



## Use of soy protein-based formulas in infant feeding

Bhatia J, Greer F, et al. for the AAP Committee on Nutrition. *Pediatrics*. 2008;121:1062-1068.

### Introduction

In May of 2008, the American Academy of Pediatrics published their updated recommendations for the use of soy protein-based formulas. These guidelines replace the AAP recommendations published in 1998. In the new guidelines, the AAP reiterates its commitment to the use of human milk as the ideal source of nutrition for infant feeding. They also recognize that (1) soy-based infant formulas have been in use for 100 years, (2) numerous studies have documented normal growth and development in term infants fed a soy protein-based formula, and (3) the US Food and Drug Administration has approved these formulas as safe for use with term infants.

### Position Paper Purpose

- This report reviews the indications and contraindications of soy protein-based formulas. It also reviews the potential harmful effects of soy protein-based formulas and the phytoestrogens contained in these formulas.

### Position Paper Summary

In this paper, the AAP reviews the composition of soy protein-based infant formulas, including soy isoflavones. The AAP states that although there have been studies by numerous investigators in various species, 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. The AAP also notes studies suggesting a protective effect of isoflavones against certain adult chronic diseases.<sup>1,2</sup>

AAP authors summarize indications and contraindications for the use of soy protein-based infant formula in term infants, as follows:

- In infants with disorders of carbohydrate metabolism (e.g. galactosemia and primary lactase deficiency, both of which are rare), soy protein-based formulas are found to be safe and cost-effective.
- In infants with acute diarrhea and secondary lactase deficiency, recovery was generally similar between breast fed, cow milk-based formula fed, and soy protein-based formula fed infants. However, some studies reported a shorter duration of diarrhea in soy-fed infants, and a reduced duration of liquid stools when additional soy polysaccharide fiber was included.

- In infants with colic and ‘formula intolerance’ where formula change is a common choice in seeking relief, the authors acknowledge some calming benefit attributable to the sucrose and fiber content in soy protein-based formula, but state that controlled trials have not demonstrated a significant benefit from soy.
- In infants with cow milk protein-induced enteropathy or enterocolitis (non-IgE-mediated), soy protein-based formulas are not recommended because of the reported high-frequency of sensitivity to both cow milk and soy antigens.
- For prevention of atopic disease, the authors conclude that there is no proven value for either healthy or high-risk infants.
- For infants in situations in which a vegetarian diet is preferred, soy protein-based formulas may be used to provide nutrition for normal growth and development.

In summary, AAP guidelines suggest that use of a soy-based formula is warranted for (1) infants with galactosemia, (2) infants with hereditary lactase deficiency, (3) some infants with secondary lactose intolerance, and (4) infants in situations where a vegetarian diet (non-milk-based formula) is preferred.

In summary, AAP guidelines suggest that use of a soy-based formula is warranted for (1) infants with galactosemia, (2) infants with hereditary lactase deficiency, (3) some infants with secondary lactose intolerance, and (4) infants in situations in which a vegetarian diet (a non-milk-based formula) is preferred.

### AAP Qualifier Statements

- As a supplement for the breastfed infant, soy protein-based formula has no advantage over cow milk protein-based formula, unless the infant has 1 of the indications noted previously.
- For infants with documented cow milk protein allergy, extensively hydrolyzed protein formula should be considered, because 10% to 14% of these infants will also have a soy protein allergy.
- Infants with documented cow milk protein-induced enteropathy or enterocolitis frequently are as sensitive to soy protein and should not be given isolated soy protein-based formula. They should be provided formula derived from hydrolyzed protein or synthetic amino acids.
- Most previously-well infants with acute gastroenteritis can be managed after rehydration with continued use of human milk or standard dilutions of cow milk based formulas. Isolated soy protein-based formulas may be indicated when secondary lactose intolerance occurs.
- Soy protein-based formulas are not designed for or recommended for preterm infants.
- The routine use of isolated soy protein-based formula has no proven value in the prevention or management of infantile colic or fussiness.
- The routine use of isolated soy protein-based formula has no proven value in the prevention of atopic disease in healthy or high-risk infants.

## Discussion

Soy protein-based formulas account for 20-25% of the formula market in the United States. The AAP recognizes a limited number of indications for the use of soy protein-based formulas and recognizes that soy protein-based formulas may be used to provide nutrition for normal growth and development in term infants. Further research is needed to substantiate roles of soy protein-based formulas for other specific clinical indications.

## References

1. Bhathena SJ, Velasquez MT. Beneficial role of dietary phytoestrogens in obesity and diabetes. *Am J Clin Nutr.* Dec 2002;76(6):1191-1201.
2. Cross HS, Kallay E, Lechner D, Gerdenitsch W, Adlercreutz H, Armbrecht HJ. Phytoestrogens and vitamin D metabolism: a new concept for the prevention and therapy of colorectal, prostate, and mammary carcinomas. *J Nutr.* May 2004;134(5):1207S-1212S.