



THE FUTURE OF SOYA FOR HEALTH & SUSTAINABILITY

Part 2 of 3

Soya isoflavones and the endocrine system

September 2022

Proceedings from the second of a three-part series: *the future of soya for health and sustainability – sharing global learnings*. Internationally-acclaimed experts present the latest research from across the globe.

Organised by the Alpro Foundation in partnership with the Fuji Foundation for Protein Research and MyNutriWeb.

Symposium held on the 20th September 2022

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About

Alpro Foundation

Alpro Foundation has been a scientific platform for over 25 years dedicated to supporting research and the dissemination of evidence-based knowledge on plant-based nutrition and its impact on health and environment amongst academics, healthcare professionals and key stakeholders in nutrition.

The ultimate aim is to help drive the transition to more healthful plant-based diets for human and planetary health.

Underpinning Alpro Foundation's scientific integrity is an independent Scientific Advisory Board of seven leading academic experts who provide direction and advice and ensure the scientific credibility of the education tools.

Additionally, Alpro Foundation celebrates and supports innovative scientific research by providing research grants and awarding young scientists for plant-based nutrition research. Alpro Foundation's research grant scheme has resulted in over 34 scientific publications to date.

Fuji Foundation for Protein Research

Recognising soya as an important plant-based source of protein, the Research Committee of Soy Protein Nutrition was established in 1979 in Japan by the Fuji Oil Group to advance both basic research and applications knowledge relating to soya. This Committee was the forerunner of the Fuji Foundation for Protein Research, a Japan-registered charity that promotes research on plant protein, in particular soya.

Since 1991, the Foundation has made grants to Japan-based research groups investigating plant protein in 4 subject areas:

- Nutrition & health
- Functionality
- Plant cultivation
- Food culture

There is an annual call for project proposals, which are then judged by the Foundation Committee's eminent panel of researchers and awards are distributed across the four categories given above. To date, these awards are only made to Japan-based researchers and the focus has been on soy protein research. However, the Foundation plans to expand the range of its activities in future years. New activities open to overseas researchers will be announced on this website from 2022 onwards.

MyNutriWeb

MyNutriWeb's mission is to empower all professionals who act as change agents in food and health, through online learning. The MyNutriWeb team is made up of experts with over 20 years' experience in nutrition and health communications.

They offer CPD-accredited and free to attend and on-demand, online learning opportunities to enable health professionals to keep up-to-date with the latest scientific evidence and everyday practice. The learnings cover a broad range of hot nutrition and health topics presented by leading experts in the field in various formats including webinars, symposia, journal clubs and round tables.

Executive summary

- Soya is a uniquely rich source of the isoflavones genistein, daidzein and glycitein. As naturally occurring plant compounds (phytoestrogens) they can bind to oestrogen receptors (ER), mainly to ER beta, in the body and have both weak estrogenic effects and anti-estrogenic effects.
- The health benefits of soya foods and of isoflavones have been rigorously investigated over the past 30 years with a large database of observational and clinical studies being published showing they are both effective and safe for human consumption.
- There is consistent evidence showing that soya foods and soya isoflavones do not act as endocrine disruptors, do not cause hormonal abnormalities nor have adverse health effects on a wide range of outcomes. This is the case for both primary and recurrent breast cancer, thyroid function, male and female reproductive function and the onset of puberty in children.
- Soya isoflavones have benefits for preventing age related oestrogen-deficient bone loss in women especially if combined with regular physical activity. Individual variations in response to isoflavones may result from population heterogeneity in the ability to produce the active metabolite equol from daidzein in the gut.
- Soya foods and isoflavones also show protective effects against hormone related cancers such as breast cancer. There are a variety of potential mechanisms of action including inhibition of the action of oestrogen dependent cancer cell proliferation.
- In addition to oestrogen receptor (ER) dependent mechanisms of action there appears to be an ER- independent mechanism of equol on the inhibition of cancer cell proliferation for cancers beyond those linked to oestrogen.

