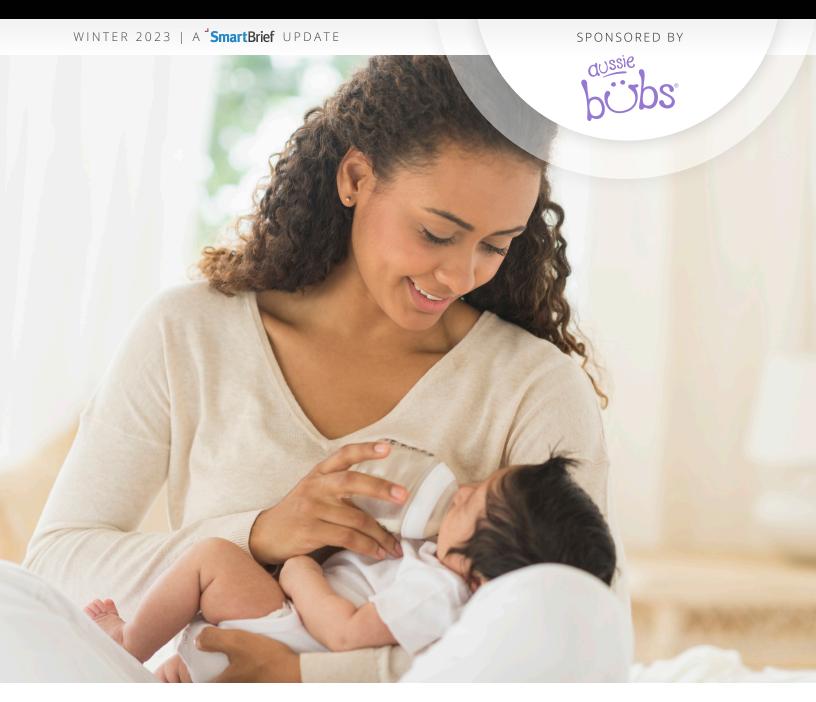
#### SmartFocus on goat milk infant formula



## Goat milk infant formula brings new option to pediatricians, parents

THE SCIENCE AND BENEFITS BEHIND WHOLE FAT GOAT MILK INFANT FORMULA

ediatricians in the US have long relied on traditional infant formula options, particularly cow milk infant formula, to ensure babies are well nourished, happy and healthy. These formulas have typically been in plentiful supply, leaving little need to explore new options.



The US infant formula crisis in 2022 changed that and caused some parents to turn to unsafe homemade infant formula recipes and purchase unregulated gray market product imports online.

The American Academy of Pediatrics (AAP) and the FDA advise strongly against giving infants homemade formulas, which may lack critical nutrients. The FDA has received reports of infants hospitalized with hypocalcemia after being fed homemade formula. Other potential dangers from homemade and gray market formulas include contamination that can cause life-threatening nutritional imbalances and foodborne illnesses.

With the general support of the AAP and the FDA, goat milk infant formula emerged as a new product in the US at the height of the formula crisis as an alternative to standard cow milk-based formulas. The FDA worked with premium international brands to ensure safe formula was available to families and granted enforcement discretion to select brands, including Bubs Australia, to allow for importation to help meet the US demand.<sup>3</sup>

As a direct result of the infant formula shortage, the US infant formula market is diversifying, and families now have access to high-quality, FDA-regulated imports. Consumer awareness of goat milk infant formula is growing, and pediatricians can expect to see increased interest – and questions – about why goat milk infant formula might be the right choice for their patients.

Bubs Australia advisor Michael B. Montalto, Ph.D., a scientific expert on infant formula, says goat milk infant formula is fully fortified with folic acid and iron, is nutritionally comparable to infant formulas already on the US market and can be fed to babies under the same circumstance as other milk-based infant formulas.

