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The SOY Connection

Health & Nutrition News About Soy

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FEDERAL PANEL WEIGHS IN ON SOY FORMULA FOR INFANTS

By Thomas Badger, Ph.D.

An expert panel convened by the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) on December 16–18, 2009 concluded that there was minimal concern for adverse developmental effects in infants fed soy formula (SF).

Because of a dearth of comparative data on reproductive tissues in children fed the three most widely used diets (breast milk, cow's milk formula, and soy formula), the panel considered almost exclusively data from animal studies in its deliberations. Unfortunately, animal data considered to have the most relevance did not involve feeding soy formula to newborn animals, but rather were from animals in which purified soy isoflavones were initiated during pregnancy, or immediately after birth, or in weanling rats. Neither of those conditions are good models for the feeding of SF to human infants for at least two important reasons. First, SF is fed only to newborns, so for an animal study to be an adequate model for SF-fed human infants, the studies should be conducted between birth and when the animals are weaned to standard foods. Second, SF, not isolated isoflavones, should be studied, because of individual dietary factors that are removed from a food and studied individually can produce different, in fact sometimes the opposite, effects than when studied as a whole food. The CARET study is an excellent example of this point.

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Federal Panel Weighs in on Soy Formula

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Because epidemiologic and animal studies showed that consumption of fruits and vegetables high in ß-carotene and vitamin A, or human subjects with high serum ß-carotene were associated with low lung cancer risk, the now famous ß-Carotene and Retinol Efficacy Trial (CARET) was conducted.[1] In that study, 18,314 men and women at high risk for developing lung cancer were treated daily with 30 mg ß-carotene + 25,000 IU vitamin A (equivalent to two servings of kale, sweet potatoes, carrots or Romain lettuce). The study had to be terminated after 21 months, because it was discovered that there were 28% more lung cancers and 17% more deaths in the treatment group. Thereafter, animal studies confirmed that purified ß-Carotene at the same dose produced squamous metaplasia in control animals and this was exaggerated in animals exposed to tobacco smoke. Thus, the reductionist approach to relating the effects of a food to a single food component can lead to misleading (often opposite) effects. This is a major limitation of the NTP-CERHR report.

The Arkansas Children's Nutrition Center has been conducting a prospective, longitudinal study (The *Beginnings Study*) of breast-fed, milk formula-fed and soy formula-fed children from birth through age six years. Many measures of growth and development, body composition, metabolism, endocrine function, psychological development, and brain function are being studied in the same children during this six year period. This study is approximately 60% completed and more than 100 infants per group have been studied through age two years. Preliminary data from *Beginnings* have replicated results from many other studies showing that all three diet groups grow and develop within normal and standardized ranges. Relative to the NTP-CERHR report, reproductive organ development of 120 infants in the *Beginnings Study* were assessed by ultrasonography, and no adverse effects of SF were found in this preliminary report.[2] The NTP-CERHR panel did not consider these data to be of sufficient quality or strength to consider in its evaluation of SF. The National Institute of Environmental Health Sciences (NIEHS) also started a study of SF in infants in 2009, the details of which are not available.

The NTP is now soliciting public comment on the expert panel report and will use any of these comments deemed relevant to prepare the draft NPT Brief that expresses the NTP's level of concerns for SF (scheduled for release in March, 2010). This Brief will be released for public comment and peer-reviewed by the NTP Board of Scientific Counselors in May, 2010, and final conclusions on soy formula released in the

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Federal Panel Weighs in on Soy Formula

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form of the NTP Monograph containing the NTP Brief, expert panel report and public comments.

American Academy of Pediatrics Statement On Formula

The American Academy of Pediatrics (AAP) recommends breast-feeding (BF) rather than formula feeding, and cow's milk formula (MF) over SF, because MF has a long track record of safety and efficacy and there is no evidence for an advantage of SF over MF for general use.[3] The AAP recommends SF only for a few medical indications (infants with galactosemia, hereditary lactase deficiency, and secondary lactose intolerance), as well as in situations in which a vegetarian diet is preferred. It has been estimated that since the late 1960s, SF has been fed to 20–25% of all formula-fed infants in the United States at some point during the first year of life,[3,4] perhaps amounting to more then 20 million infants. This is a large number of infants, when one considers that less than 5% of infants are diagnosed with the medical conditions in which SF is recommended.