Human research and the safety of soya foods

Prof. Mark Messina

In the opening session Professor Mark Messina, Director of Nutrition Science and Research at the Soy Nutrition Institute Global, focussed on the safety of soya foods for human consumption. Most of the controversy around this topic has related to the fact that soya is a uniquely rich source of the isoflavones, genistein, daidzein and glycitein, providing approximately 25 mg of isoflavones per food serving.

Intakes of isoflavones vary considerably between areas of the world being substantially higher in Japan and the Far East compared with Europe and the US.^{1,2,3,4,5,6} See Figure 1.

Figure 1. Approximate per capita adult isoflavone intake

Region	mg / day
Japan	30-40
United States	<3
Europe	<3
United Kingdom	~5

Traditional soya foods

3-4mg isoflavones per g protein
1 servings, ~25mg

Isoflavones are classed as naturally occurring plant oestrogens (phytoestrogens) which bind to oestrogen receptors and have both weak estrogenic effects and anti-estrogenic effects.

When considering the strength of research on the safety of soya it is important to consider the hierarchy of evidence. See Figure 2

Animal studies have raised some concerns that isoflavone intake may exert adverse effects as endocrine disruptors. However, animals such as rodents, metabolise isoflavones in a markedly different way than humans and do not necessarily offer insights into their role in humans.⁷

¹ Bai W, Wang C, Ren C. Intakes of total and individual flavonoids by US adults. *Int J Food Sci Nutr*. 2014; 65 (1): 9-20. doi: 10.3109/09637486.2013.832170.

² Keinan-Boker I, Peeters PHM, Mulligan AA, et al. Soy product consumption in 10 European countries: the European Prospective Investigation into Cancer and Nutrition (EPIC) study. *Public Health Nutr*. 2002; 6B:1217-26 doi: 10.1079/PHN2002400.

³ Messina M, Nagata C, Wu AH. Estimated Asian adult soy protein and isoflavone intakes. *Nutr Cancer*. 2006; 55: 1-12. doi.org/10.1207/s15327914nc5501_1.

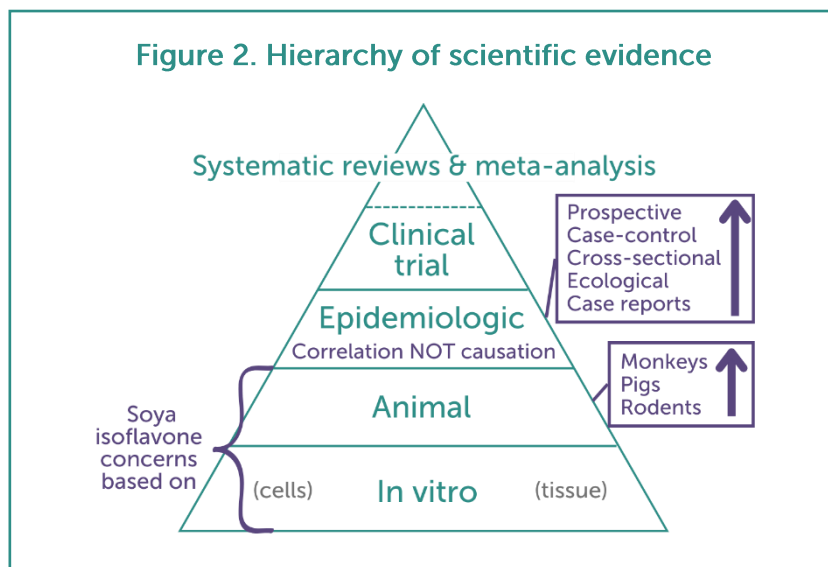
⁴ Konishi K, Wada K, Yamakawa M, et al. Dietary soy intake is inversely associated with risk of type 2 diabetes in Japanese women but not in men. *J Nutr*. 2019 ;149 :1208-1214. doi :10.1093/jn/nxz047.

