

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

WORKING GROUP ON PHYTOESTROGENS

Submission from Infant and Dietetic Foods Association (received 14/08/00)

Background

1. The Infant and Dietetic Foods Association (IDFA) is the UK trade association representing manufacturers of infant and dietetic foods. The submission contains a letter and a document titled 'Phytoestrogens and Soya Infant Formulas' summarising IDFA's position on the safety of soya-based infant formulae.

Submission

2. IDFA state that standards for composition, labelling and marketing are specified in UK legislation (Infant Formula and Follow-on Formula Regulation (SI No 77 1995 & 1997 amendments) based on European Directive 91/321/EEC. In the UK around 3% of formulae fed infants are given soya formulae & 80% of these are by prescription. IDFA support the advice given by the Department of Health (July 1996): "Soya infant formulas should only be used on the advice of health professionals and that those parents who have been advised by their doctor or health care professionals to feed their baby with soya-based infant formula should continue to do so."

3. IDFA reiterate the isoflavone intake estimate for infants fed on soy-based formulas (4mg/kg bw/day during the first 4months of life) provided by MAFF (November 1998). They state that phytoestrogens are very weak estrogens and effects are dependent on a number of factors such as species, age, dose & duration of exposure. IDFA suggest that infant exposure to phytoestrogens does not necessarily imply biological or clinical activity & there is no evidence to date indicating the occurrence of isoflavone-mediated estrogenic effects in infants fed soya formulae (Setchell *et al*,1997; Cruz *et al*,1994). A review by Klein (1998) is highlighted which suggests isoflavones are consumed by millions of infants with no reports of adverse effects on growth, timing of puberty & fertility.

4. IDFA state that the effect of soya-based formula consumption on thyroid function has also been well studied but many of these studies are inconclusive and have not established a cause and effect relationship (Divi *et al*, 1996; Fort *et al*, 1990). IDFA point out that since the 1960s soya formulae have been supplemented with iodine & that problems with thyroid function would have been expected to show up in studies of infant growth.

5. IDFA state that they are unaware of any studies that link the consumption of soya infant formula to changes on the onset of puberty & that studies of delays in puberty are inconclusive. They highlight two studies. Biro F (1995) examined the effect of steroidal hormones on male pubertal maturation. The authors concluded that

there is no evidence for a change in the onset of puberty in boys over the past 30 years. The study did not study phytoestrogen intake. Freni-Titulaer *et al* (1986) investigated the association between onset of premature thelarche and consumption of soya-based formula. IDFA suggest the results of the two studies are inconclusive & that the increased incidence of early onset of puberty in girls is due to improved nutrition.

6. IDFA highlight studies that suggest phytoestrogens may be beneficial to health, in particular studies suggesting a chemoprotective role for genistein (Murril *et al* 1996; Lamartiniere *et al* 1995). These studies were included in the paper on beneficial effects (PEG/2000/16).

7. Reference is made to a retrospective study conducted in Iowa comparing adults fed soya-infant formulas with those fed cows-milk infant formulae. This study is considered in detail in submission PEG/2001/11. IDFA also refer to a study suggesting soya infant formulas do not constitute a large enough source of estrogenic compounds to invoke an adverse effect in the reproductive tract of mature mice. This study is unpublished and cited as a private communication from Milligan and Pocock.

8. IDFA conclude that on the basis of the clinical evidence presented soya infant formulae are safe and that current concerns are unfounded. Although a theoretical risk has been postulated, IDFA suggest there is no clinical evidence to show that infants fed soya infant formulas are at risk & there is no medical or scientific basis on which to recommend changes to soya infant formulae.