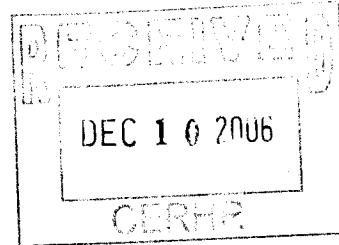


850 New North Rd
Mt Albert
Auckland 1032
New Zealand

CERHR Director, NIEHS
P.O. Box 12233, MD EC-32
Research Triangle Park, NC 27709
shelby@niehs.nih.gov



10th December 2006

Re: Written comments on the NTP-CERHR Draft
Expert Panel Reports on the Reproductive and
Developmental Toxicity of Genistein and Soy
Formula, and request for time for oral public
comments during the March 15-17 Expert Panel meeting FR Doc. E5-7412)

Attention: Dr Michael D. Shelby

Dear Dr Shelby

I am writing to comment on the NTP-CERHR report: 'The reproductive and Developmental Toxicity of Soy Formula'. I am a consultant environmental scientist with no affiliations to any branch of the food industry; dairy, meat, soy or any other. My interest in genistein and soy formulas stems back to 1993 when I was approached by a private citizen to review the toxicity of soy-based foods. The approach was made because the individual concerned, who is New Zealand's largest private parrot breeder, believed soy-based bird feeds had caused growth abnormalities, infertility and deaths in his captive parrots.

I took time to visit his aviaries and was particular struck by the rapid development of adult plumage in the male Crimson Rosellas. Figure 1 shows a pair of adult Crimson Rosellas; the female is green and the male is red. In normal circumstances male birds develop their adult plumage around 12 to 18 months but what I found remarkable was the juvenile birds I saw had adult plumage after just 10 to 12 weeks. Perhaps even more remarkable was the advertising for a bird feed that was new to New Zealand, which hailed the fact that rapid development could be achieved (Figure 2). The bird feed contained soy whereas previous feeds used did not.

This was a long-winded introduction, but I know you appreciate that observations from the animal kingdom frequently lead scientists to think about what it means for humans. Ultimately my observations led me to review of soy toxicity and myself and three other New Zealand Scientists to write to the New Zealand Medical Journal regarding our concerns regarding the potential effects of soy formulas on infants (Irvine et al. 1995).

Our concerns about soy formulas were based on the effects of genistein on diverse animal species: rats, mice, cheetah, sheep, quail and a preliminary study indicating showing biological in humans (Cassidy et al 1994). These concerns about the known effects of genistein and the potential effect on humans were not new having been noted in 1973 by Martin Stob:

“The availability of sensitive methods for the analysis and detection of the major phytoestrogens would seem to guarantee that food containing appreciable quantities of the compounds would not be used for human consumption”.

However, it was not the potential known effects of genistein that troubled me most; rather it was the unknown effects of feeding an endocrine disrupting compound to young infants for a significant period of their early lives. More than a decade on the scientific community is still divided as to whether the concern is warranted or not. In spite of what has been published over the past decade my basic position has not changed; why should we allow the sale of soy formulas if there is even a hint of a risk?

I have read the submissions made by other parties. I note the major arguments in rejecting the reproductive and developmental toxicity of genistein appear to be: animal models are inappropriate for comparison with humans and if genistein caused a problem in infants “it would have showed up by now”.

It is a fact that certain animal models are less useful than others when predicting the effects on human infants. But forget the debate on why genistein may or may not act in humans, forget the debate on genistein’s estrogenic potency and forget the debate on how much genistein may be conjugated in the human infant’s plasma. These become irrelevant when viewed next to the negative (and frightening) effects of feeding soy formula for **JUST** 5-6 weeks in marmosets, which are a decent animal model (Sharpe et al. 2002, Tan et al. 2006).

I continue to be bemused by the claims the work of show that soy formulas are safe. The study of Strom et al. (2002) is much cited by soy formula proponents as evidence for safe use. But does anybody actually read the fine print anymore? The study is not particularly good and was funded by the Fomon institute, which in turn receives funding from major soy formula manufacturers.

I am amazed that one of your submitters, a well respected scientist, would argue that if genistein were a problem for infants fed soy formulas it would be obvious. There are numerous examples in the body of scientific literature were the subtle, yet devastating effects, of toxins were not easily detected in large populations. I will not insult the Expert Panel’s intelligence by quoting them verbatim, but please recall the story of DES and fetal alcohol syndrome.

The same submitter appears irate that the soy formula debate has made its way into the media. This is laughable considering the millions that the soy industry spends each year on advertising their products in the media as the miracle cure for all manner of diseases and disorders. The presence of genistein in soy formulas has been known about for decades, as have the potential risks to infants, and yet it took media involvement in the mid 1990s before the issue got looked at with the attention it deserved. More than a

decade later, many thousands of infants, chiefly from the United States, have unnecessarily been exposed to genistein even though the outcome of such exposures is uncertain.