⁵ Hara A, Sasazuki S, Inoue M, et al. Isoflavone intake and risk of gastric cancer: a population-based prospective cohort study in Japan. *Am J Clin Nutr*. 2012;95(1): 147-154 doi: 10.3945/ajcn.111.020479.

⁶ Murai U, Sawaga N, Charvat H, et al. Soy product intake and risk of incident disabling dementia: the JPHC Disabling Dementia Study. *Eur J Nutr*. 2022 ; E Pub ahead of print. doi 10.1007/s00394-022-02937-5

⁷ Setchell KDR, Brown NM, Zhao X, et al. Soy isoflavone phase II metabolism differs between rodents and humans: implications for the effect on breast cancer risk. *Am J Clin Nutr*. 2011; 94(5):1284-94. doi: 10.3945/ajcn.111.019638

Figure 2. Hierarchy of scientific evidence



Isoflavones and soya foods have been rigorously investigated over the past 30 years with a large body of observational (epidemiological) and clinical data being published on a broad range of health outcomes. A recent technical review shows that neither soya foods nor isoflavones warrant classification as endocrine disruptors and are safe for human consumption.⁸ In addition, the US Food and Drug Administration (USFDA) have concluded that an intake of soya protein needed for a cholesterol lowering claim in relation to heart health is safe.⁹ Although the review focused on the efficacy of soya protein, most safety concerns evaluated related to isoflavones.

A comprehensive reference guide for health professionals on the current state of knowledge regarding the safety and health benefits of soya which was recently published can be useful when discussing soya with clients and patients.¹⁰

The health effects of soy. A reference guide for health professionals

Authors: Messina M, Duncan A, Messina M, et al.

Journal: Front Nutr. 2022 Aug;9:970364

The ultimate guide for health professionals covering all topics relating to soya and isoflavones from nutrition basics through to all health associations. For each topic, the authors provide an in-depth critique of the published data and a concise summary with top line practical implications that health professionals can share with their patients.

16 soya & isoflavone topics

20-pages • over 550 references

Each topic comes with a 500-word summary & practical implications

⁸ Messina M, Blanco Mejia S, Cassidy A, et al. Neither soy foods nor isoflavones warrant classification as endocrine disruptors: a technical review of the observational and clinical data. Crit Rev Food Sci Nutr. 2022; 62(21): 5824-5885. doi: 10.1080/10408398.2021.1895054.

⁹ U.S. Food and Drug Administration (FDA). Proposed rules. Food labeling: Health claims; soy protein and coronary heart disease. Fed Reg. 2017; 82: 209.

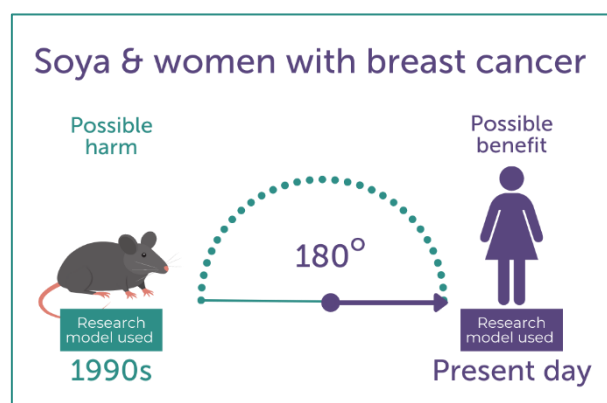
¹⁰ Messina M, Duncan A, Messina V, et al. The health effects of soy: a reference guide for health professionals. Front Nutr. 2022; 9:970364. doi: 10.3389/fnut.2022.970364

The publication summarises the data for several key areas relating to safety of soya foods in adults.

Breast cancer

Soya foods and soya isoflavones do not adversely impact markers of breast cancer risk such as breast tissue density or breast cell proliferation.^{8,10}

Several major organisations have concluded that soya foods are safe for breast cancer patients and/or that isoflavones do not adversely affect breast tissue. The organisations include the American Institute for Cancer Research, the World Cancer Research Fund, the American Cancer Society, Canadian Cancer Society, Cancer Nutrition Consortium,



Irish Society of Medical Oncology, the European Food Safety Authority and the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation).

