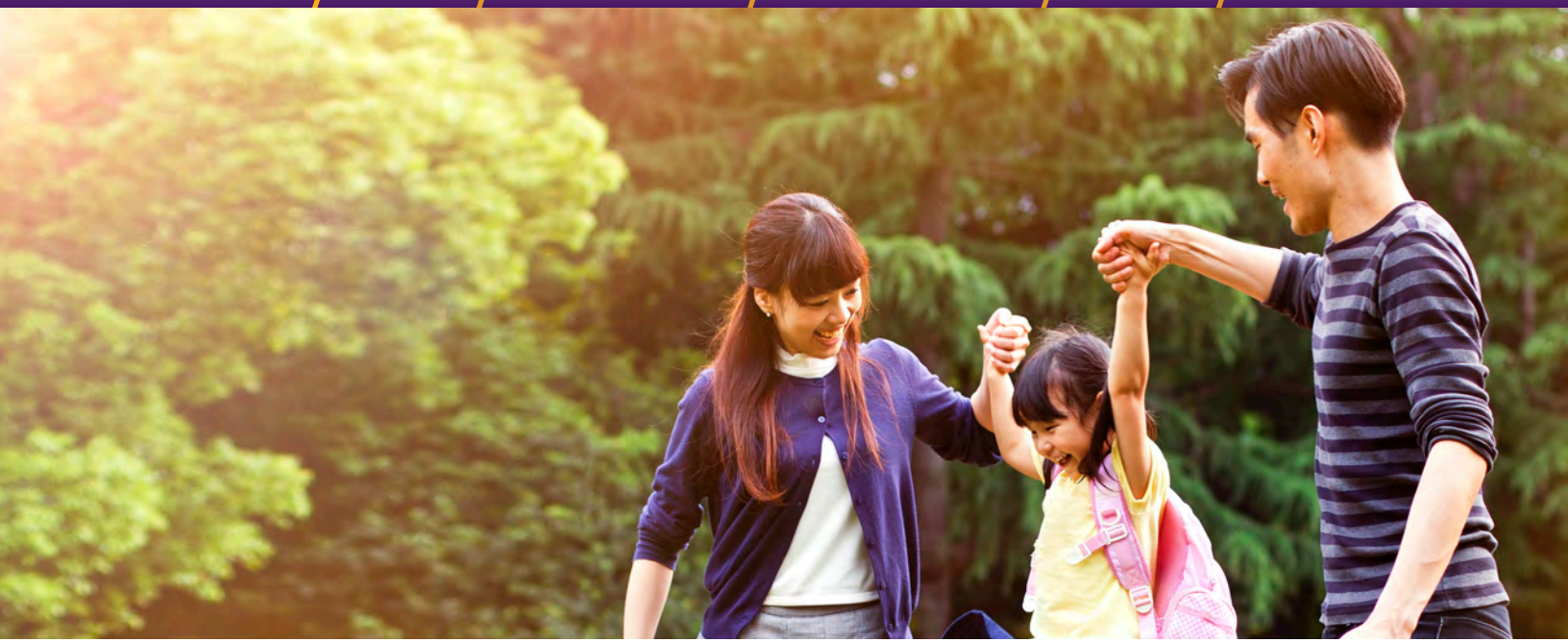
SOY MYTHS & FACTS

HORMONAL BALANCE | FERTILITY | THYROID FUNCTION | BREAST CANCER RISK | ALLERGIES | SOY INFANT FORMULA



SOYFOODS ARE COMMON IN ASIAN AND MANY HEALTH-CONSCIOUS WESTERN DIETS, AND THUS IT IS PERTINENT TO EXPLORE THE SAFETY OF SOY AS DOCUMENTED IN THE BODY OF ACCUMULATED RESEARCH. CONSUMERS CAN BE ENCOURAGED TO CONTINUE FEEDING THEIR FAMILIES SOYFOODS FOR GENERATIONS TO COME.

