



SOY MYTHS & FACTS



ASIAN SOY CONSUMPTION	HORMONAL BALANCE	FERTILITY
THYROID FUNCTION	BREAST CANCER PROGNOSIS	MINERAL ABSORPTION
ALLERGIES	SOY INFANT FORMULA	PUBERTY ONSET
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Introduction

Traditional soyfoods have played an important role in Asian cuisines for centuries and have been consumed by health-conscious individuals in Western countries for many decades. More recently, soyfoods have gained greater acceptance among mainstream consumers in the West as the health and environmental benefits of plant-based diets have received increased attention. Nevertheless, soyfoods are not without controversy as concerns have arisen that they may exert adverse effects in some individuals.



Most of these concerns, which are based primarily on the results of animal studies, have been raised because soybeans are a uniquely rich source of isoflavones.¹ However, the totality of the clinical and epidemiologic research shows these concerns are without scientific merit – as discussed in the text below. Health organizations and academic groups support this conclusion.²⁻⁴ Most notable in this regard are the conclusions of the European Food Safety Authority (EFSA), the U.S. Food and Drug Administration (FDA), and the Permanent Senate Commission on Food Safety of the German Research Foundation (SKLM).

In 2015, after an extensive review of the pre-clinical, clinical, and observational data, the European Food Safety Authority (EFSA) concluded isoflavone supplements (soyfoods were not evaluated) do not adversely affect the three organs examined: breast, thyroid, and endometrium for peri- and post-menopausal women.⁵

In 2017, as part of the process for reevaluating evidence in support of the cholesterol-lowering effect of soy protein, the FDA conducted a comprehensive safety review. In addition to examining the scientific literature, the FDA examined hundreds of comments submitted during the open comment period, many of which dealt with safety concerns. Although the efficacy analysis focused on soy protein, the public comments centered on isoflavones. The FDA did not change their previous conclusion that “the use of soy protein at the levels [25 g/d] necessary to justify a [health] claim has been demonstrated, to our satisfaction, to be safe...”⁶

In 2018, the SKLM concluded that “the available human studies do not indicate that an isoflavone exposure as reported in the thoroughly studied Asian population or as investigated in clinical studies (i.e., about 100 mg/day) negatively influences breast cancer risk or the thyroid hormone system in healthy women.”⁷

Several specific topics related to soy are discussed below.

Asian Soy Consumption

Many Asian studies have been published over the past 25 years, some involving thousands of individuals, which have included detailed questionnaires about soy consumption. These questionnaires make clear several important points. One is that soy consumption among Asian countries and within regions of the same country markedly varies. Japan is at the high-end of the spectrum whereas Hong Kong is at the low end.⁸ Two, most soy consumed throughout the world is in unfermented form because ethnic Chinese consume little in the way of fermented soyfoods.⁸⁻¹⁰

The clearest ways to express soyfood intake is either as grams of soy protein or milligrams of isoflavones. Because there are approximately 3.5 mg isoflavones per gram protein in traditional soyfoods, soy protein intake can be estimated from isoflavone intake and vice versa.⁸ However, this ratio does not apply to many modern soy products based on soy protein ingredients (concentrated sources of soy protein), such as soy protein isolate and soy protein concentrate, because the processing used to make these ingredients typically results in the vast majority of the isoflavone content being lost.^{11,12} Soy protein isolate and soy protein concentrate, are comprised of $\geq 90\%$ and 65–90%, protein, respectively.¹³

In Japan, the daily intake of soy protein by older individuals is approximately six to 11 g, which represents about 10 percent of total protein intake.^{8,14} Isoflavone intake ranges from about 25 to 50 milligrams per day (mg/d).^{15,16} Chinese soy intake varies markedly among regions.¹⁰ Large studies from Shanghai, a high-soy-consuming region, indicate men consume about 12 g of soy protein per day,¹⁷ the latter figure representing about 15 percent of total protein intake.¹⁸

