

# Soy and Children's Health

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## **Introduction**

Soy protein currently plays a major role in the nutrition of approximately 25 percent of formula-fed infants in the United States and has a variety of applications for older children as well. In the past decade, there has been a considerable amount of research on the effects of soy consumption, in various forms, on growth and development. This fact sheet discusses the major nutritional and public health considerations related to the expanding role of soy in the diets of infants and children.

## **Soy protein in the diet of infants**

It is well documented that human breast milk is the preferred source of nutrition for infants (1). In times when breastfeeding is not an option, commercially prepared, iron-fortified infant formulas are appropriate to supplement or replace human milk for babies who are no longer breast fed during the first year of life (2). The major role of soy protein during infancy is to serve as a primary source of essential and non-essential amino acids. Most infants in the United States are fed some infant formula by two months of age, and approximately 25 percent of these bottle-fed babies consume a soy-based infant formula (3). Consequently, the nutritional adequacy and safety of soy protein is of paramount importance to this vulnerable segment of the population.

## **Nutritional adequacy of soy protein**

Soy is a nutritionally complete protein that has an unusually well-rounded amino acid profile (4). Although methionine is the first limiting amino acid, diets using soy as the sole protein source are capable of providing adequate amounts of all of the essential amino acids to meet the needs of infants, children and adults (5).

The common misconception that soy is an incomplete protein stems from the fact that animal bioassays (including the protein efficiency ratio performed in rats) find that its biological value is only 62-92 percent compared to casein. However, these animal assays underestimate the biological value of soy protein because rats have a different amino acid requirement than humans. Human feeding studies have shown that soy protein is nutritionally equivalent to beef or egg protein when fed at amounts sufficient to meet protein needs (6).



## **Allergenicity of soy protein**

Soy protein can cause an allergic reaction in susceptible individuals, and several fractions responsible for this effect have been isolated and characterized (8). Nevertheless, the prevalence of soy allergy is low. Only about 0.5 percent of normal infants and 5 percent of those in high-risk populations (e.g. infants with atopic dermatitis or family history of food allergy) are allergic to soy (9). The population-based prevalence of soy allergy is less than that for cow's milk (1.9 to 3.2 percent of infants and young children), egg (2.6 percent of children by age 2.5 years) or peanut (0.4 to 0.6 percent of children less than 18 years) (10).

Soy protein-based formulas are often used for the prevention or treatment of cow's milk allergy in infants (11). The American Academy of Pediatrics (12) has concluded that soy formulas are appropriate alternatives for infants with IgE-mediated cow's milk allergy even though a small percentage of such infants (8 to 14 percent) may not be able to tolerate them. Severe reactions to soy (i.e. anaphylaxis) are extremely rare, and infants who fail to tolerate soy formulas can easily be switched to a hypoallergenic, casein-hydrolyzed regimen. Soy formulas are not recommended for infants with non-IgE-mediated reactions to cow's milk (e.g. proctocolitis and enterocolitis) due to a higher rate of intolerance.

Soy protein-based formulas have not been shown to be more effective than cow's milk-based formulas for the prevention of atopic disease (one of the manifestations of food allergies) in high-risk infants. Therefore, they are not recommended for this purpose (3).

Fortunately, most infants who are allergic to soy protein outgrow this condition in later life. Specifically, all 11 infants who reported adverse symptoms to soy in a study by Bock (13) overcame this reaction by three years of age, and two-thirds of atopic infants with a soy-positive oral challenge in a study of 113 patients no longer responded two years later (14). In addition, although 5.1 percent of Danish infants were classified as soy allergic at the beginning of a prospective study (15), there were no instances of soy allergy by age three.

## **Safety of soy formulas**

As noted above, modern soy protein-based infant formulas have been used for approximately 40 years without any obvious ill effects. Nevertheless, such formulas contain substantial amounts of the isoflavones characteristic of soy protein isolates. The total isoflavone content of commercially available soy formulas range from 32 to 47 mg/L (approximately 65 percent in the form of genistein glycosidic conjugates) compared to only 5.6 µg/L for human milk (16). Isoflavone conjugates are readily hydrolyzed in the intestinal lumen and are absorbed and excreted in the urine. The plasma concentration of total isoflavones in soy formula-fed infants ranges from 552 to 1775 µg/L compared to 9.3 and 4.7 µg/L for infants fed cow milk formula and human milk, respectively (16).