INTRODUCTION

Traditional soyfoods have played an important role in East Asian diets for centuries and have been consumed by health-conscious individuals in Western countries for decades. More recently, soyfoods have become increasingly popular among mainstream consumers in the West, largely because of research suggesting they offer health benefits independent of the nutrients they provide and because of an increased interest in plant-based diets. Possible benefits include reduced risk of coronary heart disease,[1-3] osteoporosis[4-6] and some forms of cancer.[7] Many of the purported benefits of soyfoods are attributed to their uniquely rich isoflavone content. However, isoflavones, which are diphenolic molecules with estrogen-like properties, are also the primary reason that concerns about the potential adverse effects of soyfoods have been raised.

The FDA concluded that soyfoods are safe in its review when approving the health claim for soy protein and coronary heart disease.

However, as listed below, several health agencies and academic groups after extensively reviewing the data have concluded that soyfoods do not exert untoward effects:

*In **1999**, as part of the process for approving the soy and coronary heart disease-health claim, the U.S. Food and Drug Administration (FDA) concluded that soyfoods are safe for all except those who are allergenic to soy protein.[8] Most of the concerns being raised today were considered by the FDA.*

*In **2005**, the Agency for Healthcare Research and Quality identified only minor problems associated with the intake of large amounts of soy, such as mild gastrointestinal disturbances.[9]*

*In **2009**, a meta-analysis conducted by Austrian researchers, which was undertaken specifically to address the safety of isoflavone supplements, concluded they have a safe side-effect profile.[10]*

In **2014**, *Health Canada, which is analogous to the U.S. FDA, approved a health claim for soy protein and coronary heart disease and concluded after reviewing the data that the adverse effects of soy consumption were generally minor and gastrointestinal in nature.*[11]

In **2015**, *the European Food Safety Authority (EFSA), which is analogous to the U.S. FDA, concluded that the evidence does not suggest there are harmful effects on the three organs considered for their assessment – mammary gland, uterus and thyroid gland.*[12]

Several specific issues related to soy are discussed below, but first, comments about evaluating research are provided.

CONSIDERATIONS IN EVALUATING SOY RESEARCH

Most scientists agree that there is a legitimate basis for discussion about potential adverse effects of soy consumption, at least in some individuals and under certain circumstances. It is not surprising that among the approximate 2,000 soy-related scientific papers published annually that some studies, especially in vitro and animal studies, have raised a potential concern.

However, the relevance of in vitro and animal studies to understanding the effects of soyfoods in humans is questionable. Clearly, in vitro conditions cannot duplicate the complexity of living organisms, human or otherwise. Furthermore, by necessity, these studies typically examine the effects of isolated compounds, which may be quite different from the effects seen when these compounds are examined in their natural milieu. The biological impact of one nutrient or non-nutrient in a food can be affected by the presence of others.[13, 14]

Studies in rats and mice often have limited value for predicting effects in humans because of the many physiological and anatomical differences between rodents and humans. In the case of soy, there is an additional caveat; most animals, including rodents and non-human primates, metabolize isoflavones very differently than humans.[15-22] Therefore, one may derive at most, only very limited insight about the possible effects of soyfoods in humans based on the results from studies in which rodents are fed isoflavone-rich soy protein or mixed isoflavones as are naturally found in soybeans.

It is also important to recognize that many highly investigated foods and food components have been linked with adverse effects in a small minority of studies, including foods that are routinely recommended by nutritionists for their healthful properties. For example, whole grains contain phytate (as do soyfoods), which can decrease mineral absorption.[23] Nevertheless, the nutrition community recommends the intake of whole grains because the overwhelming preponderance of evidence indicates they are nutritionally beneficial.[24, 25] Conclusions about the healthfulness of any food need to be based on the totality of the evidence with careful consideration given to the strengths and weaknesses of study designs.

HOW MUCH SOY PROTEIN AND ISOFLAVONES DO ASIANS AND AMERICANS CONSUME?

