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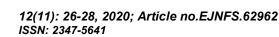
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Soy Intake and Possible Adverse Health Effects in Nordic Children and Pregnant Women (Unborn Children)

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Authors' contributions

This work was planned and carried out in collaboration among all authors. Author SF was responsible for the dietary analysis. Author LB managed the literature searches. First draft of the manuscript was written by authors SF, JB and LB. All authors read and approved the final manuscript.

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Grey Literature

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ABSTRACT

Background: The intake of plant-based foods is currently increasing in the Nordic countries and many of these products are based on soy. For example, soy-based products with appearances close to minced meat are marketed as substitutes for meat, and many soy-based milk alternatives are replacing cow's milk. The rising interest in such products can partly be attributed to an increasing number of persons identifying themselves as vegetarians or vegans. An increased intake of soy-based products as replacements of milk and meat may be beneficial to health, but there is also a concern for adverse health effects in certain population groups. The natural content of estrogen-like substances (e.g. isoflavones) in soy gives rise to concern for endocrine disrupting effects in children and unborn children (i.e. pregnant women).

Aims: The aims of this project were to:

1) Explore available data on soy intake,

2) Propose intake scenarios for children and pregnant women from the Nordic countries with high intake of soy products,

- 3) Estimate the nutritional impact of substituting conventional products of animal origin with soy products and
- 4) Clarify whether health-based guidance values (HBGVs) can be determined for isoflavones for children and women of childbearing age.

Methods: A dietary exposure scenario with substantial substitution of animal products with soybased products in the diet of Danish women (age 18-45 years) and children (age 4-10 years) was established for the exploration of effects of soy-based products on dietary intake and nutrition. The basis of these calculations was the Danish National Survey of Diet and Physical Activity 2011-2013 (DANSDA); a nationwide, cross-sectional survey assessing diet and physical activity of the Danish population. In addition, dietary exposure to isoflavones from such a substantial soy-substituted diet was estimated based on recently published data on isoflavone content in different foods. A literature search including five different databases for the investigation of animal and human studies relevant for a risk assessment of isoflavones (genistein, daidzein and glycitein) was performed.

Results: In the scenario of a substantial soy-substituted diet the intake of soy was higher in children than in women, due to higher intake of milk products among children. Approximately 60% of the intake of soy was derived from substituted dairy products (milk and cream products). Only minor changes occurred in the intake of energy, protein, carbohydrates and fats among women and children, while the intake of various micronutrients changed by this substitution. Intake of vitamin A, riboflavin and vitamin B_{12} was reduced 20% or more among both women and children, while the intake of vitamin E increased more than 20% among women and children. Among children, the intake of calcium and iodine decreased 20% or more, while the intake of magnesium increased. This does, however, not change the degree of fulfilling recommended intake levels of micronutrients, as the intake was near or above recommended intake both with and without substitution for most substances, except for vitamin D and iron, which was low regardless of substitution or not.

In this scenario with substantial soy substitution, the estimated genistein exposure ranged between 0.04-0.06 mg/kg bw per day for women, 0.09-0.2 mg/kg bw per day for girls and 0.1-0.2 mg/kg bw per day for boys. The estimated daidzein exposure was similar to the genistein exposure, while estimated glycitein exposure was considerably lower for all groups. The total estimated isoflavone exposure (sum of genistein, daidzein and glycitein) ranged between 0.05-0.1 mg/kg bw per day for women, 0.1-0.3 mg/kg bw per day for girls and 0.2-0.4 mg/kg bw per day for boys.

A total of 6,304 references were identified in the literature search for human and experimental animal toxicity data on soy and soy constituents. After assessment for relevance, five animal studies, 23 human studies and three review papers were included in the hazard identification and characterization. Among the human studies four major endpoints were identified, i.e., timing of puberty, breast cancer, hypospadias and thyroid function. These endpoints were also identified among the animal studies with the addition of fertility and markers of impaired reproductive development.

Among the four included endpoints, no critical effect of isoflavones on children or pregnant women (unborn children) in the human studies was identified. Two animal studies were considered suitable for deriving an HGBV for genistein exposure of children and pregnant women. Results from a multi-generational study in rats were thus used for HBGV derivation for genistein exposure of pregnant women (0.09 mg/kg bw per day corresponding to 6.3 mg per day for a person weighing 70 kg). A study on post-weaning exposure of mice was used for HBGV derivation of genistein for exposure of children (0.07 mg/kg bw per day corresponding to 2.1 mg per day for a child weighing 30 kg). The critical effects for both HBGVs were timing of puberty and early mammary development.

Conclusions: It was possible to address all aims of the project:

 The available data on soy intake among the general population in Denmark was explored by analysing data from the dietary survey and conducting research regarding available soybased products on the Danish market.

- 2) Intake of soy in women and children with high intake of soy was estimated in scenarios using substitution of foods that realistically could be substituted by soy-containing products. The results showed that intake of soy is higher in children than in women, due to higher intake of milk products among children.
- 3) No adverse nutritious impacts on either macro- or micronutrients were identified when substituting animal-based products with soy-based varieties.
- 4) An HGBV could be determined for genistein for children and pregnant women. Based on estimated intake of genistein from a substantial soy-substituted diet there is no concern for pregnant women (unborn children). On the other hand, for girls and boys (age 4-10 years), the HGBV for genistein is slightly exceeded after intake of a soy-substituted diet, indicating a potential health concern for children eating a substantial soy-substituted diet.

Keywords: Soy; genistein; isoflavones; children; pregnant; foetus; risk assessment; exposure.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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