Shanghai women consume about 9 g soy protein per day.¹⁹ Individuals in the upper quarter of intake consume about 15 to 20 g soy protein daily. Approximately 1.5 servings of a traditional soyfood provides about 10 g soy protein since one serving provides about 7 g protein, although some soyfoods can provide considerably more than this amount. In Korea, the national survey, which involved over 11,000 healthy adults aged ≥ 19 y, revealed that mean isoflavone intake was approximately 24 mg/d.²⁰

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 percent of all soy consumed.^{15,21,22} In contrast, in Shanghai, and throughout much of China, nearly all of the soy consumed is unfermented as soymilk, tofu and processed soy products other than tofu account for about 80 percent of total soy consumption.²³ In Korea, about 70 percent of the soy consumed is in unfermented form.²⁴



Hormonal Balance

The classification of isoflavones as phytoestrogens has led to considerable investigation of the effect of soyfoods on hormone levels in both men and women, especially reproductive hormones. Concerns regarding hormonal disruptions and feminization in men can be traced back to two case reports describing a single individual who experienced either an increase in estrogen²⁵ or a

decrease in testosterone²⁶ levels. However, both men reportedly ingested 360 mg/d isoflavones in the context of an unbalanced diet, an intake that is about nine-fold higher than is typical for older Japanese men.

In contrast to these case reports, in 2021 a statistical analysis (meta-analysis) of 41 clinical studies found no effects of soy or isoflavones on reproductive hormone levels in men.²⁷ Total testosterone and free testosterone (biologically active form) levels were measured in 1,753 and 752 men, respectively, and estradiol and estrone levels were measured in 1,000 and 239 men, respectively. Sub-analysis of the data according to isoflavone dose (< 75 mg/d vs ≥ 75 mg/d) and study duration (≤ 12 weeks vs > 12 weeks) also showed no effect. In addition, neither of the two placebo-controlled clinical studies that evaluated the effects of isoflavones on breast tissue in men found evidence of gynecomastia. One study intervened with 66 mg/d isoflavones for 3 months²⁸ and the other, ~ 100 mg/d for 3 years and involved > 300 men.²⁹

As is the case for men, the clinical data indicate soy does not affect estrogen levels in women. This conclusion is based primarily on a meta-analysis by Hooper et al.³⁰ of 35 studies involving postmenopausal women and 11 studies involving premenopausal women that was published in 2009. There was also no effect on sex hormone binding globulin (SHBG) concentrations. SHBG is a protein made by the liver that binds estrogen and testosterone in the blood thereby determining concentrations of the free and biologically active form of the hormone. In general, studies published subsequent to the meta-analysis by Hooper et al.³⁰ show a lack of effect of isoflavone exposure on hormone levels in women.³¹⁻³⁹

Fertility

It is interesting that concerns about soy intake and fertility have been raised given the large populations of countries that have traditionally consumed soyfoods. However, older research showed that soy intake significantly increased menstrual cycle length (MCL), though ovulation was just delayed, not prevented.^{40,41} In 2009, based on a meta-analysis of 10 studies, Hooper et al.,³⁰ concluded that soy/isoflavone intake increases MCL by 1.05 d. Menstrual cycle function is suggested to be an indication of fertility.^{42,43} However, short, rather than long, menstrual cycles have been linked to 11–36% longer time to pregnancy.^{44–46}