### A high-quality option backed by research

While pediatricians have been trained that unfortified goat milk is deficient in key nutrients like iron and folate, goat milk infant formula is a safe, nutritionally complete and well-tolerated option with a mild taste and similarities to human milk. Like all FDA-regulated infant formulas, goat milk formulas such as Bubs Easy-digest are fortified to meet specific nutritional requirements for healthy growth and development.

Randomized, controlled studies comparing the growth of infants fed goat milk formula with those fed cow milk infant formula have found no statistically significant differences between the two cohorts. 4,5,6,7,8,9

In 2012, the European Food Safety Authority (EFSA) issued a scientific opinion stating that goat milk protein is suitable for infant formulas and supports healthy growth and development.<sup>4</sup> That opinion was based on compositional data from an infant formula made from whole goat milk that retained the natural whey-to-casein ratio of goat milk; data from a double-blind, randomized, controlled trial at three sites; and a re-analysis of the data from an earlier trial. Researchers found no differences in weight, length or head circumference development in infants randomized to receive either goat milk infant formula or a cow milk infant formula when fed exclusively for at least four months.

In a recent meta-analysis of published studies, researchers reviewed data from four





randomized, controlled clinical trials, with 670 infants, to evaluate the effects of goat milk formula compared with cow milk formula on infant growth and development. The researchers concluded that growth and development of infants fed goat milk infant formula are not different from the growth and development of infants fed cow milk infant formula in regard to weight, length and head circumference. Rates of adverse events such as reflux, fussiness, colic and flatulence were similar. The review of these studies concludes that goat milk infant formulas are safe and well tolerated.<sup>5</sup>

#### Naturally easy to digest

Beta-casein is a major protein in milk that has two primary subvariants: A1 and A2. Goat milk is naturally dominant in A2 beta-casein protein, which is similar to the casein in human milk, while cow milk is primarily a blend of A1 and A2 proteins. 10,11 A1 and A2 beta-casein differ by a single amino acid at a specific position in their protein sequence. This small difference results in different peptides being formed during digestion. 10,11 Studies have shown that A2 beta-casein protein is less likely to form the peptide beta-casomorphin-7, which has been associated with gas, bloating and changes in stool characteristics in sensitive individuals. 10

"I think any healthy baby will grow and develop well if fed goat milk infant formula," pediatrician Tanya Altmann, M.D., says. Altmann particularly recommends goat milk infant formula for babies with digestive symptoms who seem gassy or fussy, and for babies who don't like the flavor of other formulas. "Parents in my practice report babies do have an easier time digesting goat milk infant formula, possibly because it naturally contains A2 protein and the lipid composition is more similar to human milk."

#### **Favorable nutritional profile**

Infant formulas are required to meet certain requirements to mimic the complex fatty



# Aussie Bubs Easy-digest goat milk infant formula product features

- Nutritionally complete, easy-to-digest infant formula that meets US Infant Formula Act nutrient requirements.
- Whole-fat goat milk with naturally occurring MFGM and plant-based DHA and ARA.
- Easily digestible A2 beta-casein protein with added whey protein from goat milk.
  - 60-40 whey-to-casein ratio.
- 100% lactose -- no added sucrose, corn syrup or maltodextrin.
- Naturally occurring prebiotics along with added GOS.
- Non-GMO.
- No added artificial growth hormones, artificial colors or artificial preservatives.

- Clean Label Project Purity Award Tested for 400-plus toxins and contaminants, including heavy metals, pesticide residue and plasticizers.
- Awarded for meeting the highest purity standards.
- Clean Label Project First 1,000 Days Promise
  Uses elements of European food regulations to recognize brands that are below contaminant thresholds in products for pregnant women, lactating mothers, infants and children.
- 2023 FDA inspection of Bubs' manufacturing facility confirmed it is in compliance with all current good manufacturing practice standards.
- No. 1 goat milk infant formula in the US based on sales. ■

acid profile of human milk.<sup>10</sup> This is typically achieved by adding milk fats, vegetable oils and docosahexaenoic (DHA) and arachidonic acids (ARA).<sup>12</sup> Whole fat goat milk infant formula has a favorable nutritional profile, and it includes a naturally occurring lipid composition and a structure similar to human milk, which may support digestion as well as brain and immune system development.<sup>12,13</sup>