In fact there has been a shift from the view that isoflavone exposure is contraindicated for breast cancer survivors to the view, based on observational data, that post diagnosis soya consumption is safe and may in fact reduce the risk of cancer recurrence.^{11,12}

Professor Messina also explored the hypothesis that breast cancer protection in Asian women consuming traditional diets may be in part derived from early life exposure to soya foods.^{13,14} The years before the birth of a first child appear to be critically important in establishing future risk of breast cancer and there may be potential benefits in encouraging girls to consume a serving of soya foods daily.

Reproductive health

In men, the totality of the clinical research shows no adverse effects of soya or soya isoflavones on sperm or semen parameters, fertility, testosterone or oestrogen levels nor the development of breast tissue (gynecomastia). In addition, there are no significant effects on fertility or reproductive hormone levels in women.^{8,10}

Thyroid function

No adverse effects of soya or soya isoflavones have been found on normal thyroid function, thyroid hormone (T3 and T4) levels or in the impairment of thyroid function in individuals with sub clinical hypothyroidism or where iodine intake is marginal.^{8,10}

¹¹ Chi F, Wu R, Zeng YC, et al. Post-diagnosis soy food intake and breast cancer survival: a meta-analysis of cohort studies. *Asian Pac J Cancer Prev*. 2013 ;14(4): 2407-12. doi: 10.7314/apjcp.2013.14.4.2407.

¹² Rock CL, Thompson CA, Sullivan CR, et al. American Cancer Society nutrition and physical activity guideline for cancer survivors. *CA: a Cancer Journal for Clinicians*. 2022; 72(3): 230-262. doi: 0.3322/caac.21719

¹³ Lamartiniere CA, Zhang JX, Cotroneo MS. Genistein studies in rats: potential for breast cancer prevention and reproductive and developmental toxicity. *Am J Clin Nutr*. 1998; 68(6 Suppl):1400S-1405S. doi: 10.1093/ajcn/68.6.1400S.

¹⁴ Colditz GA and Frazier AL. Models of breast cancer show that risk is set by events of early life: prevention efforts must shift focus. *Cancer Epidemiol Biomarkers Prev*. 1995;4(5):567-71.

Children and soya

There is less research on the safety of soya in children, but overall, the evidence suggests soya is safe for children. There are secular trends worldwide towards earlier onset of puberty in both soya and non-soya consuming countries. Soya intake does not appear to influence onset of menarche in adolescent girls nor hormone levels in children.^{15,16,17,18}

Take home messages

There is consistent evidence showing that soya foods and soya isoflavones do not act as endocrine hormone disruptors, do not cause hormonal abnormalities nor have adverse health effects on a wide range of outcomes. This is the case for both primary and recurrent breast cancer, thyroid function, in male and female reproductive function and the onset of puberty in children.

A recently published technical review and reference guide for health professionals are available covering the safety and health effects of soya which can aid practitioners discussing this topic with clients and patients.^{8,10}

With regard to future risk of breast cancer there may be potential benefits in encouraging girls to regularly consume soya foods.

¹⁵ Messina M, Macedo Rogero M, Fisberg, M et al. Health impact of childhood and adolescent soy consumption. *Nutr Rev.*2017 ;75(7) :500-515. doi :10.1093/nutrit/nux016.

¹⁶ Segovia-Siapco S, Pribis P, Messina M, et al. Is soy intake related to age at onset of menarche? A cross-sectional study among adolescents with a wide range of soy food consumption. *Nutr J.* 2014; 13: 54 doi: 10.1186/1475-2891-13-54.