Concerns have been raised about potential adverse consequences of SF, despite: long-term use of SF in a large number of infants worldwide in which there are many reports of normal growth and development; the lack of any reports in peer-review medical journals of adverse effects; and the AAP statement that *"although studied by numerous investigations 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."*[3] However, Australia, Canada, France, Ireland, New Zealand, Switzerland, and the United Kingdom limit the use of SF because of concerns about potential estrogenic effects of soy isoflavones.[4,5]

Complete references can be found at ***www.soyconnection.com***

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F.Y.D.

From Your Dietitian

Frequently Asked Questions About Soy Allergy

By Mary Jo Strobel

How common is allergy to soy?

It is estimated that approximately 12 million Americans have a food allergy, and that 3 million of them are children. Soybean allergy is one of the more common food allergies, especially among babies and children. Soy is one of the top eight foods that cause 90% of allergic reactions. Other foods include milk, eggs, peanuts, tree nuts (walnuts, pecans, almonds, etc.), wheat, fish, and shellfish. *(Editor's note: The eight food groups are not equally allergenic and the separated incidence of allergy to soy is actually quite small).*

What are the symptoms of an allergic reaction?

Symptoms of soy allergy are typically mild, although anaphylaxis (a severe, potentially fatal allergic reaction) is possible. Anaphylaxis related to soy is rare, however, and usually occurs in the case of someone who is also asthmatic or has an allergy to another food, such as peanuts.

Symptoms may include one or more of the following: itching, rashes, a tingling sensation in the mouth, swelling of the tongue and the throat, difficulty breathing, hives, vomiting, abdominal cramps, diarrhea, drop in blood pressure, loss of consciousness, and even death. Symptoms typically appear within minutes to two hours after the person has eaten the food to which he or she is allergic.

What foods commonly contain soy?

Soybeans are a major part of processed food products in the United States. Soy can be found in baked goods, canned tuna, cereals, crackers, infant formulas, chicken nuggets, sauces, and soups, to name just a few items. It is sometimes used as a binder in various deli meats. You may also find soy listed as an ingredient in some cosmetics, soaps, lotions, and even some medications.

Avoiding products made with soy can be difficult. Soybeans alone are not a major food in the diet, but because they're in so many products, eliminating all those foods can result in an unbalanced diet. Consult with a dietitian to help you plan for proper nutrition.

How should a soy allergy be managed?

If you are allergic to soy, avoid eating foods that contain this ingredient. Because soy is one of the top eight food allergens, food manufacturers are required by the Food Allergen Labeling and Consumer Protection Act to declare its presence in plain language, either on the ingredient label of the product or in a parenthetical statement in the list of ingredients, even if it is present in tiny amounts, such as in colors, flavors, or spice blends.

Managing a soy allergy, as with any food allergy, requires vigilant label reading. Read ingredient statements carefully before purchasing a food item, even if it is a food that you have safely eaten in the past, as ingredients may change without warning.

When dining out in restaurants, notify staff about your food allergy and which ingredients you must avoid.

Should I avoid soy oil or soy lecithin?

Most individuals with a soy allergy can safely eat soy lecithin, a popular emulsifier widely used for many processed foods. You should discuss avoidance of soy lecithin with your physician.

Studies show that most soy-allergic individuals can safely consume soy oil that has been highly refined (not cold pressed, expeller pressed, or extruded soybean oil). Soy oil should be safe under most circumstances, but it is important to recognize exceptions and to take precautions, particularly in food service situations in which oils may be used to fry a variety of foods, thereby creating potential for a reaction due to cross-contact of food proteins. The FDA exempts highly refined soybean oil from being labeled as an allergen. If you are allergic to soy, consult with your physician about whether or not you should avoid soy oil.

Where can I find more information?

The Food Allergy & Anaphylaxis Network (FAAN) can answer questions you have about food allergies. For more information, visit FAAN's website at www.foodallergy.org.