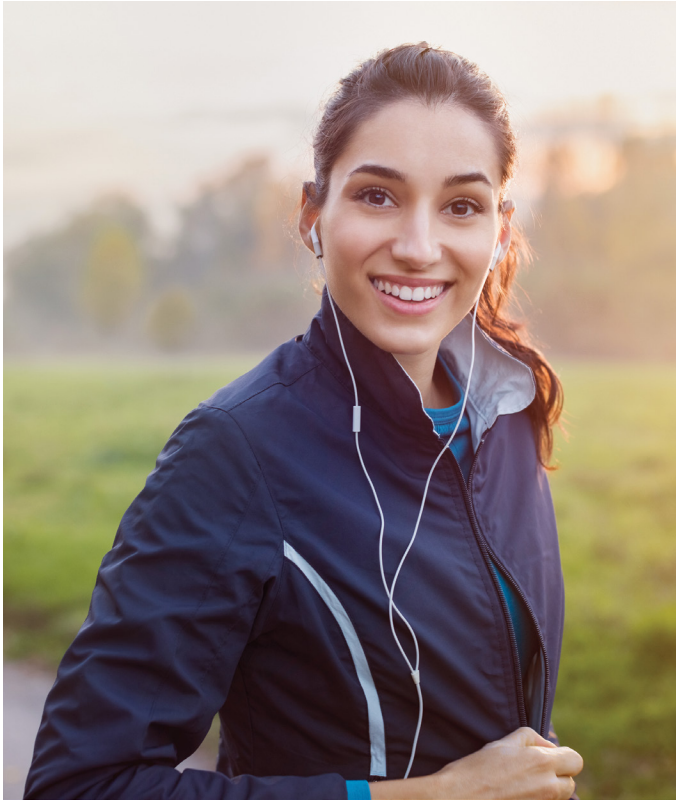
Furthermore, some evidence suggests that soy intake may increase the likelihood of becoming pregnant, at least in some situations. For example, a prospective study found that among 315 women who collectively underwent 520 assisted reproductive technology cycles, soy isoflavone intake was positively related to live birth rates. In fact, women in the highest isoflavone intake category were nearly twice as likely to have a live birth.⁴⁷ Another study reported that soy consumption may negate the adverse reproductive effects of the endocrine disruptor bisphenol A (BPA). Among 63 women undergoing in vitro fertilization, urinary BPA levels were inversely related to live birth rates per initiated cycle. In contrast, BPA levels were unrelated to birth rates among the 176 women who consumed soy.⁴⁸

Concerns about male infertility were sparked largely by a small pilot cross-sectional study by Chavarro et al.⁴⁹ that found very modest soy consumption was associated with lower sperm concentration – sperm count was not decreased – but there were some weaknesses to this study. 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 group of investigators were subsequently unable to provide support for their findings. In a follow-up cross-sectional study involving 184 men from couples undergoing infertility treatment with in vitro fertilization, the male partner's intake of soyfoods and soy isoflavones was unrelated to fertilization rates, proportions of poor-quality embryos, clinical pregnancy, and live birth among couples attending an infertility clinic.⁵⁰

Finally, and most importantly, none of the three clinical studies to evaluate the impact of isoflavone intake on sperm or semen parameters showed any adverse effects.^{51–53} Isoflavone doses ranged from 40 to 480 mg/d and duration from approximately 2 to 3 months. Interestingly, according to a case report, 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.⁵⁴





Thyroid Function

Concerns about the effect of soy on thyroid function are based primarily on in vitro research^{55,56} and studies in rodents administered isolated isoflavones.^{57,58} However, these concerns are contradicted by a wealth of human data, including the results of a 2019 meta-analysis that examined the effect of soy and isoflavones on thyroid hormones. This analysis, which included 18 clinical studies, found no significant changes in healthy subjects on levels of the two main thyroid hormones, thyroxine (T₄) and triiodothyronine (T₃).⁵⁹ These findings align with the conclusions of the EFSA⁵ and the SKLM,⁷ as was noted previously.

Nevertheless, there is still concern that 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. The latter concern is based on the potential for isoflavones to be iodinated instead of the amino acid tyrosine, thereby

inhibiting the synthesis of thyroid hormone.⁶⁰ However, clinical research published in 2012 showed that the iodination of isoflavones is negligible and therefore is unlikely to result in thyroid function disruption.⁶¹

Regarding subclinical hypothyroid patients, one cross-over study reported that 16 mg/d isoflavones provided by 30 g/d soy protein isolate for 8 weeks increased the likelihood of progressing from subclinical to overt hypothyroidism.⁶² However, a follow up study by these researchers in which participants consumed for 8 weeks the same amount of soy protein isolate, but a much larger dose of isoflavones (66 mg/d), did not confirm these findings.⁶³

