HEALTH SCIENCES BULLETIN

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Frequently Asked Questions about Soy

There are Several Websites Strongly Debating the Health Benefits of Soy. What is Shaklee's Opinion about these Websites?

Discussions about the safety of soy do occur on a number of websites, of which many offer links to scientific studies. Given the volume of research that has been conducted on soy and soy isoflavones, it's not a surprise that some studies have shown negative results. However, the weakness of these "anti-soy" websites is that they focus on only a few studies rather than evaluating soy in the context of the body of literature supporting the health benefits of soy. This, in turn, can give consumers a skewed perception of the safety of soy and this simply causes more confusion than providing people with a truly balanced perspective.

As in all areas of research, there can be findings from some studies that directly conflict with the majority of existing data. When it comes to soy, most of the studies showing undesirable effects are in-vitro studies (laboratory studies) or have been conducted in animals, so their relevance to humans should be considered with great caution. Furthermore, many of these studies examine the effects of isolated compounds in high doses (i.e., isoflavones) which often exert very different effects than when these compounds are examined in their natural environment (in soy based foods). What's most important is to keep in mind the abundance of research findings showing that when soy foods and isoflavones are consumed as part of an overall healthy diet, they appear to be exceedingly safe.

Shaklee has a long history of being a strong proponent of soy protein for its health promoting qualities. Soybeans contain all the amino acids essential to human health and soy protein products are a healthy vegetarian alternative to other protein foods that are often high in saturated fat and cholesterol. When viewed in the context of the body of literature on soy, the majority of scientific data strongly supports the value of soy protein as part of a healthy diet for heart health, breast and prostate health, bone health and for managing menopausal symptoms.

Is Soy Safe to Consume in Women with a History of Breast or Endometrial Cancer?

Despite the rigorous investigation of the anticancer effects of soy over the past 15 years, in particular breast and prostate cancers, concerns have been raised that the estrogen-like effects of soy isoflavones may increase the risk of developing hormone related cancers in some women, in particular, those women already at high risk or with a history of these conditions. Because isoflavones have a similar chemical

structure to the hormone estrogen, they bind to estrogen receptors in tissues and exert weak estrogen-like effects under some experimental conditions. However, depending on the stage of a women's life, isoflavones can either exert weak estrogen like effects or may exert anti-estrogenic effects, which would theoretically provide a protective effect against the stimulant effects of estrogen. In pre-menopausal women when endogenous estrogen levels are normal, isoflavones may actually exert anti-estrogenic effects because they take up space on estrogen receptors but exert much weaker effects than endogenous estrogen itself.

In menopausal women who have significantly lower levels of endogenous estrogen, the act of soy isoflavones binding to estrogen receptors may actually have the opposite effect, exerting weak estrogenic effects.

Currently, there is no evidence that consumption of soy foods increases one's risk of developing estrogen-sensitive cancers. However, unresolved issues do still exist related to the action of soy isoflavones, specifically in women with a history of estrogen receptor positive breast cancer. This type of cancer is stimulated by estrogen. While estrogen medications are contraindicated in this case, the effect of soy isoflavones is currently unknown. They could be protective against breast cancer reoccurrence or have a weak stimulatory effect. Long-term, randomized controlled studies with thousands of breast cancer survivors would be needed in order to better understand the risks of soy consumption in this subset of the population and unfortunately such studies have not yet been conducted.

While the preponderance of evidence to date suggests that neither consuming soy isoflavones nor soy protein isolate increases the risk of breast cancer, the bottom line is that definitive data is not available. Therefore, it is Shaklee's position that until it is available, women at high risk for breast cancer or women with a history of breast cancer should discuss the use of soy protein as part of an overall healthy diet with their personal physician in order to make the appropriate decision about soy consumption.

Because of the relationship between estrogen and endometrial cancer, many clinical trials examining the various health effects of soy consumption have also included effects on endometrial tissue. Unlike estrogen replacement therapy studies, these trials have found that isoflavones <u>do not</u> stimulate endometrial tissue proliferation. Population based studies also support this notion. In summary, the evidence to date indicates that soy has no effect and may even reduce the risk of endometrial cancer. To be prudent, though, we recommend that women concerned about the effects of soy on endometrial or cervical cancer risk should discuss with their physician.

Does Soy Negatively Impact Thyroid Function?

