

Dr. Michael D Shelby
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4th December 2006

Dear Dr. Shelby

The Sanitarium Health Food Company wishes to submit the following comments for consideration in the development of your final conclusions and recommendations regarding the draft briefs on genistein and soy infant formula that were released in October 2006. The Sanitarium Health Food Company is a leading Australian manufacturer of health foods, and has produced leading brands of soymilks and soy based meals for over 35 years.

We would like to reiterate the concerns expressed in our letter dated 1st March 2006 regarding our comments on the draft expert panel reports on genistein and soy infant formula. In addition, we would like to submit our comments and concerns on the changes outlined in the October 2006 brief, upgrading the level of concern from 'minimal' to 'possible' for the impact of genistein and soy infant formula on reproduction and development.

Sanitarium is concerned that the NTP has changed the expert panels recommendation because of a single new rodent study showing toxicity at blood concentration levels similar to those reported in human infants. In this animal study, rodents were injected during gestation with free (pure) genistein. It is inappropriate to apply these findings to humans for several reasons:

- Children raised on soy formula do not consume pure genistein – in fact genistein accounts for less than 2% of the isoflavone content of most western soy foods including soy infant formula.
- Injecting genistein bypasses the digestive system and liver, resulting in a much different exposure in type and intensity compared to the effects of eating soy foods or formula.
- Levels of genistein injected into rodents are often much higher than what would be consumed naturally through the diet.
- Newborn rodents are not comparable to newborn human infants - they are equivalent to a human fetus in the first three months of pregnancy.

Sanitarium questions the validity for justification of the NTP changes to the expert panel recommendations. Upgrading the level of concern to 'possible' for the impact of genistein and soy infant formula on reproduction and development, based on one rodent study, is extremely inappropriate.

Sanitarium does not support the new conclusion of the NTP upgrading the level of concern from 'minimal' to 'possible' for the impact of genistein and soy infant formula on reproduction and development. Sanitarium is concerned that conclusions made about the rodent study presented in the draft brief will lead to unnecessary and unfounded claims regarding the demonstrated health benefits of including soy foods as part of a balanced and varied diet.

Sanitarium believes there is sufficient evidence to support the health and safety of soy foods and soy infant formulas. Some 20 million infants worldwide have been raised on soy-based infant formula for more than 30 years with no scientific reports of adverse health conditions. A robust body of science has clearly demonstrated its safety and efficacy.

The American Academy of Pediatrics (AAP)¹, the Food and Drug Administration (FDA) and Food Standards Australia New Zealand (FSANZ)² have concluded that soy-based infant formula is a safe and acceptable way to support the normal growth and development of healthy infants.

Several studies show that eating a diet rich in soy early in life can enhance the overall health of adults and reduce the risk of heart disease and certain cancers. Recent studies in China and the United States show that groups of women who regularly consumed soy foods early in life had a lower risk of breast cancer in later adulthood.^{3 4}

We trust that these comments are useful for consideration by the committee.

Thank you.

Kind regards,

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On behalf of the –
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1. American Academy of Pediatrics Committee on Nutrition. Soy protein-based formulas: Recommendations for use in infant feeding. Pediatrics 1998;101:148-153.
2. Australia New Zealand Food Authority (now FSANZ), Phytoestrogens – an assessment of the potential risks to infants associated with exposure to soy-based infant formula, March 1999
3. Shu XO; Jin F; Dai Q; et al, Soyfood intake during adolescence and subsequent risk of breast cancer among Chinese women, Cancer Epidemiol Biomarkers Prev 2001;10:483-8
4. Wu AH et al, Adolescent and adult soy intake and risk of breast cancer in Asian-Americans, Carcinogenesis 2002;23(9):1491-1496.