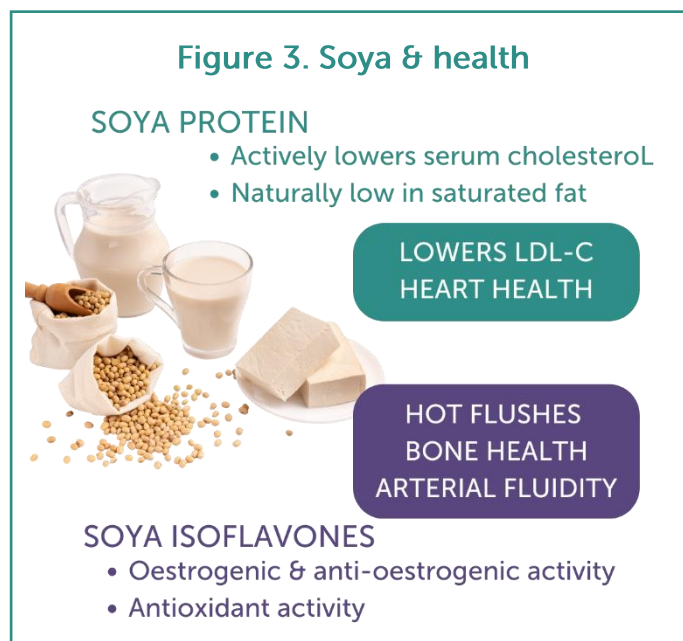
¹⁷ Maskarinec G, Morimoto Y, Novotny R, et al. Urinary sex steroid excretion levels during a soy intervention among young girls: a pilot study. *Nutr Cancer.* 2005 ;52(1) :22-28 doi: 10.1207/s15327914nc5201_3.

¹⁸ Zung A, Shachar S, Zadik Z, et al. Soy-derived isoflavones treatment in children with hypercholesterolemia: a pilot study. *J Pediatr Endocrinol Metab.*2010; 23(1-2): 133-41 doi: 10.1515/jpem.2010.23.1-2.133.

Soya and women's health: a focus on bone and fat metabolism

Prof. Yoshiko Ishimi

Professor Yoshiko Ishimi from the NODAI Research Institute at Tokyo University of Agriculture, gave an overview of some of the nutrients and functional components found in soya and their role in relation to health including benefits for lipid metabolism¹⁹ and cardiovascular health and for bone health. See Figure 3



There is evidence that, through selective oestrogen receptor modulation, isoflavones have beneficial effects against age related oestrogen-deficient bone loss which can lead to osteoporosis. A recent systematic review and meta-analysis has shown that soya isoflavones exert a protective effect on bone mineral density in peri and post-menopausal women.²⁰

Research has shown that despite having structural similarity to oestrogen, soya isoflavones do not exhibit estrogenic action in the uterus making them a safe and effective treatment as a natural selective oestrogen receptor modifier for the maintenance of bone health with ageing.^{21,22}

There also appears to be a complementary effect between soya isoflavone intake and physical activity. In postmenopausal women a combined intervention of isoflavone

¹⁹ Mejia SB, Messina M, Li SS, et al. Meta-analysis of 46 studies identified by the FDA demonstrates that soy protein decreases circulating LDL and total cholesterol concentrations in adults. J Nutr. 2019;149(6):968–981. <https://doi.org/10.1093/jn/nxz020>

²⁰ Lambert MNT, Hu LM and Jeppesen PB. A systematic review and meta-analysis of the effects of isoflavone formulations against oestrogen-deficient bone resorption in peri- and postmenopausal women. Am J Clin Nutr. 2017 ; 106(3) :801-811 doi.org/10.3945/ajcn.116.151464

²¹ Ishimi Y, Miyaura C, Ohmura M et al. Selective effects of genistein, a soybean isoflavone, on B-lymphopoiesis and bone loss caused by oestrogen deficiency. Endocrinology. 1999; 140(4): 1893-1900 . doi: 10.1210/endo.140.4.6663

²² Ishimi Y, Arai N, Wang X et al. Difference in effective dosage of genistein on bone and uterus in ovariectomized mice. Biochem Biophys Res Commun. 2000; 274 (3): 697-701. doi: 10.1006/bbrc.2000.3175.