ABOUT THE AUTHOR

Mary Jo Strobel is Managing Editor of The Food Allergy & Anaphylaxis Network (FAAN), a non-profit organization based in Fairfax, VA., FAAN's mission is to raise public awareness, to provide advocacy and education and to advance research on behalf of all those affected by food allergies and anaphylaxis (a severe allergic reaction).

Soy Protein-Based Infant Formulas

Important clinical tools for solving common infant feeding problems

By Christopher T. Cordle, Ph.D.

Modern soy-based infant formulas (SF) are safe and provide balanced nutrition supporting normal growth and development of term infants. SF has been successfully used for more than four decades to manage a number of clinical problems associated with infant feeding.

The Committees on Nutrition of the American Academy of Pediatrics[1] (AAP) and the European Society of Paediatric Gastroenterology, Hepatology, and Nutrition[2] (ESPGHAN) indicate that SF are safe and effective for use in infants with severe persistent lactose intolerance including primary (hereditary) lactase deficiency and classic galactosemia. AAP also recommends SF in cases of secondary lactase deficiency following acute diarrhea.[1] Both AAP and ESPGHAN indicate that SF are appropriate for term infants whose parents desire vegetarian diets for religious, philosophical, or ethical reasons.

Using SF to manage cow's milk-protein allergy (CMA) is controversial, in part due to failure to distinguish IgE-mediated allergy from cell-mediated syndromes. Since 1990, ten well-controlled studies of SF in IgE-mediated CMA patients have been reported.[3-12] A meta-analysis shows that 394 of 428 infants (92%) with IgE-mediated CMA were effectively managed with SF. This efficacy level is slightly lower than the 97–98% efficacy level of extensively hydrolyzed hypoallergenic formulas (EHF). However, EHF have poor palatability that limit compliance, and are also more expensive. Finally, a few extremely sensitive CMA patients react severely to EHF but tolerate SF.[13] Hence, there is a place for SF in managing CMA.

The most frequent clinical use of SF is in managing cow milk-based "formula intolerance" (FI), which is an ill-defined, multi-component syndrome affecting up to 30% of infants during the first 9 months. FI symptoms include fussiness, gassiness and spit-up. The physiology of FI is complex, with many known and unknown causes. FI is not life-threatening but it is problematic, and a frequent cause of physician office visits and consultation. In clinical studies of FI, a substantial placebo effect is typically seen. FI research is also complicated by subjective symptom evaluation and the variability in symptom descriptions. Perception of the intensity of FI symptoms can also be biased by parental frustration and fatigue, and there are no validated symptom scales. Despite these challenges, several interesting studies demonstrate the benefits of SF in managing FI.

For example, Polack et al.[14] studied 175 US infants 30–210 days old. Thirty-six percent changed from milk-based formula mainly to SF. Colic and regurgitation were the main drivers. Mothers made 47% of switch decisions and 44% were made by the pediatrician. Following the formula change, mothers reported improvement or complete symptom resolution in 80% of infants.

In agreement, Berseth et al.[15] reported a randomized, blinded trial of 158 infants up to nine weeks old whose parents considered them very or extremely fussy. Infants were fed either a low lactose whey/casein partial hydrolysate (n=76) or SF (n=82). Parents scored infant fussiness and gassiness for 28 days. Results show significant decreases in fussiness (day 1 ~ -30%, day 2 ~ -45%, p>0.001) and gassiness (day 1 ~ -25%, day 2 ~ -33%, p>0.001) with no significant differences reported between the formulas. Benefits lasted throughout the 28 day study.

Finally, in a subgroup post-hoc analysis from a larger tolerance study, not yet published by Abbott Nutrition, responses to SF of infants intolerant to a single cow milk-based formula (CMF) were reported. Enrollment criteria required FI symptoms serious enough for the treating physician to recommend formula change. Fifty-nine infants were randomized to receive blinded either SF or the CMF they received before enrollment ("no formula switch" control) on a blinded basis. Parents recorded FI symptoms including vomiting, spit-up, gassy, crying, fussing, in pain, problems sleeping, and inconsolable. Correlation among various symptoms was analyzed using Cronbach's Alpha Coefficient of Reliability to identify symptoms related to a single clinical element (cluster). Data reported as Day three and Day 15 net benefit (symptoms resolved minus symptoms developed). Results showed 82% of infants switched to SF had net improved symptom cluster scores versus 48% improvement for infants fed their enrollment CMF ($p = 0.006$).