Speculation has arisen that soy may adversely affect thyroid function in susceptible individuals and interfere with the absorption of synthetic thyroid hormone. This particular concern stems from research beginning in the 1930s when iodine deficient rats fed raw soy beans developed a goiter, an enlarged thyroid. However, when iodine was introduced into the rat's diet, the goiter was prevented. Case reports of soy formula fed infants born with hypothyroidism requiring an increased dose of thyroid hormone replacement and laboratory studies (in vitro and in vivo rat studies) showing soy isoflavones inhibit the activity of thyroid peroxidase, an enzyme normally found in the thyroid that plays an important role in thyroid hormone

production, has further fueled this concern. However, evidence to date indicates that in healthy people, moderate soy consumption does not negatively impact thyroid function. In fact, in a fairly recent article published in the journal *Thyroid*, soy experts evaluated 14 published studies in which the effects of soy foods and isoflavones on at least one measure of thyroid function were assessed in healthy subjects. With one exception, either no effects or only very modest changes were noted.

The one exception was a Japanese study which has been criticized for its study design as it failed to provide details about the nutritional composition of the soy based product used in the study and the iodine status of the study subjects. Thus, collectively the scientific findings to date provide little to no credible evidence that in healthy individuals soy foods or isoflavones adversely affect thyroid function.

The research in people with abnormal thyroid function reveals a few published case reports involving one adult and five infants with hypothyroidism. These people consumed soy and continued to suffer from hypothyroidism despite the administration of thyroid medication. In some cases the dose of thyroid medication needed to be increased. In these cases the interaction between soy foods and thyroid replacement medication appeared to be the result of malabsorption of the medication and not a systemic effect on the thyroid. The one case report in an adult involved a 45-year-old woman consuming a soy supplement who had previously underwent a complete thyroidectomy. As a result, she required a very high dose of thyroid replacement medication to suppress TSH levels. Interestingly, separating the timing of consumption of the medication from that of the soy precluded the need for the increased dose.

Based on the majority of evidence from clinical trials conducted in healthy adult men and women, soy protein and soy isoflavone consumption does <u>not</u> appear to adversely affect thyroid function. Although the evidence for a potential interaction of soy protein and the absorption of thyroid medication is limited to one case report, it may be prudent for adults with hypothyroidism who take thyroid medication to separate the timing of their soy supplement use from their thyroid medication to avoid any potential interference with drug absorption. Thyroid hormone is usually taken as a single dose 30 minutes to 1 hour prior to eating breakfast and is generally absorbed almost completely within an hour. Therefore, properly following direction for medication use should help minimize any possible effects of soy. It is also recommended that adults with hypothyroidism consult with their physician and have their thyroid function reassessed on a regular basis.

Does Soy Consumption Negatively Impact Male Sexual Development and Function?

Because soy isoflavones exert estrogen-like effects, concerns have been raised that consumption of soy early in life (in utero or during infancy) might cause abnormalities in sexual differentiation and feminization in males, low testosterone levels and impaired semen quality leading to infertility in adult men. These concerns stem mainly from animal studies where rats have been injected with extremely large amounts of isoflavones during development. Results of such studies have shown variable results and application of these findings to human adult males should be questioned as it is well known that the affects of isoflavone consumption on reproduction varies greatly among species. In fact, the American Academy of Pediatrics supports the use of soy infant formula as a safe and effective alternative

to provide nutrition for normal growth and development in term infants, when breast feeding is not feasible and or an infant cannot tolerate cow's milk based formulas.

Although there have been no studies in human infants evaluating the direct effects of soy on sexual development, there has been one follow up study of 120 men who consumed soy formulas during infancy. Results of this study found no effects on pubertal maturation, fertility or hormonal disorders. In a recent study, conducted at Harvard School of Public Health, researchers assessed the relationship between soy and isoflavone intake and sperm count in a group of men being treated at a fertility clinic. Results indicated those men who consumed the most soy had a drop in sperm concentration (the number of sperm per ml) however values were still considered to be within a normal range.

It's also important to note that this relationship was more pronounced in men with higher than normal sperm concentrations to begin with and in men who were overweight or obese, which accounted for 72% of the study subjects. No other differences were seen in total sperm count, sperm motility, ejaculate volume or sperm morphology. In addition, there have been a small number of other studies conducted in men examining the effects of soy consumption on plasma hormone concentrations, revealing mixed results with questionable relevancy.

Although animal studies suggest a theoretical risk of reproductive problems in men exposed to soy isoflavones during development or as adults, it's important to remember there is great variability among species in this respect and negative impacts on sex hormones have been observed at only extremely high doses. Human studies with men have shown overall conflicting results on the impact of soy consumption on serum sex hormone levels, sperm concentration and no evidence of an effect on sperm quality or fertility has been reported. Based on the body of available evidence at this time, Shaklee believes there is no reason to think that moderate soy consumption as part of a healthy diet and lifestyle will cause reproductive abnormalities or feminization in men.