There is confusion about the role soy plays in the diets of Asian populations and about how much soy protein and isoflavones Americans consume. Soy protein is widely used by the U.S. food industry and is found in small amounts in an extensive array of foods. Soy protein is added to foods primarily for its functional purposes, e.g., to improve shelf stability and texture. Consequently, U.S. daily per capita soy protein intake is only 1 to 2g per day, representing about 2% of total protein intake.[26] Since soy protein intake is low, isoflavone intake is also very low. This is true not only because of the minimal amounts of soy protein consumed but because the protein used by the food industry is typically quite low in isoflavones. According to a recent analysis, which used the USDA isoflavone database and the National Health and Nutrition Examination Survey III 24-hour dietary recall data to estimate intake, adult Americans ingest only 2.35mg isoflavones daily.[27] There are approximately 25mg isoflavones in one cup of soymilk.

Soy consumption among Asian countries markedly differs. Japan is at the higher end of the dietary spectrum whereas Hong Kong is at the lower end. In Japan, the daily intake of soy protein by older individuals is approximately 8 to10g, which represents about 10% of their total protein intake.[28] Chinese soy intake varies markedly among regions. Large studies from Shanghai, a high-soy-consuming area, indicate men consume anywhere from about 9g to as much as 12 to 13g of soy protein per day,[29] the latter figures represent about 15% of total protein intake.[30] Shanghainese women consume about 9g per day.[31] Individuals in the upper quarter of intake consume about 15 to 20g soy protein daily. Ten grams of soy protein translates to about 1.5 servings since one serving of a traditional soyfood provides about 7g protein, although some soyfoods can provide considerably more than this amount.

Surprisingly, there is also confusion in the popular media about the type of soy consumed in Asia as it is common to see stated that only fermented soyfoods are used. In actuality, unfermented soyfoods play a bigger role. In Japan, approximately half of the soy consumed comes from unfermented foods, with four foods – tofu, miso, natto and fried tofu – accounting for about 90% of all soy consumption.[32, 33] In contrast, in Shanghai, and throughout much of China, most of the soyfoods consumed are unfermented, and soymilk, tofu and processed soy products other than tofu account for about 80% of total soy consumption.[1]

Finally, soy protein intake can be used to estimate isoflavone intake because in traditional Asian soyfoods, each gram of protein is associated with approximately 3.5mg isoflavones. However, because the processing used in the making of more refined soy products such as isolated soy protein (ISP) can cause as much as 80% of the isoflavone content to be lost, estimating isoflavone intake when a mix of modern soy products and traditional Asian soyfoods is consumed is difficult.

HORMONAL BALANCE

Isoflavones bind to and transactivate estrogen receptors and can potentially influence steroid hormone synthesis and metabolism via their effects on enzymes involved in a variety of metabolic pathways.[34, 35] Not surprisingly, there has been investigation of the effects of isoflavone-rich soy products and isoflavone supplements on hormone levels in both men and women. Some of this research was aimed at determining whether decreases in testosterone and estrogen levels might account for the proposed role of soy in reducing risk of hormonally influenced cancers. However, the clinical data indicate that levels of these hormones are not affected.

According to the conclusions of two meta-analyses, neither soyfoods nor isoflavone supplements show clinically relevant effects on reproductive hormone levels in men[36, 37] or women[38-40] despite in many studies exposure greatly exceeding typical Japanese intake. One meta-analysis, which included 32 studies and 36 treatment groups, evaluated the effects of soy products on total and free testosterone in men.[41] The other, which included

47 studies, evaluated the effects of soy products on levels of estradiol and other reproductive hormones in pre- and postmenopausal women.[42] In addition, a comprehensive review of the clinical research, found no evidence that isoflavone exposure affects circulating estrogen levels in men.[43] Estrogen is typically thought of as a female hormone, but men also synthesize estrogen; in fact, estrogen levels in older men are higher than in older women.[44, 45]

FAST FACTS ABOUT ISOFLAVONES

- Isoflavones are one of five chemical classes of anticarcinogens found in soy
- Soyfoods are the only significant natural dietary source of isoflavones
- Research shows isoflavones may prevent the onset of osteoporosis and may protect against various forms of cancer

