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SOY & THYROID FUNCTION: SAFETY ISSUES EXAMINED

By Alison M. Duncan, Ph.D., R.D. and Barbara L. Dillingham, M.Sc.

A QUICK TASTE

The vast amount of research that has linked soy to human health[1] has generated considerable interest from consumers. One particular area that warrants attention is the relation of soy to thyroid health. This review will summarize the historical and current research examining the relationship between soy, soy isoflavones and thyroid function.

Introduction

The relevance of soy to thyroid health has focused on its constituent isoflavones. Isoflavones are similar in structure to thyroid hormones,[2] providing a theoretical basis for their interaction with thyroid function. Evidence to support this theory comes from cell culture[3] and animal experiments[4] showing that isoflavones inhibit thyroid peroxidase (TPO), an enzyme involved in the synthesis of thyroid hormones. This effect is not unique to isoflavones as numerous compounds of plant origin are able to inhibit TPO activity.[5]

Historical Observations

An effect of soy on thyroid function was first reported in 1933 by McCarrison,[6] who observed that when raw soybeans were added to an iodine-deficient diet of rats, they developed goiter, an enlarged thyroid that can arise from an elevation in thyroid stimulating hormone (TSH) secondary to inadequate thyroid hormones.[2] This observation was replicated in other early animal experiments[7-9] with further study revealing that the addition of iodine to the diet could prevent the goiter.[7-9] This active area of research led to the idea that soybeans contain a goitrogenic factor.

Infants and Children

Other historical observations linking soy to thyroid health occurred in the late 1950s and early 1960s when a few case studies documented the incidence of goiter in infants fed soy-based formula.[10-12] This prompted the inclusion of iodine to soy-based infant formula, which eliminated any further occurrences of goiter.[2]

There have since been reports of elevated TSH in hypothyroid infants consuming soy-based formula,[13-15] with some infants requiring an elevated dose of thyroid replacement.[15] However, a recent review of hypothyroid infants consuming soy-based formula concluded that elevated TSH did not result in the need for any alteration in

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EXPERT PANEL REPORTS ON GENISTEIN & SOY FORMULA

Soy infant formula has been commercially available in its present form (with only slight modifications over time) for approximately 40 years, and during this period, approximately 20 million infants have used the formula at some point in their development. All evidence indicates soy formula produces normal growth and development as assessed

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by common measures such as height and weight. Nevertheless, in recent years the use of soy formula has become somewhat controversial and the subject of scientific debate. At issue is the high exposure to soybean isoflavones, especially genistein.

On January 16, 2006, the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) issued two draft reports entitled "NTP-CERHR Expert Panel on the Reproductive and Developmental Toxicity of Soy Formula" and "NTP-CERHR Expert Panel on the Reproductive and Developmental Toxicity of Genistein." On March 15-17, the 14-member panel met to discuss the reports and to form conclusions. The public had an opportunity to comment on the reports in written form between January 16 and March 1, to present oral testimony on March 15, and to participate in the two-and-a-half-day meeting.

The conclusions of the expert panel were as follows:

Genistein

Even though there is a scarce amount of available human data on exposure to purified genistein, the expert panel expressed negligible concern for reproductive and developmental effects from exposure of adults in the general population. The expert panel expressed negligible concern for adverse effects in neonates and infants who consume up to 0.01-0.08 mg/kg body weight/day of genistein aglycone contained in soy formula.

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thyroid replacement dose.[16] Regardless, these observations warrant close medical follow-up of TSH levels and thyroid replacement dosing in cases where soy-based formula is fed to hypothyroid infants.[16]

With respect to children, there is limited evidence of a potential increased incidence of autoimmune thyroid conditions in those who consumed soy-based formula as infants. Studies by Fort *et al.*[17, 18] report that when compared to breast-fed infants, soy formula-fed infants have a greater incidence of positive thyroid antibodies[17] and are more likely to develop autoimmune disorders, such as food allergies, later in childhood.[18] However, these observations have been challenged[19, 20] on several methodological issues that highly question the studies' conclusions.

The relationship between soy isoflavones and thyroid function in children was recently examined by Milerova *et al.*[21] who related serum isoflavones with parameters of thyroid function in children without overt thyroid disease. Serum genistein was positively associated with free thyroxine (T_4) and thyroglobulin antibodies and negatively associated with thyroid volume. The authors concluded that the associations were modest but could become important if iodine intake is insufficient.[21] Also noteworthy is that the low levels of serum isoflavones[21]compromised the study's ability to adequately detect a relationship between isoflavones and thyroid health.