Soy isoflavones have weak estrogenic properties and can function as estrogen agonists, antagonists or selective estrogen receptor modulators depending on the metabolic environment (17). Although isoflavones appear to be necessary for many of the beneficial effects of soy, concerns have been expressed that high exposure to these phytoestrogens could result in negative effects in vulnerable populations (17, 18). Very large doses of phytoestrogens have been shown to have negative effects on the reproductive organs in animals, but these studies are not applicable to the infant population (16, 17, 19).

For example, Australian sheep that graze on clover with a very high isoflavone content experience reproductive disorders and infertility. However, this disorder is caused by exposure of the mature reproductive system to very high concentrations of the estrogenic isoflavone, equol – a compound that is undetectable in the soy formula-fed infant (17). In addition, captive cheetahs were shown to experience infertility due to high amounts of dietary isoflavones. However, unlike humans, cheetahs do not have a key liver enzyme (UDP-glucouronyltransferase) necessary for metabolizing steroid hormones (16). On the other hand, Rhesus monkeys fed diets containing 20 percent of soy protein with isoflavones for six months experienced no reproductive effects compared to monkeys fed similar diets with the isoflavones removed (20).

There are no human data to suggest that isoflavones have an effect on development or reproduction. Soyfoods have been used for many years in the Asian population without any evidence of untoward effects (17, 21) and soymilk intake was found *not* to be associated with alterations of sex hormones in pre- or postmenopausal British women (22), or men (23).

In addition, a retrospective cohort study of 811 young adults (20 to 34 years of age) who had been fed soy formula (n = 282), or cow milk formula (n = 622) as part of randomized, clinical trials during infancy exhibited no differences in general health or reproductive outcomes (24). The soy-fed subjects reported slightly longer duration of menstrual bleeding and greater discomfort with menstruation, but the implications of these findings are uncertain and the authors concluded, "...our findings are reassuring about the safety of infant soy formula."

In March 2006, the National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) convened an independent panel of 14 scientists to review recent scientific data and deliberate on whether exposure to genistein in soy infant formula might cause adverse effects on reproduction and development (25). The panel analyzed various animal and human studies and considered the quantity, quality and strength of existing scientific evidence. They concluded that there is negligible concern for neonates and infants consuming soy infant formula in terms of reproductive and/or developmental health (26).

## **Soy in the diets of older children**

The nutritional adequacy of soy protein is critically important for soy-formula fed infants because it is the sole source of protein in the diet. However, soy protein can make valuable contributions to the diets of older children as well. For example, many soy products such as tofu, soy-based smoothies, soy nutrition bars, tempeh and texturized vegetable protein help children meet dietary needs for protein and fiber, and fortified soy products such as soymilk contribute calcium and vitamin D (27).

Soy products have been shown to provide a variety of other nutrition and health benefits to older children. For example, soy protein has been used to lower the fat and saturated fat content in school lunch entrees (28) and to have beneficial effects on serum lipid profiles in hypercholesterolemic children (29, 30).

A perceived lack of palatability has been a barrier to increased consumption of soy products among some consumers. However, such products are readily accepted by preschoolers (31) and the popularity of soyfoods has grown dramatically as food manufacturers have introduced more and better tasting products including meat and soy burgers and crumbles, meat alternatives, cereals, snack mixes, bars, beverages, breads and cereals. The soyfoods market was valued at over \$4 billion in 2005 and although it is showing signs of becoming a mature market, innovative subcategories continue to drive the growth trend (32).

## **Summary and conclusions**

Soy protein is a versatile ingredient that makes substantial contributions to the diet of U.S. infants and children. Soy is a complete protein that contains the full complement of essential amino acids, and can serve as the sole source of protein in the diet of humans. Although soy protein is allergenic in susceptible individuals, the prevalence of this condition in the general population is lower than that of other common allergens, and most infants outgrow the condition. Infants fed soy formulas consume substantial amounts of isoflavones, but there is no evidence from human studies that this exposure impacts reproductive development or fertility. Finally, soy products can play a major role in the diets of older children, and their popularity is likely to grow as more pleasant-tasting products become available, and consumers increasingly demand that health benefits be an integral part of everyday foods.

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