intake (75mg /day) and walking exercise (45 minutes duration on 3 days per week) over the course of one year showed a greater effect on the prevention of bone loss than either intervention alone.²³

There is however some variation in the response found to soya isoflavones for skeletal health and this may be in part due to differences in the ability of individuals within populations to produce equol an active metabolite of daidzein formed by the action of the gut microbiota.²⁴

There is interesting emerging evidence that isoflavones, taken in conjunction with other food items such as green kiwi fruit, lead to greater improvements in markers of bone health in postmenopausal women.²⁵ This suggests a possible role of vitamin K and/or other bioactive components of plant foods in supporting bone mineralisation

Take home messages

Soya isoflavones have benefits for preventing age related oestrogen-deficient bone loss in peri and post-menopausal women especially if combined with regular physical activity.

Variations in response to soya isoflavones may be a result of population heterogeneity in the ability to produce the active metabolite equol from daidzein in the gut. Further research is needed to explore whether this can be enhanced by the inclusion of other dietary factors.

²³ Wu J, Oka J, Tabata I et al. Effects of isoflavone and exercise on BMD and fat mass in postmenopausal Japanese women: a 1-year randomized placebo-controlled trial. *J Bone Miner Res.* 2006; 21(5):780-9. doi: 10.1359/jbmr.060208.

²⁴ 24. Tousen Y, Ezaki J, Fujii Y et al. Natural S-equol decreases bone resorption in postmenopausal, non-equol-producing Japanese women: a pilot randomized, placebo-controlled trial. *Menopause* . 2011; 18(5): 563-574. doi: 10.1097/gme.0b013e3181f85aa7

²⁵ Kruger MC, Middlemiss C, Katsmata S et al. The effects of green kiwifruit combined with isoflavones on equol production, bone turnover and gut microflora in healthy postmenopausal women. *Asia Pac J Clin Nutr.* 2018 ; 27(2) :347-358 doi: 10.6133/apjcn.062017.06

Evidence on the effect of soya food consumption on breast cancer risk

Prof. Sabine Ellinger

Professor Sabine Ellinger, from the Department of Nutrition and Food Sciences at the University of Bonn in Germany delved more deeply into the role of soya isoflavones in breast cancer.

From the field of epidemiology case control studies suggest that high intakes of soya isoflavone reduce the risk of breast cancer in Asian women.²⁶ This appears to be dose-dependent and is found in both pre- and post-menopausal women. However in Western populations, the risk of breast cancer has not been shown to be different between high and low isoflavone intakes. Meta-analysis of prospective cohort studies have also found no association between high, moderate and low isoflavone intake on breast cancer risk but high versus low soya food consumption reduces the risk of breast cancer on average by 13%.²⁷

Professor Ellinger outlined the potential physiological mechanisms of action by which the protective effects of isoflavones might occur.^{28,29,30,31} These include:

- Lowering the conversion of oestrogen precursors to oestrogens
- Altering oestrogen metabolism to decrease cancerous metabolites and increase those with lower oestrogen activity
- Reducing oxidative stress and the activation of inflammatory and proliferative pathways
- Binding to oestrogen beta receptors (ER β) receptors to decrease stimulation of cell growth and proliferation in breast tissue.

Despite interesting epidemiological data and potential physiological mechanisms, a causal relationship for the role of soya isoflavones can only be established by experimental trials. Professor Ellinger presented the results from a systematic review of randomized controlled trials (RCTs) in which she was a co-author.³² The review looked at the effects of soya isoflavones from food or supplements on a range of biomarkers for breast cancer risk in healthy subjects over periods ranging from 1 to 36 months.