Lipids in human milk are present as fat globules that include triglycerides and proteins stabilized by a three-layer phospholipid membrane called the milk fat globule membrane (MFGM). Whole fat goat milk also contains naturally occurring MFGM composed of triglycerides, phospholipids and proteins. Fats play a crucial role in providing energy, supporting brain development, and aiding in the absorption of fat-soluble vitamins A, D, E and K.

Goat milk also has a high level of naturally occurring prebiotic oligosaccharides, similar to those found in human milk, Montalto says. Oligosaccharides are present in high levels in human milk and may have an anti-adhesive and anti-inflammatory effect on the gut and may support immune system development.<sup>14</sup>

#### **Embracing a new option**

Goat milk infant formula has long been embraced around the globe and is now gaining traction in the US market. The one silver lining to the infant formula crisis "is that we now have more high-quality infant formula options available in the United States," Altmann says.

In May 2022, Bubs Australia was one of the first international formula makers to respond to the shortage. The FDA exercised enforcement discretion to ensure a stable supply of infant formula in the US and has allowed imported formula products, like Aussie Bubs, to stay on the market as their manufacturers work toward full



All Aussie Bubs formulas meet the nutrient content requirements of the US Infant Formula Act and are undergoing a US-based growth monitoring study to secure permanent FDA authorization.

regulatory approval.<sup>3</sup> All Aussie Bubs formulas meet the nutrient content requirements of the US Infant Formula Act and are undergoing a US-based growth monitoring study to secure permanent FDA authorization.

Bubs infant formula has been available outside the US for 18 years, is consumed in at least 10 countries and has experienced no quality problems, Montalto says. Bubs uses the same pasteurization and drying methods that are used in other US infant formulas. Goat milk infant formula is a popular choice of parents in Australia, suggesting that it is well-tolerated and supports normal growth and development.

The diversification of the US formula market means pediatricians can recommend goat milk infant formula as a high-quality alternative for any baby who would do well on cow milk formula. Additionally, whole fat goat milk formula supports the needs of infants who are fussy, gassy or experiencing digestive issues, says registered dietitian Lizzie O'Connor, RD. Goat milk, like human milk, has small fat and protein molecules that mix together easily, making goat milk infant formula an excellent option in the first year of life.

Bubs provides high-quality, clean-label, whole fat goat milk infant formula that helps satisfy growing demand for alternatives to cow milk formulas and provides pediatricians and families with additional nutritionally complete options.

For more information about whole fat goat milk infant formula or to request in-office samples of Bubs Easy-digest, scan the QR code below.