Adults

The relationship between soy, soy isoflavones and thyroid function in adults has been extensively analyzed in a recent review by Messina *et al.*[22] A Japanese study published in 1991 is the only one to document anti-thyroid effects in adults.[23] The study followed three groups of adults of heterogeneous age, gender and menopausal status who consumed soybeans pickled in rice-vinegar for one or three months.[23] When compared to baseline, there were no changes in triiodothyronine (T_3) or T_4, but there was a significant increase in TSH and occurrence of goiter among 11 of the 37 subjects.[23] Unresolved issues from this study include its lack of control group, lack of detail about the nutritional composition of the pickled soybeans, uncertainty regarding the iodine intake of the subjects and the high incidence of reported side effects; unusual among a population that commonly consumes soy foods.

To increase the knowledge about soy and thyroid function in adults, several researchers have included circulating thyroid hormones as endpoints in their intervention studies designed to evaluate various health effects of soy. Most have included postmenopausal women, which is relevant because among the general population, postmenopausal women have a

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relatively higher incidence of sub-clinical hypothyroidism[24] and are most likely to consume dietary supplements.[25] Among the eight studies that have included postmenopausal women, the majority show no significant effects of consuming soy protein isolate (SPI) of varying isoflavone content[26-30] or an isoflavone supplement[20] on circulating thyroid hormones including total T_3[20, 26, 29], free T_3[26, 28], total T_4[20, 26, 29, 30], free T_4[26] or TSH.[20, 26-30] Three studies found a single effect of SPI including decreased thyroid binding globulin (TBG) relative to baseline[26, 31] and decreased free T_4[28], while another study reported multiple effects of SPI including increased total T_3, total T_4, free thyroxine index and TSH, although the authors noted that the magnitude of changes observed are unlikely to be clinically important.[32]

Studies in premenopausal women have reported that total T_3 did not significantly change, but total T_4 increased in the follicular phase and decreased in the luteal phase with consumption of an isoflavone supplement,[33] and free T_3 significantly decreased during the follicular phase, but no other thyroid hormones changed during any menstrual cycle phase with consumption of SPI.[34] Finally, studies in men have shown few effects of SPI on thyroid hormones, with one study reporting significantly increased total T_4 and free thyroxine index relative to baseline,[35] but the rest reporting no significant effects on total T_3[35, 36], free T_3[36], total T_4[30, 36], free T_4[36], TSH[27, 30, 35, 36] or TBG.[36]

One area of potential concern with adults, similar to that of infants,[16] is the use of soy among hypothyroid adults receiving thyroid replacement. To this issue, there has been one case study reporting on a female consuming a soy supplement who required an elevated dose of thyroid replacement for her complete thyroidectomy.[37] Interestingly, separating the timing of consumption of the medication from that of the soy precluded the need for the increased dose.[37]

Thyroid Cancer Risk

Since prolonged elevation in TSH can excessively stimulate the thyroid[2] and there is support for estrogens in the etiology of thyroid cancer,[38] it is relevant to consider the relation of soy and soy isoflavones to thyroid cancer risk. A Japanese study related tofu consumption to a non-significant elevation in thyroid cancer risk among women,[39] however; in contrast, a more recent North American study found that thyroid cancer risk was significantly reduced among women who consumed greater amounts of soy-based foods, and this relationship was unaffected by ethnicity or menopausal status.[40] Isoflavone consumption also was associated with a reduced thyroid cancer risk but did not reach statistical significance.[40]

Summary

There is a growing body of research that has examined soy and thyroid function. Historical observations of goiter caused by consumption of soybeans in animals or soy-based formula in infants were in cases of insufficient iodine intakes and primarily resolved with iodine repletion. There remains potential concern for hypothyroid infants consuming soy formula, however for hypothyroid adults, since thyroid hormone dose is titrated to serum levels, there is no reason for hypothyroid adults on medication to avoid using soy foods.[22] Isoflavones have been identified as a goitrogenic factor in soybeans, but studies in adults evaluating isoflavones in the form of SPI and supplements have produced minimal changes in circulating thyroid hormones, with the exception of one study that observed goiter but has been challenged on many methodological issues. Soy and soy isoflavones have been associated with a reduced thyroid cancer risk, although there are more studies needed to replicate these observations. Overall, the area of soy and thyroid function warrants continued study and critical evaluation.

Alison M. Duncan, Ph.D., R.D.

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Barbara L. Dillingham, M.Sc. is currently a manager for Nutritional Fundamentals for Health (NFH), a nutritional supplement company. Her master's degree in nutritional sciences from the University of Guelph focused on the hormonal effects of soy isoflavones in men.

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SUPPLY & DEMAND FOR NEW SOY OIL VARIETIES

By Richard Galloway

In 1998, executives of various food companies met with representatives of the United Soybean Board and sent a very clear message: the food industry would reduce its usage of hydrogenated oils due to impending FDA regulations requiring *trans*-fat content labeling. The soybean industry was already at work on the development of a low linolenic soybean variety, and other fatty acid traits were being developed. But the economics of bringing new varieties to market were problematic.