In contrast to that expected from the epidemiological data, most of the studies did not detect a difference between isoflavone and control or placebo treatment. This was despite good compliance to isoflavone treatment and was irrespective of intervention

²⁶ . Wu AH, Yu MC, Tseng CC, et al. Epidemiology of soy exposures and breast cancer risk. Br J cancer. 2008; 98(1): 9-14. doi: 10.1038/sj.bjc.6604145

²⁷ Zhao TT, Jin F, Li JG, et al. Dietary isoflavones or isoflavone-rich food intake and breast cancer risk: A meta-analysis of prospective cohort studies. Clin Nutr. 2019 ;38(1): 136-145.doi: 10.1016/j.clnu.2017.12.006.

²⁸ Mal R, Magner A, David J, et al. Oestrogen Receptor Beta (ER β): A ligand activated tumor suppressor. Front Oncol. 2020; 10:587386. doi: 10.3389/fonc.2020.587386.

²⁹ Duursen M. Modulation of oestrogen synthesis and metabolism by phytoestrogens in vitro and the implications for women's health. Toxicol Res. 2017; 6 (6): 772-794 .doi.org/10.1039/c7tx00184c

³⁰ Ibarreta D, Daxenberger A, Meyer HH. Possible health impact of phytoestrogens and xenoestrogens in food. APMIS. 2001; 109(3): 161–184. doi:10.1034/j.1600-0463.2001.090301.x

³¹ Cosentino G, Plantamur I, Cataldo A ,et al. MicroRNA and oxidative stress interplay in the context of breast cancer pathogenesis. Int J Mol Sci. 2019; 20 (20): 5143. doi: 10.3390/ijms20205143

³² Finkeldey L, Schmitz E, Ellinger S. Effect of the intake of isoflavones on risk factors of breast cancer—a systematic review of randomized controlled intervention studies. Nutrients. 2021;13(7):2309. doi.org/10.3390/nu13072309

type, isoflavone dose or length of treatment. At present considering the risk of bias and methodological limitations, there is little evidence that isoflavone treatment modulates risk factors of breast cancer in pre- and postmenopausal women. However, this lack of significant findings does not imply an absence of benefit. Future studies are recommended to calculate sample sizes to detect possible effects and consider methodological details to improve study quality.

Take home messages

Epidemiological studies show benefits of soya isoflavones and soya food consumption for the reduction of breast cancer risk in pre- and post-menopausal women.

There are several potential mechanisms of action by which soya isoflavones may exert protective effects against breast cancer.

At present systematic reviews of randomised control trials have not found benefits from soya isoflavone intake on biomarkers for breast cancer risk in healthy women but future studies with improved methodology may detect possible effects.