FERTILITY

Given the large populations of Asian countries that have historically consumed soy, it is somewhat ironic and almost nonsensical that concerns regarding soy intake and fertility have been raised. On the other hand, in many respects the biological effects of isoflavones first came to the attention of the scientific community in the 1940s because of breeding problems experienced by female sheep in Western Australia grazing on a type of clover rich in isoflavones.[46-48] Also, two decades ago it was established that isoflavone-rich soy, which was part of the standard diet of cheetahs in North American zoos, was a factor in the decline of fertility in these animals.[49]

However, problems in the cheetah are thought to have arisen because felines are poorly able to glucuronidate phenolic compounds, a major step in the bodily elimination of isoflavones – a good example of differences in isoflavone metabolism between animals and humans.[50-53] In the case of sheep, serum levels of equol – a bacterially synthesized metabolite of the soybean isoflavone daidzein – far exceeded anything approaching human levels simply because daily isoflavone intake was estimated to be several grams,[54] which dwarfs the 40mg typically consumed by older Japanese.[28]

In women, soyfoods appear to increase the length of the menstrual cycle. However, ovulation is not prevented, but is simply delayed by one day.[42] Interestingly, longer cycles, are associated with a decreased breast cancer risk.[55] Furthermore, there is actually some evidence that isoflavones aid fertility. For example, a prospective study found that among 315 women who collectively underwent 520 assisted reproductive technology cycles, soy isoflavone intake was positively related to live birth rates.[56] Also, soy consumption appears to negate the adverse reproductive effects of the endocrine disruptor bisphenol A (BPA). In a study involving 239 women undergoing in vitro fertilization, among those who did not consume soyfoods, urinary BPA levels were inversely related to live birth rates per initiated cycle whereas no such relationship existed among soy-consumers.[57] Although the low isoflavone intake among the soy-consumers (mean intake, 3.4mg/d) would normally raise doubt about the plausibility of these findings, they do agree with animal data.[58, 59]

In men, a small pilot cross-sectional study found that very modest soy consumption was associated with lower sperm concentration (sperm count was not decreased), but there were many weaknesses to this

study.[60] In fact, much of the decreased sperm concentration occurred because there was an increase in ejaculate volume in men consuming higher amounts of soy, a finding which seems biologically implausible. Furthermore, this same research group subsequently found, in a cross-sectional study involving 184 men from couples undergoing infertility treatment with in vitro fertilization, that male partner's intake of soyfoods and soy isoflavones was unrelated to fertilization rates, proportions of poor quality embryos, accelerated or slow embryo cleavage rate, and implantation, clinical pregnancy and live birth among couples attending an infertility clinic.[61]

More importantly, all three of the clinical studies conducted show that isoflavones have no effect on sperm concentration or quality.[62-64] Interestingly, a case report indicated that daily isoflavone supplementation for six months in the male partner of an infertile couple with initially low sperm count led to normalization of sperm quality and quantity and allowed the couple to conceive.[65]

SOY, ISOFLAVONES AND THYROID FUNCTION

The first animal studies investigating the effects of soy intake on thyroid function were published 80 years ago.[66-68] Concerns about the anti-thyroid effects of soy are based primarily on in vitro research[69, 70] and studies in rodents administered isolated isoflavones.[71, 72] Although several cases of goiter were attributed to the use of soy infant formula, this problem was eliminated in the mid-1960s with the advent of iodine fortification of the formula.[66, 67, 73]

A comprehensive review published in 2006 that included 14 clinical trials found that the totality of the evidence showed that neither soyfoods nor isoflavones adversely affect thyroid function in healthy men or women.[74] Studies published since this review are supportive of the conclusion.[75-79] One of these is a three-year study that included more than 200 postmenopausal women who were given daily supplements that provided either 80mg or 120mg isoflavones.[80] Another study, which found no effects of isoflavones on thyroid function, is especially notable not only because of its three-year duration but because in addition to measuring thyroid hormones (thyroid stimulating hormone, thyroxine and triiodothyronine), very sensitive indicators of thyroid function – thyroid hormone receptor and retinoid receptor expression from peripheral blood monocytes – were assessed.[81] Not surprisingly, as noted previously, the EFSA concluded that isoflavone supplements don't affect thyroid function.[12]

Although soy has no effect on thyroid function in euthyroid individuals, soyfoods may increase the amount of thyroid medication needed by hypothyroid patients, not because of an effect on the thyroid, but because soy protein may interfere to some extent with the absorption of the medication.[82-85] Soy is not unique in this regard however as many herbs and drugs and fiber and calcium supplements have similar effects.[86-94] In any event, it is not necessary for thyroid patients (with the exception of infants with congenital hypothyroidism) to avoid soyfoods since thyroid medication is taken on an empty stomach and dosages can easily be adjusted to compensate for any effects of soy.