Due in part to efforts of USB's Better Bean Initiative and QUALISOY Board, three varieties of soybean seeds were introduced into the marketplace for planting in the spring of 2005: VISTIVE™ from Monsanto, low linolenic soy from Pioneer, and "Ultra Low Lin" from Asoyia. A total of 154,000 acres of these varieties were planted in 2005, producing approximately 60 million lbs. of refined low linolenic soybean oil for the 2005-06 crop year (October 2005 – September 2006). This past spring, these three seed companies expected a total of over 700,000 acres of these varieties to be planted, yielding an expected 280 million lbs. of low linolenic soybean oil for the 2006-07 crop year. There is potential for 1.6 million acres in 2007 yielding 650 million lbs. of low linolenic soybean oil. [1,2,3]

While working with seed companies to estimate supply, QUALISOY also works to analyze demand. USDA projects that total domestic usage of soybean oil during the 2005-06 crop year will be 18 billion lbs.[4] Objective statistics are not gathered and published on vegetable oil hydrogenation, but it is estimated by numerous trade sources that the portion of U.S. soybean oil that is hydrogenated probably peaked during late 2004 or early 2005 at something approaching 45 percent of refined soybean oil

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Soy Formula

There are insufficient human or experimental animal data available to permit a determination of the developmental or reproductive toxicity of soy infant formula.

In its position paper on soy infant formula written in 1998, the American Academy of Pediatrics (AAP) states: "In term infants whose nutritional needs are not being met from maternal breast milk or cow milk-based formulas, isolated soy protein-based formulas are safe and effective alternatives to provide appropriate nutrition for normal growth and development." The AAP is currently updating its position paper.

Finally, considerably more developmental data on the use of soy formula will be available in the not too distant future as ongoing USDA-funded research is comparing the health status of infants fed breast milk, cow milk formula, and soy formula over a several year period.

The final expert panel reports are available at http://cerhr.niehs.nih.gov and are available in printed text from CERHR.

TOFU QUICHE

By Chef Elaine R. Cwynar, M.Ed.

This recipe is a simple way to incorporate soy products into your everyday diet.

Yield: Eight 5 oz. servings

Ingredients:

½ cup	Onion, peeled, diced, caramelized
½ cup	Fennel bulb (base only), diced, caramelized
2 Tb.	Butter, unsalted
1	Ready-to-use 9" deep-dish pie crust
4 cups	Dried (uncooked) beans or rice
6 oz.	Tofu, silken style
6 oz.	Soy cream cheese
3 cloves	Garlic, peeled and minced
2	Eggs
1/3 cup	Soymilk, plain, low-fat
1 Tb.	Fresh thyme leaves, chopped
1 Tb.	Fresh basil, chopped
¼ cup	Grated cheese (Romano, Parmesan, Asiago or Cheddar)
1 Tb.	Flour
¼ tsp.	Salt ½ tsp. Black pepper, ground
4 oz.	Canadian bacon, cooked and drained
3 Tb.	Grated cheese for garnish

Method of Preparation:

1. Melt 1 Tb. of butter in one skillet and 1 Tb. of butter in another skillet. Place onions in the first skillet and the fennel in the second skillet. Caramelize (bring to a golden brown) onions and fennel by cooking for 30-40 minutes over medium heat, stirring often, until each turns a caramel color.
2. Preheat oven to 400° F. Prick pie crust base. Place an empty pie pan over the unbaked crust and fill with beans or rice (to prevent crust shrinkage). Place pie crust in the middle of the oven and bake for 10 minutes. Remove pie crust from oven and remove the top pie pan of beans or rice.
3. Reduce oven to 350° F.
4. Combine tofu, soy cream cheese, garlic, eggs, soymilk, thyme, basil, cheese, flour, salt and pepper and set aside.
5. Mix onions and fennel together and place in pie crust.
6. Add the tofu mixture on top of fennel and onion.
7. Sprinkle with bacon and cheese, and bake for 30-40 minutes. Let stand for 10 minutes before cutting.

Chef's Notes: Asparagus, broccoli or spinach can be added as desired.

Nutritional Analysis:

Calories: 349	Carbohydrates: 18 g
Total Fat: 25 g	Fiber: 1g
Saturated Fat: 9 g	Cholesterol: 89 mg
Protein: 12 g	Sodium: 520 mg

Soy Protein: approx. 23.5 g

NAVIGATING THE ALLERGY LABEL

By Leigh Ann Edwards, M.P.H., R.D.