I respectfully ask the Expert Panel to consider the following questions:

If genistein were not a naturally occurring compound would it be permitted to be added to soy formulas?

Do parents feeding soy formulas have any idea they contain endocrine disrupting compounds and if so do they deserve the right to know?

Are you 100% certain genistein is safe for infants?

Yours faithfully,

Mike Fitzpatrick PhD

Figure 1:

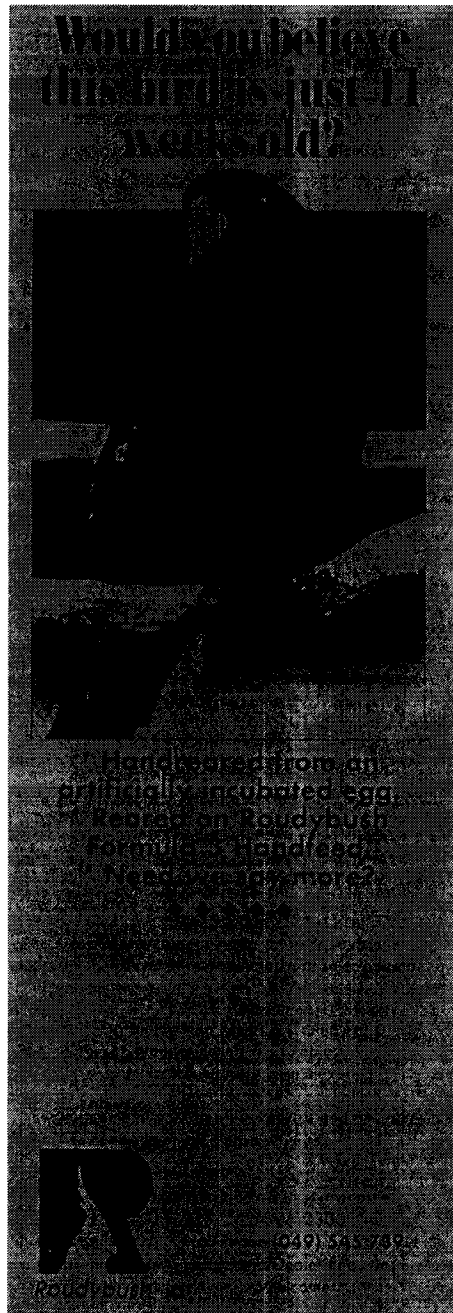
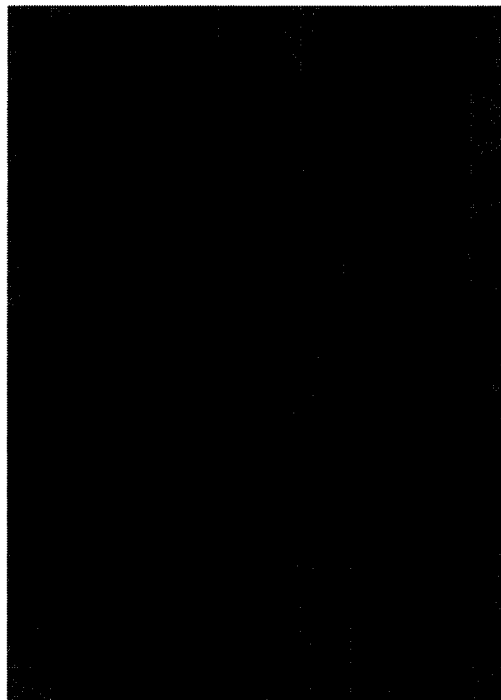


Figure 2:



References:

Cassidy A, Bingham S, Setchell KD, 1994: Biological effects of a diet of soy protein rich in isoflavones on the menstrual cycle of premenopausal women, *Am J Clin Nutr.*;60(3):333-40.

Irvine C, Fitzpatrick M, Robertson I and Woodhams D, 1995: The Potential Adverse Effects of Soybean Phytoestrogens in Infant Feeding. *NZ Med J*, 108: 208-209.

Sharpe RM, Martin B, Morris K, Greig I, McKinnell C, McNeilly AS, Walker M, 2002: Infant feeding with soy formula milk: effects on the testis and on blood testosterone levels in marmoset monkeys during the period of neonatal testicular activity. *Hum Reprod.* 17(7):1692-703.

Strom BL, Schinnar R, Ziegler EE, Barnhart KT, Sammel MD, Macones GA, Stallings VA, Drulis JM, Nelson SE, Hanson SA, 2001: Exposure to soy-based formula in infancy and endocrinological and reproductive outcomes in young adulthood, *JAMA.* 286(7):807-14.

Stob M: Committee on Food Protection, National Academy of Sciences (1973).

Tan KA, Walker M, Morris K, Greig I, Mason JI, Sharpe RM, 2006: Infant feeding with soy formula milk: effects on puberty progression, reproductive reproductive function and testicular cell numbers in marmoset monkeys in adulthood. *Hum. Reprod.* ;21(4):896-904.