According to a recent position paper from the Pharmacy and Therapeutics Committee of the Lawson Wilkins Pediatric Endocrine Society, it is not necessary to avoid any particular food, or even to take thyroid hormone during the fasting state, but rather, it is important to maintain consistency in medication administration and dietary habits. As long as the medication is taken in a consistent manner and the amount of soyfoods consumed is relatively constant, soyfoods are not an issue.[95]

> One serving of a traditional soyfood provides about 20 to 35mg of isoflavones.

Another thyroid-related question is whether soy may worsen thyroid function in those whose thyroid function is compromised such as subclinical hypothyroid patients and in those whose iodine intake is marginal. Of course, all individuals should be sure to consume adequate iodine. The concern about iodine intake is based on the potential for isoflavones rather than the amino acid tyrosine to be iodinated, thereby inhibiting the synthesis of thyroid hormone.[96] However, clinical research published in 2012 indicates that the iodination of isoflavones is negligible and clinically irrelevant.[97]

Only one study has evaluated the effect of soy on subclinical hypothyroid patients. Approximately 5% of the general adult population, and a higher percentage among individuals over the age of 60, have this condition.[98] With time, a certain percentage (~2-6%/year) of these patients, who have normal triiodothyronine and thyroxine levels but elevated levels of thyroid stimulating hormone, will spontaneously progress to overt hypothyroidism.[99]

The study in question involved 60 middle-aged, overweight British patients (52 females). They consumed in random order for eight weeks, 30g ISP containing 2 or 16mg isoflavones separated by an eight-week washout.[100] During the entire six-month study period, six (10%) of the participants consuming the higher-isoflavone-ISP progressed to overt hypothyroidism whereas none did in the low isoflavone group.

These results were unexpected given the relatively small isoflavone intake of the study participants and because the progression of subclinical to overt hypothyroidism among Japanese patients is not elevated;[101] nor does Japan have higher rates of hypothyroidism.[102] Since this study is the only one to be conducted, it isn't possible to reach any firm conclusions about soy and subclinical hypothyroid patients. Furthermore, in response to the higher-isoflavone-ISP, all of the participants in this study, including those who became hypothyroid, experienced marked reductions in systolic and diastolic blood pressure, insulin resistance and inflammation (as assessed by C-reactive protein). Therefore, in theory, isoflavones markedly reduced risk of cardiovascular disease and diabetes in these patients.

ISOFLAVONE CONTENT OF SOYFOODS

SOYFOOD	SERVING SIZE	TOTAL (MG) ISOFLAVONE/SERVING
Miso	1 tbsp	7
Soybeans, Green, Cooked	½ cup	50
Soybeans, Black, Cooked	½ cup	40
Soybeans, Yellow, Cooked	½ cup	78
Soybeans, Roasted, Plain	¼ cup	78
Soymilk, Plain, Unfortified	1 cup	10
Soymilk, Plain, Fortified	1 cup	43
Soy Flour, Defatted	¼ cup	42
Soy Flour, Full-Fat	¼ cup	33
Soy Flour, Low-Fat	¼ cup	50
Soy Crumbles	½ cup	9
Soy Protein Isolate Powder, Plain	⅓ cup	53
Textured Soy Protein, Dry	¼ cup	33
Tempeh	½ cup	53
Tofu	½ cup	25