The Food Allergen, Labeling and Consumer Protection Act of 2004 (FALCPA) requires that food product labels identify in plain language the most common food allergens. All foods containing milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts and soybeans – the top eight allergens – must be accurately and specifically labeled. FALCPA, which went into effect January 1, 2006, was sparked by fears that many food labels either did not include allergens in the listed ingredients or allergens were listed with names that were not easily recognizable. No action is required for products labeled prior to January 1, 2006, and these foods may remain in the market for an unspecified period of transition.

Manufacturers may use one of two options for clearly identifying allergens:
1) List the plain English food name adjacent to the ingredient derivative in the ingredient list—"Tofu (soy)"
2) Notify consumers of the allergen in close proximity to the ingredient list – "Contains Soy"

Manufacturers must also disclose the specific type of tree nut and species of fish or shellfish. The amended legislation applies only to foods monitored by the U.S. Food and Drug Administration (FDA), thus meat and poultry are not subject to the legislation. Fresh fruits and vegetables are not affected by FALCPA's requirements, either.

Consumers should read labels thoroughly because food manufacturers are not required to implement both options. If the ingredient already contains the common name (i.e. soy protein isolate), manufacturers are not required to incorporate the word 'soy' in parenthesis or in a separate 'contains soy' listing. However, the definition of "major food allergen" excludes any highly refined oil derived from one of the eight foods or food groups. Thus, any ingredient derived from such an oil, such as soy derived vegetable oil, would not have to be declared because the allergenic proteins in soy would have been removed during processing. In contrast, soy lecithin, a commonly used food ingredient, has most, but not all, of the soy protein removed in processing. Thus, lecithin derived from soy must be declared according to the options for clearly identifying allergens set forth in the act.

Precautionary statements such as "may contain," "processed in a facility with," or "processed on equipment that makes," are allowed, but the FDA cautions manufacturers to remain diligent in work to control and avoid allergen contamination risk. New standards for, or restricted use of, precautionary statements may later develop as a result of a FALCPA required report FDA must submit to Congress, which will assess consumer preferences for risk information and advisory labeling.

A safe food supply for all is essential and the FALCPA supports that goal by ensuring that common food allergens must be clearly labeled. Dietitians can assist consumer understanding of the changes set forth in this legislation.

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Leigh Ann Edwards, M.P.H., R.D. serves as Manager of Scientific Affairs for the Soyfoods Association of North America (SANA). She received her master's in public health from the University of North Carolina at Chapel Hill in 2005.

See Page 4 for a tasty Soy Recipe, "Tofu Quiche."

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production. Because of some food companies' reformulation away from hydrogenated oils, somewhat less hydrogenation capacity is being utilized today.

Census Bureau statistics indicate that 96 percent of total domestic usage of soybean oil is consumed in edible products.[5] Based on this statistic, we can assume that the potential domestic demand for edible soybean oil is currently 17.28 billion lbs. (18.0 billion lbs. times 96 percent). From this estimate we can conclude that there is a demand for 7.58 billion lbs. of edible oil with the stability created by hydrogenation (17.28 billion lbs. times 45 percent). Much of this hydrogenated soybean oil is used in baking and frying applications that are not readily adaptable to low linolenic soy. To be conservative, one can assume that half of this demand cannot be met by low linolenic soy. This leaves potential demand at a minimum of 3.8 billion lbs. of low linolenic soybean oil.

At the current rate of seed supply growth, it is possible that enough low linolenic seed could be available to meet the 3.8 billion lbs. of potential demand by 2010. In case the low linolenic characteristic alone cannot provide the stability and functionality needed to meet all of this demand, research is well under way on soybean varieties with over 50 percent oleic fatty acid along with the reduced linolenic acid. This characteristic will add considerable oxidative stability to the oil along with the added flavor stability of low linolenic. Additionally, this "mid-oleic" soy is likely to meet the needs of much of the other half of the traditionally hydrogenated soybean oil market that is not met by the functionality of low linolenic. Commercial quantities of mid-oleic soy should be on the market in about three years.

Many nutritionists wonder why enhanced products, such as low linolenic soybean oil, are not quickly and readily available on supermarket shelves. First of all, reformulating food products in a manner that satisfies consumer expectations can be challenging. Food scientists must take into account the texture, flavor and shelf life of the finished product. Second, the bottled oil market relies largely on low price and high volume in a fight to win grocery store shelf space. Nevertheless, the market is changing in favor of more awareness of the nutritional value in the food that we eat and the food ingredients we buy.

For more information on QUALISOY, visit www.qualisoy.com/health.

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Richard Galloway, president of Galloway & Associates, LLC, has built a 25-year career in the soybean processing and vegetable oil refining business. He provides strategic, commercial, marketing, sourcing and similar services to agri-processing businesses, their suppliers and their customers. Among his clients are the United Soybean Board and the QUALISOY Board.

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