Finally, soy protein likely inhibits the absorption of levothyroxine, but this is true for food in general and many dietary supplements, herbs, and drugs.⁶⁴ Recommendations do not call for soyfoods to be avoided by hypothyroid patients as one can opt to temporally separate ingestion of levothyroxine from soyfood ingestion. General recommendations are to consume levothyroxine 30 to 60 minutes before breakfast or 4 hours after the last meal.⁶⁵ An alternate approach to temporal separation is to be consistent in medication administration and food consumption so that, if necessary, the levothyroxine dose can be appropriately titrated.⁶⁶



Fast Facts About Isoflavones

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



Breast Cancer Prognosis

Despite the historically low breast cancer incidence rates in soyfood-consuming countries⁶⁷ and evidence suggesting soy intake reduces breast cancer risk,⁶⁸ there is concern that because soyfoods contain isoflavones, which are classified as phytoestrogens, they worsen the prognosis of women with breast cancer and increase the risk of developing breast cancer in women who are at high risk for this disease.⁶⁹ It is worth noting however, that although estrogen does stimulate the growth of some types of breast tumors, evidence that estrogen therapy increases breast cancer risk is not robust.

In fact, in the Women's Health Initiative trials, estrogen therapy led to a statistically significant decreased risk of developing breast cancer and dying from this disease, whereas combined hormone therapy (CHT, estrogen plus progestin) led to a significant increased incidence.^{70,71} This observation is potentially relevant to soy since isoflavones possess estrogen-like, but not progestin-like, activity.⁷²

No intervention study involving women diagnosed with breast cancer has examined the impact of soy consumption on breast cancer recurrence or mortality. However, there has been considerable investigation of the impact of soy on several established markers of breast cancer risk, including mammographic density^{73,74} and breast cell proliferation.⁷⁵ Breast tissue that is denser is at higher risk of developing tumors and cells that proliferate more quickly, are more likely to be transformed into cancer cells.⁷⁶

The results of intervention studies assessing mammographic density and breast cell proliferation are reassuring as they show that even when isoflavone exposure greatly exceeds typical Japanese intake (25–50mg/d),⁸ breast tissue is not adversely affected.^{38,77–83} These results align with the conclusions of the EFSA⁸⁴ and the SKLM.⁷ Also, the lack of effect of isoflavones on breast cell proliferation contrasts with the proliferative effects of CHT, which markedly increases proliferation^{85,86} and as noted previously, increases breast cancer risk.⁷¹

Not only are the clinical data supportive of safety, but the observational data are suggestive of benefit. The first prospective observational study to examine the impact of post-diagnosis soy intake on the prognosis of breast cancer patients was published in 2009.⁸⁷ Among women participating in the Shanghai Breast Cancer Survival Study, post-diagnosis soy intake was significantly associated with a decreased risk of recurrence and breast cancer-specific mortality. Subsequently published observational studies conducted in the U.S.^{88,89} and China^{90,91} align with these findings as was summarized by meta-analyses published in 2013⁹² and 2019.⁹³ Protective effects were observed in both estrogen receptor (ER) positive and ER negative patients.

Finally, in 2012, the American Cancer Society⁹⁴ and the American Institute for Cancer Research,⁹⁵

[updated in 2021⁹⁶] in 2014, the World Cancer Research Fund International,⁹⁷ and in 2015, the Canadian Cancer Society,⁹⁸ all concluded that women with breast cancer can safely consume soy.



