Phytoestrogens

An assessment of the potential risks to infants associated with exposure to soy-based infant formula

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In summary, assuming that the assumptions taken from the literature are valid, the soy formula would provide phytoestrogens to infants consuming 1L milk daily with at least 24 000 ng of oestrogen-equivalent material compared to 100 ng /day of endogenous oestrogens from breast milk. Therefore, soy-formula provides at least 240 times higher 'hormone' level than breast milk. At parturition, the levels of oestrogens in breast milk may approach the levels found in soy formula, but these levels persist in humans only for a very short time after birth.

5.4 Summary of dietary exposure of infants

Infants are exposed to approximately 47 mg isoflavone/day from soy-based infant formula, which is similar to the daily exposure levels in adults consuming soy foods. Adjusting for body weights, the upper level of dietary exposure is about 9 mg/kg bw/day in 6 kg infants, compared to about 0.7 mg/kg bw/day in 65 kg adults, a factor of thirteen.

Infants fed soy food have high levels of plasma phytoestrogens. When converted to oestrogenic activity, these levels are about 20 times higher than the infant's endogenous 17β-oestradiol levels (using 1,000-fold scaling factor to convert phytoestrogens to 17β-oestradiol equivalents). The dietary exposure and the plasma level data indicate that infant are able to take up phytoestrogens from their gut at a rate similar to that in adults. The consequent hormonal 'load' is therefore much higher in infants than that in adults consuming soy foods.

Soy-formula provides infant consuming 1L of formula daily wit at least 240 times higher 'hormone' levels than breast milk. At parturition the levels of oestrogens in breast milk may approach the levels found in soy formula, but these levels persist in humans for only a very short time after birth.

6 RISK ASSESSMENT

There is concern that human exposure to phytoestrogens via soy based infant formula, during the first year of life, has the potential to adversely affect subsequent sexual development and fertility.

The toxicological and dietary exposure data on the exposure of infants to phytoestrogens is insufficient for risk assessment. In particular, data on absorption and pharmacokinetics and bioavailability of phytoestrogens in infants precludes a complete toxicological analysis of phytoestrogens in infants.

While it is clear that phytoestrogens pose a potential hazard to the consumer of soy foods, they are also suggested to have benefits. The hazard consists of the potential changes in hormonal levels in adults and infants, and includes effects arising from oestrogen agonism;