SOYFOODS AND BREAST CANCER RISK

The estrogen-like effects of isoflavones form the theoretical basis for concern that soyfoods are contraindicated for women with an increased risk of developing breast cancer and for women with estrogen-sensitive breast cancer.[103-107] However, the evidence that estrogen therapy increases risk of developing breast cancer is unimpressive. This point is reinforced by the results of the Women's Health Initiative Trial, which involved over 10,000 women, half of whom received a placebo and the other half conjugated equine estrogens (CEE). Over a 13-year period (average duration of use, 7.2 years), women in the CEE were significantly less likely to develop invasive breast cancer than were women in the placebo group (p=0.02).[108]

Nevertheless, in one mouse model, isoflavones stimulate the growth of existing estrogen-responsive mammary tumors.[109, 110] However, not all rodent models show that soy or isoflavones stimulate the growth of existing mammary tumors[111-113] and even in the rodent model that does, minimally processed soyfoods do not have this effect.[114] Furthermore, slightly tweaking this model causes a complete loss of the ability of isoflavones to stimulate tumor growth.[112] And, as has been already mentioned, because rodents metabolize isoflavones differently than humans, the value of rodent studies for understanding effects in humans is in doubt.[15-20] More importantly, the human data indicate that isoflavones, regardless of the source, do not exert harmful effects on breast tissue.

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Although no clinical trials evaluating the effects of soy or isoflavones on breast cancer recurrence have been conducted, many studies have investigated effects on markers of breast cancer risk, including mammographic density[115, 116] and in vivo breast cell proliferation.[38, 117-121] The latter studies require taking biopsies at study enrollment and termination. These studies show isoflavone exposure, even at doses much higher than typical Japanese intake, do not adversely affect breast tissue. In contrast to the lack of effects of isoflavones, estrogen plus progestin therapy, which increases breast cancer risk,[122] increases breast cell proliferation four to ten-fold within just 12 weeks.[123, 124]

Furthermore, the prospective epidemiologic data show that post-diagnosis soy intake improves prognosis. To this point, a meta-analysis of five prospective studies, two from the United States and three from China, involving over 11,000 women with breast cancer, found soy consumption after a diagnosis of breast cancer was associated with reductions in both breast cancer recurrence (hazard ratio, 0.85; 95% confidence interval: 0.77, 0.93) and mortality (hazard ratio, 0.79; 95% confidence interval: 0.72, 0.87). Importantly, soy consumption is similarly beneficial in Asian and

non-Asian women. Also, in contrast to studies in mice, the epidemiologic data suggest that soy consumption may actually enhance the efficacy of chemotherapeutic agents used to treat breast cancer.[125, 126]

Given the above data, it is not surprising that after a multi-year comprehensive review, the EFSA concluded that isoflavone supplements do not increase breast cancer risk when taken by postmenopausal women.[12] Both the American Cancer Society[127] and the American Institute for Cancer Research[128] have concluded that soyfoods can be safely consumed by breast cancer patients. And the World Cancer Research Fund International concluded there is a possible link between consuming soyfoods and improved breast cancer prognosis.[129]

The American Cancer Society concluded that soyfoods can be consumed by breast cancer patients.

EFFECTS OF SOY ON MINERAL STATUS

Soyfoods are frequently used in place of animal foods, many of which are good sources of iron, zinc and, in the case of dairy foods, calcium. Relatively little red meat is needed to meet daily iron and zinc requirements, so questions about the effects of soy on the status of these two minerals pertains mostly to those eating a predominately plant-based diet.[130]

As noted previously, soybeans, like other legumes and whole grains, are high in phytate,[131] which reduces the absorption of some minerals, including zinc and iron.[132] Zinc absorption from soyfoods is only modestly lower than that from other sources. However, because soybeans contain relatively little zinc, unfortified soyfoods are not particularly good sources of this mineral.[133-136] Zinc status is difficult to assess[137, 138] and those consuming a plant-based diet are advised to identify good plant sources of zinc in their diet or to take a zinc supplement.[139-143]

In contrast to zinc, soyfoods are relatively high in iron.[144] Until fairly recently, it was believed that the iron in essentially all plant foods, including soyfoods, was poorly absorbed. However, relatively new research utilizing improved methodology indicates that iron absorption from soy may be much higher than previously thought because most of the iron in soy is in the form of ferritin. Although there is debate about the bioavailability of ferritin iron, two important clinical studies in which participants were fed either soyfoods or soybean ferritin show it to be highly bioavailable.[145, 146]