Mineral Absorption

Soyfoods are frequently used in place of animal foods, many of which are good sources of iron and zinc and in the case of dairy foods, calcium. Consequently, questions about the status of these minerals in soyfood-consumers have been raised. However, because relatively little red meat is needed to meet daily iron and zinc requirements, concerns about these minerals relate primarily to those eating a predominately plant-based diet.⁹⁹

Like other legumes and whole grains, soybeans are high in phytate,¹⁰⁰ which acute studies show reduces the absorption of zinc and iron.¹⁰¹ In the U.S., the Food and Nutrition Board (FNB) recommends a zinc intake for vegetarians whose diet contains generous amounts of grains and legumes that is 50 percent higher than the recommended dietary allowance (RDA) for non-vegetarians; although, the FNB has not formally

established a vegetarian RDA.¹⁰² In Europe, zinc intake recommendations are based on the phytate content of the diet. For example, the population reference intake (the intake that is adequate for virtually all people in a population group) for men consuming a diet containing 300 mg phytate is 9.4 mg/d whereas it is 16.3 mg/d, for men consuming a diet containing 1200 mg zinc.¹⁰³

Zinc absorption from soyfoods is only modestly lower than that from animal sources.¹⁰⁴⁻¹⁰⁷ However, because soybeans contain relatively little zinc, unfortified soyfoods are not particularly good sources of this mineral. Because zinc status is difficult to assess,^{108,109} those consuming a plant-based diet are advised to specifically identify good plant sources of zinc in their diet and/or to take a zinc supplement.¹¹⁰⁻¹¹³

In contrast to zinc, the soybean is high in iron, especially compared with other legumes,^{114,115} which means some soyfoods contain more than 1 mg/serving of this mineral.¹¹⁶ Until recently, it was believed that iron was poorly absorbed from all plant foods, including soyfoods. For this reason, the U.S. vegetarian iron RDA is 80 percent higher than that for non-vegetarians. This higher RDA derives from the assumption that the bioavailability of iron from a vegetarian diet is about 10 percent, whereas that from a non-vegetarian diet is 18 percent.¹¹⁷



However, research utilizing newer methodology indicates that iron absorption from soy may be higher than previously thought because much of the iron in soy is in the form of ferritin. Although there is debate about the bioavailability of ferritin iron, clinical studies in which participants were fed either soyfoods or soybean ferritin show it to be bioavailable.¹¹⁸⁻¹²⁰

Finally, a study published in 2015 suggests that in contrast to older understanding,¹²¹ there may be adaptation to the inhibitory effects of phytate on iron absorption.¹²² For this study, 32 nonanemic premenopausal women with suboptimal iron stores were randomly assigned to a high or low-phytate diet for eight weeks. The serum iron response over four hours after a test meal containing 350 mg 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 percent increase in the area under the curve. In contrast, no change was observed in the low-phytate group.

It is reasonable to speculate that chronically consuming a high-phytate diet will lead to a mitigation of the inhibitory effects of phytate on the absorption of not just iron, but possibly other minerals as well. However, whether this “adaptation” to the inhibitory effects of phytate represents a specific biological adaptation to phytate per se, or simply a normal homeostatic response to increase mineral absorption to meet physiological requirements, as has been observed in the case of zinc and pregnant and lactating women, has yet to be definitively determined.¹²³

In addition to phytate, soybeans are also high in oxalate, another compound that binds calcium and reduces its absorption.¹²⁴ Oxalate is one reason that even though spinach is high in calcium, it is not a good source of this mineral.¹²⁵ Nevertheless, calcium absorption from soybeans



was found to be around 30% from high-phytate soybeans, comparable to milk at 37% – despite the presence of both phytate and oxalate.¹²⁶ This is also true for calcium-set tofu¹²⁷ and calcium-fortified soymilk.¹²⁸⁻¹³⁰ In fact, the absorption of calcium from these foods is comparable to the absorption of calcium from cow’s milk.