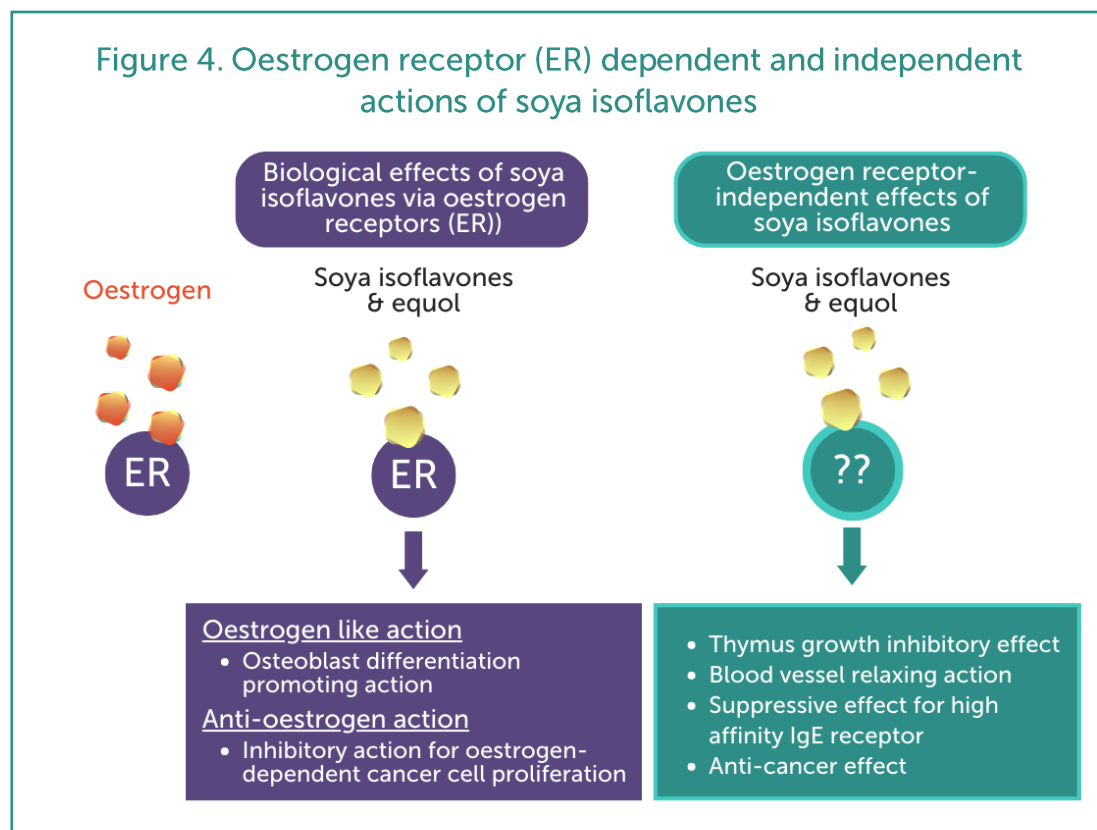
Soya isoflavones: oestrogen receptor dependent and independent actions

Prof. Hirofumi Tachibana

In final and most technical presentation, Professor Hirofumi Tachibana from the Department of Bioscience and Biotechnology at Kyushu University in Japan, looked at fascinating new research on the molecular basis of action of soya isoflavones which extends the boundaries of our understanding of their role in the body.

As discussed by previous speakers it is widely understood that soya isoflavones exhibit oestrogen receptor (ER) binding and inhibitory action for oestrogen dependent cancer cell proliferation. This finding is supported by epidemiological studies showing soya isoflavone consumption from diet is associated with a reduced risk of hormone sensitive cancers such as breast cancer.³³

However, Professor Tachibana and his team have recently shown that soya isoflavones may also have ER-independent mechanisms of action in areas of the body other than oestrogen receptors.³⁴ See Figure 4



Daidzein appears to act via its intestinal metabolite equol to inhibit proliferation in HeLa cells, a human cervical cancer cell line that does not express oestrogen receptors. Equol

³³ Yamamoto S, Sobue T, Kobayashi M et al. Soy, isoflavones and breast cancer risk in Japan. J Natl Cancer Inst. 2003; 95(12): 906- 913. doi: 10.1093/jnci/95.12.906.

³⁴ Yamashita S, Lin I, Oka C et al. Soy isoflavone metabolite equol inhibits cancer cell proliferation in a PAP associated domain containing 5-dependent and an oestrogen receptor-independent manner. J Nutr Biochem. 2022; 100 :108910 doi.org/10.1016/j.jnutbio.2021.108910

has also been shown to inhibit growth of melanoma cell lines in a mouse model. Daidzein and equol appear to act by increasing the expression of micro ribonucleic acids (mRNAs) which regulate gene expression and have known anti-cancer cell proliferation effects. Research indicates that this ER-independent mechanism of action is dependent on the RNA modifying enzyme, PAP associated domain containing 5 (PAPD5) rather than oestrogen.

Take home messages

Soya isoflavones have oestrogen dependent (ER) mechanisms of action in the body by inhibiting the action of oestrogen dependent cancer cell proliferation and helping reduce the risk of hormone sensitive cancers.

Recent research also indicates an ER-independent mechanism of equol, an intestinal metabolite of daidzein, on the inhibition of cancer cell proliferation which helps to account for the health benefits of soya for cancers beyond those linked to oestrogen.

[Click here to watch the symposium recording](#)

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