In support of these observations are the results from a study designed specifically to examine the effect of soyfoods on mineral status. In this study, young premenopausal women consumed either two or three servings of soyfoods daily or non-soyfoods matched for type of food—such as hamburgers in place of soy burgers or cow's milk in place of soymilk. Results showed there were no statistically significant effects of soy on urinary and serum zinc, serum hemoglobin and iron, or transferrin saturation.[79]

Finally, a study published in 2015 shows that in contrast to older understanding[147] there appears to be adaptation to the inhibitory effects of phytate on iron absorption.[148] For this study, 32 nonanemic premenopausal women with suboptimal iron stores were randomly assigned to high or low-phytate diet for eight weeks. The serum iron response over four hours after a test meal containing 350mg of phytate was measured at baseline and postintervention. The serum iron response to the test meal increased in the high-phytate group at post intervention, resulting in a 41% increase in the area under the curve. However, no effect was observed in the low-phytate group.

In addition to phytate, soybeans are also high in oxalate, another compound that binds calcium and reduces its absorption.[149] Oxalate is one reason that even though spinach is high in calcium it is not a good source of this mineral. Despite the presence of both phytate and oxalate, calcium absorption from soybeans is surprisingly good.[150] This is also true for calcium-set tofu[151] and calcium-fortified soymilk.[152, 153] In fact, the absorption of calcium from these foods is comparable to the absorption of calcium from cow's milk.

Bioavailability of calcium from calcium-fortified products, such as soymilk, depends to some extent on the type of supplemental calcium used.[151] When calcium carbonate is used as the fortificant in soymilk, absorption is similar to that seen with cow's milk.[152] In contrast, calcium absorption from soymilk fortified with tricalcium phosphate is about 25% lower than from cow's milk.[154] However, because of the high amounts of tricalcium phosphate added, the amount of calcium available to the body from both types of calcium-fortified soymilk is similar to that from cow's milk.[152]

Finally, there have been questions about the solubility of calcium in soymilk. Some research indicates that, even with vigorous shaking, the calcium in soymilk comes out of the solution.[155] While some sedimentation may occur in certain soymilks, this sediment is re-suspended with mild shaking for the majority of soymilk purchased in the United States.

ALLERGIES

Soy protein can cause allergic reactions in sensitive individuals, as is the case for essentially all food proteins. Soy protein is one of the eight foods responsible for approximately 90% of all food-induced allergic reactions in the United States.[156] However, these foods are not equally allergenic and allergy to soy protein is relatively rare.[157] A nationally representative telephone survey found that an estimated one in 2,500 adults reported having a doctor-diagnosed allergy to soy protein.[158] This survey found that cow's milk allergy (CMA) is about 40 times more common than soy allergy. The prevalence of soy allergy is higher in children than adults, as children are more likely to have food allergies in general. However, by age 10, an estimated 70% of children will outgrow their soy allergies.[159] Consequently, it is estimated that by that age, only approximately one out of 1,000 children are allergic to soy. It should be noted that soybean-specific IgE titers are not an effective predictor of a positive response to the food challenge test.[160]

> While mineral absorption may be very slightly improved with fermentation and may give rise to other potentially beneficial compounds, there is little evidence that these foods are superior to unfermented ones.

According to the American Academy of Pediatrics (AAP), extensively hydrolyzed protein formula should be considered as the first alternative for infants with documented CMA (especially for IgE-mediated reactions), because 10 to 14% of these infants will also have a soy protein allergy.[161] However, recently conducted British research found that of the 60% of all infants with CMA who were initially treated with soy, only 9% of patients remained symptomatic.[162] In contrast, of the 18% of patients treated with extensively hydrolyzed formula, 29% remained symptomatic. The results from a small retrospective study from Portugal, which evaluated children with persistent CMA, also suggest that soy formula may have advantages over hydrolyzed formulas.[163]

Finally, in 2013, the first systematic review and meta-analysis of studies evaluating the prevalence of IgE-mediated soy allergies in infants and children was published.[164] The analysis, which included 40 studies, found that the prevalence of soy allergies ranged from 0 to 0.5% for the general population, 0.4 to 3.1% for the referred population (those referred to an allergy clinic for evaluation of food-related problems or other allergy issues), and 0 to 12.9% for allergic (atopic) children. The authors concluded concern about soy allergy is no reason to postpone the use of soy infant formula in IgE-mediated CMA infants.