ABOUT THE AUTHOR

Christopher T. Cordle, Ph.D., is a Research Fellow at the Abbott Nutrition Division of Abbott Laboratories. His research involves immunological approaches for controlling food allergy and intolerance.

Complete references can be found at ***www.soyconnection.com***

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Allergies to Lecithin and Soybean Oil

By Steve L. Taylor, Ph.D. and Joseph L. Baumert, Ph.D.

The Food Allergen Labeling & Consumer Protection Act (FALCPA) in the U.S. mandates labeling of all ingredients derived from commonly allergenic foods, including soybeans, with the exception of highly refined oils. Commercially, soybean oil and soy lecithin are two important food ingredients.

The allergens in soybean and soybean-derived ingredients are certain naturally occurring proteins in the seed.[1] Thus, the allergenicity of soy-based ingredients will be related to the protein (allergen) content of that particular ingredient.

Highly Refined Soy Oil

Commercially, highly refined soybean oil is made by a process that uses extraction with hot solvents, bleaching and deodorization, and these processes serve to eliminate almost all soy protein, and thus allergens, from the oil.[2] While highly refined soy oil definitely contains residual soy protein, the residue levels are extremely low. The ability to accurately quantify these extremely low levels of residual protein in highly refined soy oil is somewhat questionable, as no validated methods exist for the detection of residual protein levels in soybean oils. However, FALCPA exempts highly refined oils from its source labeling provisions because highly refined soybean, peanut and sunflower seed oils have been clinically documented to be safe for consumption by individuals allergic to the source food.[1,4,6,12,13] One rather unusual case of possible soy oil-induced allergy was noted in an infant being fed exclusively on an amino acid-based formula containing a soy oil-based component.[8] The circumstances of exposure in that exceptional case are unusual and the association with the soy oil component of the formula was somewhat speculative.

Cold-Pressed Soy Oil

Cold-pressed, also known as expeller-pressed, soy oil is likely not excluded from source labeling. Although cold-pressed soybean oil has not been documented to provoke allergic reactions, this type of oil is likely to contain somewhat higher levels of residual protein by comparison to highly refined oil. The safety of cold-pressed soybean oil has not been documented by clinical challenge trials beyond one small trial in 8 soy-allergic subjects.[5] The Food & Drug Administration has not specifically provided advice on the need for source labeling of cold-pressed soybean oil but such oils would likely not be considered as highly refined.

Soy Lecithin

FALCPA also requires the labeling of soy lecithin because it is derived from soybeans and contains residual protein. While attempts have been made by the Grocery Manufacturers of America and other food industry groups to convince the Food & Drug Administration to exempt soy lecithin from the source labeling requirement of FALCPA, these efforts have not been fully successful. The Food & Drug Administration has indicated that it will exercise regulatory discretion on labeling of soy lecithin for one widespread use, which is as a stick-release or pan-release agent, a processing aid use in baking and other applications. But, source labeling is required for all other uses of soy lecithin in foods even when use levels are low. Soy lecithin is acknowledged to contain residual levels of protein, although the amount of residual protein is uncertain. The Food Chemicals Codex specification for lecithin allows a maximum of 0.3% hexane insoluble matter in food-grade lecithin. If all protein, then the upper limit for protein should be 3000 ppm. No validated method is available for the precise measurement of protein levels in lecithin. Soy allergens have been identified within the residual protein in soy lecithin by various investigators. However, the presence of residual levels of soy protein and soy allergens in soy lecithin is insufficient to document the allergenicity of soy lecithin. Only two reports exist of allergic reactions to soy lecithin among soy-allergic consumers, despite its widespread use.[9,11] The allergenicity of soy lecithin remains unknown, although the very small number of documented episodes and their questionable nature suggest empirically that its allergenicity is quite low.

Complete references and author information can be found at ***www.soyconnection.com***