Allergies

Soy protein can cause allergic reactions in sensitive individuals, as is the case for essentially all food proteins. Since over 200 foods have been shown to be allergenic,¹³¹ regulatory agencies have recognized the need to focus allergen labeling regulations on a limited set of priority allergens. Soy is one of the eight foods that comprise the “Big 8” and are responsible for approximately 90 percent of all food-induced allergic reactions in the U.S.¹³² Sesame seed may soon be added to this group.¹³³

However, the prevalence of allergy for each of these foods differs markedly. In fact, U.S. and Canadian surveys conducted over the past 15 years shows that the prevalence of soy allergy is lowest among the Big 8.¹³⁴ Estimates are that about 3 out of every 1,000 adults are allergic to soy protein.¹³⁴ In comparison, the prevalence of milk/dairy allergy is 5-10x higher than soy allergy. The prevalence of soy allergy among

U.S. children/adolescents is also lowest among the Big 8. Furthermore, estimates based on clinical experience are that approximately 70% of children outgrow their soy allergy by age 10.¹³⁵

Data from Europe helps to emphasize that soy protein allergy is uncommon. Although soy is one of the Big 14, a recently published study involving six European countries found that the prevalence of allergy to 19 foods was greater than the prevalence of allergy to soy protein.¹³⁶ In agreement, a survey of nearly 5,000 adults in Western Europe found that of 24 foods evaluated, allergic reactions to 17 of these foods were more common than reactions to soy protein.¹³⁷

It is particularly informative to note that according to a report from EuroPrevall, “... data indicate that some allergens for which labelling is mandated and for which management measures are therefore instituted (e.g. soy, mustard), appear to have a lower public health impact than some, which are not required to be declared (e.g. some fruits.)”¹³⁸ EuroPrevall is a multidisciplinary project, including 62 institutions from 22 European countries. This organization is charged with studying the prevalence and distribution of food allergies in infants, children, adolescents, and adults in Europe.¹³⁹ Finally, due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens recommended soy not be listed as global priority allergen.¹⁴⁰



Soy Infant Formula

Soy infant formula (SIF) has been in use for more than 60 years. During this time, an estimated 20 million Americans used SIF during infancy.¹⁴¹ Current data from a nationally representative sample of 1,864 infants up to 1 year of age, from the National Health and Nutrition Examination Survey, 2003–2010, show that among the 81 percent of infants who were fed formula or regular milk, 12.4 percent consumed SIF.¹⁴²

According to the American Academy of Pediatrics, SIF produces normal growth and development;¹⁴³ nevertheless, SIF use has become controversial because of its high isoflavone content.¹⁴⁴



However, in 2009, the U.S. National Toxicology Program (NTP) concluded there was minimal concern about the safety of SIF.¹⁴⁵ The first systematic review and meta-analysis focused on the safety of SIF concluded that SIF 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.¹⁴⁶ Also, the authors of a recently published systematic review and meta-analysis concluded that there is no association between SIF and the onset of puberty in boys or girls.¹⁴⁷

Nevertheless, it should be acknowledged that more research on the long-term effects of SIF is warranted. Such information will be forthcoming from ongoing studies, most notable in this regard is the Beginnings Follow-Up Study.¹⁴⁸ Thus far, findings from this study indicate that all health parameters assessed in infants fed SIF are well within the normal range.^{149–155}



Puberty Onset



The impact of soy on the onset of puberty has garnered attention in part because pubertal characteristics are occurring at an earlier age in children throughout the world,^{156–167} although this trend is occurring in soyfood- and non-soyfood consuming countries alike.¹⁶⁸ Two Korean case-control studies found urinary isoflavone levels in girls with precocious puberty were higher than in children serving as controls.^{169,170} However, there were several experimental design weaknesses to these studies¹⁷¹ and the findings contrast with the results of a U.S. cross-sectional study involving 327 Seventh-day Adventist girls 12–18 years old that examined the impact of soy intake on age of menses onset (AOM).¹⁷²

For this SDA study, current soy intake was used as a surrogate for intake prior to menses onset. The consumption of total soyfoods and the intake of three specific types of soyfoods