SOY INFANT FORMULA

Soy infant formula (SF) has been in use for more than 50 years. A nationally representative sample of 1,864 infants, 0 to 12 months old, from the National Health and Nutrition Examination Survey, 2003-2010, found that among the 81% of infants who were fed formula or regular milk, 12.9% consumed soy formula.[165] An estimated 20 million infants have used SF over the past 40 years.

SF produces normal growth and development; nevertheless, SF use has become controversial because of its high isoflavone content. In 2009, the U.S. National Toxicology Program (NTP) concluded there was minimal concern about the safety of SF.[166] In response to this conclusion, the AAP submitted a letter to the NTP, which is now part of the public record, stating that, in their view, there was negligible concern about the safety of SF. The five levels of concern are negligible, minimal, some, concern and serious concern.

Over the next few years, considerable insight to the health effects of SF will be gained as a result of research underway at the Arkansas Children's Nutrition Center, University of Arkansas for Medical Sciences. At this center, the health status of infants fed breast milk, cow's milk formula and SF is being compared. Thus far, findings indicate that all health parameters assessed in infants fed SF are well within the normal range.[167-171] Nevertheless, continued research in this area is warranted.

Finally, the first systematic review and meta-analysis focused on the safety of SF concluded that SF intake in normal full-term infants – even during the most rapid phase of growth – is associated with normal anthropometric growth, adequate protein status, bone mineralization and normal immune development.[172]

Recent research shows that only about one out of 2,500 American adults are allergic to soy protein.

SOYFOOD PROCESSING

Tofu and miso are commonly consumed soyfoods in Asia whereas in the United States, many people choose more processed forms of soy such as meat analogs and energy bars.[28] Numerous human studies demonstrate that processed soy products provide very high-quality protein.[173, 174]

Depending on processing methods, the isoflavone content of these foods can be markedly reduced.[175] The isoflavone content of a large number of soy-containing foods can be found in an online database created by Iowa State University and the United States Department of Agriculture at: http://www.ars.usda.gov/services/docs.htm?docid=6382.

Many traditional soyfoods such as miso, tempeh and natto undergo fermentation. While mineral absorption may be very slightly improved with fermentation and may give rise to other potentially beneficial compounds, there is little evidence that these foods are superior to unfermented ones. In fact, several epidemiologic studies show protective effects against different cancers of non-fermented but not fermented soyfoods.[176, 177] Non-fermented soyfoods have been consumed in Japan[178] and China[179] for at least 500 years and 1,000 years, respectively. In Japan, where many unfermented foods are popular, at least half of the total soy consumed comes from foods that are not fermented.[32, 33] And in China, most of the soy is consumed in non-fermented form.[1]

SUMMARY AND CONCLUSIONS

When evaluating the safety of soyfoods, it is imperative to consider the totality of the scientific research and to place appropriate weight on studies according to their experimental design. The research overall indicates that soyfoods can be safely incorporated into the diets of essentially all healthy individuals with the exception of those allergic to soy protein. Nevertheless, because all foods have the potential to cause undesirable effects in some individuals, people with specific health concerns should consult their healthcare provider regarding unique nutritional needs.

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The 70 farmer-directors of USB oversee the investments of the soy checkoff to maximize profit opportunities for all U.S. soybean farmers. These volunteers invest and leverage checkoff funds to increase the value of U.S. soy meal and oil, to ensure U.S. soybean farmers and their customers have the freedom and infrastructure to operate, and to meet the needs of U.S. soy's customers.
As stipulated in the federal Soybean Promotion, Research and Consumer Information Act, the USDA Agricultural Marketing Service has oversight responsibilities for USB and the soy checkoff.
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