



## Facsimile Transmission

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**Company:** Practising Midwife  
**Attention:** Ms Jilly Rosser  
**Fax Number:** 0044-117-924-1101  
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Dear Ms Rosser

Sue Dibb from the Food Commission has sent me a copy of Tessa Martyn's article on soy formulas and, also, a letter addressed from IDFA to you that concerns the same article.

I note that IDFA disagree with Dr Dan Sheehan's assessment that infants fed soy formulas have been placed at risk in a 'large, uncontrolled, and basically unmonitored human infant experiment'. For the record, Sheehan is Director of the United States Food and Drug Administration's National Centre for Toxicological Research Estrogen Base Program and if anyone understands the threat posed by hormonally active agents in the diet of infants it is he, and not IDFA.

However, it is not difficult to qualify Sheehan's comments:

1. Soy formula feeding has been conducted on a very large scale. Current estimates are that 25% of US formula fed infants are given a soy formula and over the last forty years the number of infants fed soy formulas amounts to several million. There can be little doubt that a very large number of infants have been exposed to high dietary levels of the soy phytoestrogens.
2. The exposure of infants fed soy formulas to phytoestrogens has also been uncontrolled in not only the manufacturing, but also in the regulatory and the scientific sense. How long have soy formula manufacturers known about the presence of hormonally active agents in their products? One can only guess. It is certain, however, that the activity of the soy phytoestrogens has been known about for more than 50 years and until soy formula manufacturers were found out there appears to have been no attempt to: quantify the levels of phytoestrogens in soy formulas; assess the degree of risk to exposed infants; inform the public of their presence; to conduct trials that could have answered the questions; or, as an interim precautionary measure, to remove the phytoestrogens from their products.

The basic lack of control of manufacturing practise is ultimately a reflection of the regulations governing soy formulas at the time they were introduced and it is unlikely that soy formulas containing phytoestrogens would gain regulatory approval if they were introduced today. Instead of hiding behind regulations that don't know how to deal with naturally occurring toxins, soy formula manufacturers should simply do what is morally right; act to protect infants from what is now acknowledged as real health risk and remove phytoestrogens from their products. To claim that the removal of phytoestrogens from soy formulas is too difficult makes a mockery of an array of techniques that food technologists have at their disposal. Perhaps what IDFA really means is that the removal of phytoestrogens from soy formulas is too expensive.

3. The exposure to phytoestrogens in soy formulas has also been basically unmonitored. It was not until 1987 that the first report of levels of phytoestrogens in soy formulas was published in the scientific literature and it took a further 10 years for the first studies on phytoestrogen levels in infant plasma to appear. To date there have been few formal reports on the chronic effects of phytoestrogens on infants although studies on adults and laboratory animals are not reassuring.
4. Finally, the exposure to phytoestrogens in soy formulas is an experiment because the effects are literally 'outside the boundaries' of our current knowledge. Why manufacturers of infant foods would want to continue such exposures when results are uncertain and the stakes are so high is beyond me.

Hence, Sheehan's assessment is accurate but IDFA's own claim that soy formulas are 'safe and that infants thrive well on them' is unqualified. The facts are that the soy protein isolate ingredient in soy formulas was denied GRAS status by the USFDA in 1979 because of toxicity concerns and that a GRAS assessment of soy phytoestrogens by Archer Daniels Midland was rejected by the USFDA just last year.

Although they are not acutely toxic and appear to be an adequate source of nutrients for the infant, soy formulas have not been proven to be safe. That would take an in-depth investigation of the long-term effects of soy formula feeding with particular attention being given to markers of hormonal abnormalities. Such research, which soy formula manufacturers are morally bound to conduct, is long overdue. Perhaps it is because such studies would support the findings of preliminary reports that show associations between sexual, developmental and thyroid disorders in soy formula fed infants.

Yours sincerely

Mike Fitzpatrick PhD