(meat alternatives, tofu/traditional soy, and soy beverages) was not significantly associated with AOM nor was total soy intake significantly associated with the odds of early (<12 y of age) or late (≥ 14 y of age) AOM.¹⁷² A similarly designed study involving 248 SDA boys age 12–18 y found (mean isoflavone, puberty onset) moderate (10.1 mg/d, 12.58 y) and high (54.9 mg/d, 12.50 y) isoflavone intake was significantly associated with earlier adjusted median age at pubarche (based on pubic hair development) in comparison to low-soy consumers (0.8 mg/d, 13.00 y).¹⁷³ However, no significant associations were noted between isoflavone intake and facial hair onset, which was used as a secondary measure of puberty onset. Also, even among high-soy-consuming boys, puberty onset was later than is typical for U.S. boys.¹⁷⁴

Two small clinical studies^{175,176} and one population-based study¹⁷⁷ examined the impact of soy intake on hormone levels in children. In a Japanese cross-sectional study involving 230 boys and 198 girls aged 3–6 y, after adjusting for potential confounding, higher soy intake was inversely related to urinary estrone and estradiol in boys and positively related to urinary testosterone and androstenediol in girls.¹⁷⁷ Similar findings were reported for isoflavone intake. In contrast, little to no effects of isoflavone intake on hormone levels were noted in either of the two clinical intervention studies conducted. In one, estrogen levels were measured in 17 U.S. girls who consumed for 8 weeks one serving of soy daily (average isoflavone intake, ~ 27 mg/d).¹⁷⁵ In the other, estrogen levels were measured in 8 girls and testosterone levels in 4 boys; children consumed in random order for 8 weeks, a placebo or 16 mg/d or 48 mg/d isoflavones in tablet form separated by a two-week washout period.¹⁷⁶

Soyfood Processing



In addition to the traditional Asian soy foods, in many non-Asian countries, soy is also consumed in the form of modern soyfoods, such as meat analogues and energy bars, which use as a base concentrated forms of soy protein. As noted previously, these concentrated sources of soy protein, also referred to as soy protein ingredients, which include soy protein isolate, soy protein concentrate and soy flour, are comprised of $\geq 90\%$ and 65–90%, respectively.¹³ These ingredients have been extensively used by the food industry for decades. They are added to a wide array of foods for their functional properties including hydrating capacity, solubility, colloidal stability, gelation, emulsification, foaming and adhesion/cohesion.^{178,179}

Most soyfood-related clinical studies intervene with these ingredients in various forms rather than the traditional soyfoods. For example, most

information about soy protein quality,¹⁸⁰⁻¹⁸⁷ and its ability to lower cholesterol,^{4,188-194} and to promote gains in muscle mass and strength in response to resistance exercise training¹⁹⁵ comes from is based on studies involving soy protein isolate or soy protein concentrate. Consequently, much is known about the health effects of soy protein ingredients.

The starting point for the soy protein ingredients are soybean flakes, which are produced by crushing soybeans and removing the oil using a food grade solvent such as hexane. As such, claims have been made that residual hexane in products using these ingredients is a health risk.¹⁹⁶ If the soy protein ingredients represented a health risk, neither the U.S. FDA or Health Canada would have approved a health claim for soy foods, and coronary heart disease based on the cholesterol-lowering effects of soy protein.



Summary and Conclusions

When evaluating the safety of soyfoods, it is imperative to consider the totality of the scientific research and 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, which is relatively uncommon. Nevertheless, because all foods have the potential to cause undesirable effects in some individuals, people with specific health concerns or those who have questions about feeding soy infant formula should consult their healthcare provider regarding unique nutritional needs.

There are few if any soyfood intake recommendations from independent health organizations. The U.S. FDA established 25 g/d soy protein as the threshold intake for cholesterol reduction.¹⁹⁸ However, this threshold

was established for regulatory (labeling) purposes and is not intended to suggest all hypercholesterolemic individuals should consume soyfoods. Based on the results of clinical and epidemiologic research and intake in soyfood-consuming countries, a reasonable adult intake recommendation is 15–25 g/d soy protein and 50 to 100 mg/d isoflavones. Consuming amounts that exceed these recommendations is not associated with adverse effects, but there is little historical precedent for doing so.



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