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Dear Dr. Shelby

The Sanitarium Health Food Company wishes to submit the following comments for consideration regarding the reports on genistein and soy infant formula which were released for public comment as a result of the 14-member expert panel meeting held in March 2006. Sanitarium has previously submitted comments on the initial drafting of these reports (March 2006).

We acknowledge the significant amount of work undertaken by the committee to compile and review the large number of the scientific studies in the area of genistein and soy infant formula and the discussions and debate of the expert panel meeting.

Sanitarium is pleased to see that the lack of studies in human subjects has been acknowledged regarding toxic effects of genistein. Further, we support the statements included in the soy infant formula report that highlight the differences in how rodents and humans metabolise isoflavones and the subsequent limited ability to extrapolate the findings of rodent studies to humans. We also support the recommendations outlined under 'critical data needs' for human studies to be conducted, both case-control and longitudinal. We do however, question the recommendations of the draft report for further animal studies to assess the effects of soy formula or genistein exposure on various post-natal endpoints. We refer to the editorial of Professor Ken Setchell¹, which highlights the limitation of the rodent model for assessing human infant reproductive development.

Sanitarium is also pleased to see that the minor contribution of genistein to the total isoflavone content of soyfoods has been acknowledged, as we believe that the use of purified genistein in various animal and in-vitro studies is a major limitation for extrapolating the findings to the potential impacts of humans consuming soy foods.

Overall, Sanitarium strongly supports the draft conclusions of the expert panel –

1. That there is 'negligible concern for reproductive and developmental effects from exposure of adults [to genistein] in the general population';
2. That 'adults would be unlikely to consume sufficient daily levels of genistein to cause adverse reproductive and/or developmental effects'.

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



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On behalf of the –
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¹ Setchell KDR, Assessing the risks and benefits of genistein and soy, Environmental Health Perspectives June 2006;114(6)332-333.