#### REFERENCES

- 1. Korioth, T. "Don't feed homemade formula to babies; seek help instead." American Academy of Pediatrics, Feb. 25, 2019. https://publications.aap.org/aapnews/news/8763/Don-t-feed-homemade-formula-to-babies-seek-help
- 2. US Food and Drug Administration. "Infant Formula." Oct. 10, 2023. https://www.fda.gov/food/resources-you-food/infant-formula
- 3. US Food and Drug Administration "Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies." Jan. 9, 2023. https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies
- 4. EFSA Panel on Dietetic Products, Nutrition and Allergies. "Scientific opinion on the suitability of goat milk protein as a source of protein in infant formulae and in follow-on formulae." EFSA Journal, 2012; 10(3):2603. https://doi.org/10.2903/j.efsa.2012.2603
- 5. Jankiewicz M, L. van Lee, M. Biesheuvel, E.M. Brouwer-Brolsma, L. van der Zee and H. Szajewska. "The Effect of Goat-Milk-Based Infant Formulas on Growth and Safety Parameters: A Systematic Review and Meta-Analysis." Nutrients, 2023; 15(9):2110. https://doi.org/10.3390/nu15092110
- 6. He, T., F. Woudstra, F. Panzer, A. Haandrikman, H. J. Verkade and L. van Lee. "Goat Milk Based Infant Formula in Newborns: A Double-Blind Randomized Controlled Trial on Growth and Safety." J Pediatr Gastroenterol Nutr, 2022; 75(2): 215-20. https://doi.org/10.1097/MPG.000000000003493
- 7. Xu, M., Y. Wang, Z. Dai, Y. Zhang, Y. Li, and J. Wang. "Comparison of Growth and Nutritional Status in Infants Receiving Goat Milk-Based Formula and Cow Milk-Based Formula: A Randomized, Double-Blind Study." Food Nutr Res, 2015; 59: 28613. https://doi.org/10.3402/fnr.v59.28613
- 8. Zhou, S. J., T. Sullivan, R. A. Gibson, B. Lonnerdal, C. G. Prosser, D. J. Lowry and M. Makrides. "Nutritional Adequacy of Goat Milk Infant Formulas for Term Infants: A Double-Blind Randomised Controlled Trial." Br J Nutr, 2014; 111(9): 1641-51. https://doi.org/10.1017/S0007114513004212
- 9. Grant, C., B. Rotherham, S. Sharpe, et al. "Randomized, Double-Blind Comparison of Growth in Infants Receiving Goat Milk Formula Versus Cow Milk Infant Formula." J Paediatr Child Health, 2005; 41(11): 564-8. https://doi.org/10.1111/j.1440-1754.2005.00722.x
- 10. Kay, S.S., S. Delgado, J. Mittal, R.S. Eshraghi, R. Mittal and A.A. Eshraghiet. Beneficial Effects of Milk Having A2 beta-Casein Protein: Myth or Reality? J Nutr, 2021: 151(5): 1061-72. https://doi.org/10.1093/in/nxaa454
- 11. Rahmatalla, S.A., D. Arends and G.A. Brockmann. "Review: Genetic and protein variants of milk caseins in goats." Frontiers in Genetics, 2022; 13. <a href="https://doi.org/10.3389/fgene.2022.995349">https://doi.org/10.3389/fgene.2022.995349</a>
- 12. Gallier, S., L. Tolenaars and C. Prosser. "Whole Goat Milk as a Source of Fat and Milk Fat Globule Membrane in Infant Formula." Nutrients, 2020; 12(11): p. 3486. https://doi.org/10.3390/nu12113486
- 13. Prosser, C.G. "Compositional and functional characteristics of goat milk and relevance as a base for infant formula." Journal of Food Science, 2021; 86(2):.257-65. https://doi.org/10.1111/1750-3841.15574
- 14. Sousa, Y.R.F, L.B. Medeiros, M.M.E. Pintado and R.C.R.E. Queiroga. "Goat milk oligosaccharides: Composition, analytical methods and bioactive and nutritional properties." Trends in Food Science & Technology, 2019; 92: 152-161. https://doi.org/10.1016/l.tifs.2019.07.052



#### **ABOUT** Aussie Bubs

Aussie Bubs is on a mission to nourish with integrity and foster healthy growth using the finest quality ingredients. In May of 2022, Aussie Bubs was the first international infant formula manufacturer to respond to the formula crisis - committing over 1.25 million tins of safe, high-quality infant formula to the US. Today, Aussie Bubs offers a range of nutritionally complete, whole fat, clean-label infant formulas - including Bubs Easy-digest goat milk infant formula - and is available at retailers nationwide.

All Aussie Bubs infant formulas have received FDA enforcement discretion, meet the nutrient requirements of the US Infant Formula Act, and are undergoing a US-based Growth Monitoring Study to secure permanent FDA authorization.

