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# Paediatric Specialist Group Position Statement: Use of Infant Formulas based on Soy Protein

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# Paediatric Group Position Statement

## Use of Infant Formulas based on Soy Protein for Infants

### October 2010

Update 24 April 2019

The 2010 position statement from the Paediatric Group outlined the findings of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) 2003 report on phytoestrogens and health and described the evidence at the time. The recommendations made in 2010 are still relevant today.

Although a recent study has shown that infant soya formulas can support normal growth and development in full-term infants (Vandenplas et al 2014), neither the American Academy of Pediatrics (AAP) (Bhatia & Greer 2008) nor the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) (Agostoni et al 2006) have changed their position that there are very few indications for the use of soya formulas in infant nutrition.

COT has undertaken a review of soya phytoestrogens (COT 2013) and their conclusions are included in the most recent publication, 'Feeding in the First Year of Life' from the Scientific Advisory Committee on Nutrition (SACN 2018):

*Soya - There is some uncertainty about the safety of soya-based formula and there is no scientific basis for a change in the current government advice: there is neither substantive medical need for, nor health benefit arising from the use of soya-based infant formula and it should only be used in exceptional circumstances to ensure adequate nutrition.*

*Infant formula (based on either cows' or goats' milk) is the only suitable alternative to breast milk for babies who are under 12 months old. The use of soya-based formula should only be on medical advice and the possible health effects of soya-based formula should be kept under review.*

A useful review article on phytoestrogens and soya infant formulas (Testa et al 2018) is recommended reading.

# **Paediatric Group Position Statement Use of Infant Formulas based on Soy Protein for Infants October 2010**

## **Executive Summary**

There is evidence of potential risk to health of infants fed soy infant formulas. These guidelines provide a summary of the evidence and guidance on the safe clinical use of soy formulas for infants under and over the age of 6 months. Health professionals who advise on infant formulas should be aware of this information.

In May 2003 COT (Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment) published a final report on phytoestrogens and health. COT's recommendation following their comments on recent studies on the effects of soy based infant formulas was as follows:

“The Working Group considered that the findings from these studies [outlined below] do not provide definitive evidence that phytoestrogens present in soy-based infant formulae can adversely affect the health of infants. However, the findings, together with those from studies on the mechanism of action and biological activity of phytoestrogens reviewed in this Report, provide evidence of potential risks. For this reason, the Working Group expressed concern about the use of soy-based infant formulae. The Working Group noted that the Scientific Advisory Committee on Nutrition (SACN) expressed similar concern when considering evidence presented in this Report. SACN also considered there to be no substantive medical need for, nor health benefit arising from, the use of soy-based infant formulae. However, it was noted that soy- based infant formulae were the only vegan infant formulae option available if babies were not exclusively breast fed. In light of the concerns expressed, the Working Group recommends that the Department of Health review current advice on the use of soy-based infant formulae.”

## Evidence

Since the COT report of 1996, two studies raised concern over the possible long-term effects of using soy formula in infancy. These relate to a significant increase in prolonged (0.37 days) and painful menstruation in adult women fed soy formula as infants (Strom et al 2001) and increases in the number of Leydig cells in the testes and suppression of the testosterone rise in neonatal marmosets partially fed soy formula (Sharpe et al 2002) compared with cows milk based formula.

The paper (2006) produced by the National Toxicity Program Centre for the Evaluation of Risks to Human Reproduction (NTP-CERHR) also suggests that isoflavones are present at similar blood concentrations in infants fed soy formula as in rats exhibiting adverse developmental effects.

Together with continued concern around the relevance of the Sharpe study, the possibility of adverse effects in soy based infant formula cannot be dismissed.

The Paediatric Group believes that these studies do give rise for concern, but that more extensive studies (and particularly more long-term studies) are needed to clarify the safety of soy based infant formulas

## Safety of Soy in Infants

As a precautionary measure, the Paediatric Group recommend that use of a soy based infant formula as first line treatment should be discouraged during the first six months of life for the following reasons:

Infants receiving soy based infant formula as a sole source of nutrition between the ages of 0-6 months will consume between 6-12 mg isoflavones per kg body weight/day (Setchell et al 1998). Permanent changes due to phytoestrogens are most likely to occur during this developmental stage of 4-6months.

Some infants with cow's milk allergy may also be sensitised to soy protein, particularly below the age of 6 months (Klemola 2002). The prevalence of concomitant soy allergy in infants with cow's milk allergy varies between IgE and non-IgE mediated disease (Agostoni 2006). It ranges between 10% and 14% in infants with IgE mediated allergy (Klemola 2005;Zeiger 1999) but in non IgE mediated cow's milk allergy it is significantly higher (up to 50%), especially in enterocolitis/ enteropathy syndromes (Agostoni 2006). Soy formula is not recommended before six months of age in children with food allergy (Turck 2007). This recommendation would clearly extend to soy products such as desserts and cheeses as well as soy based infant formulas.

## Clinical Need

The Paediatric Group acknowledges that there is a clinical need for feeding soy based infant formula in the following groups as any potential risk as outlined above is outweighed by the risk of withholding the formula.

Infants with cows' milk allergy/intolerance who refuse extensively hydrolysed/elemental formulas. Despite perseverance, some infants will refuse to take extensively hydrolysed/elemental formulas, although this is relatively rare in infants under six months as palatability of these formulas has improved in recent years.

Vegan mothers - these mothers should be strongly encouraged to breast feed, but if they are unable to breastfeed or choose not to do so, soy formula would be the appropriate choice

Galactosaemia – some units consider the lactose content of low lactose formulas too high for the treatment of galactosaemia and the use of extensively hydrolysed formulas not appropriate for this condition. Clearly, for these infants any potential risk of phytoestrogen intake is far outweighed by the risk posed by inappropriate treatment of their galactosaemia.

Any changes to availability of soy based infant formulas (e.g. Prescription only, ACBS) must reflect the clinical need of the above groups.

## **From the Age of Six Months**

From the age of six months soy formulas can be used for the treatment of cow's milk protein allergy/intolerance and lactose intolerance where soy is being considered/used in the weaning diet. The risks after the age of six months are likely to be reduced as the dose of phytoestrogens per kg body weight will be lower as the infant begins to take solids. Also, the infant's potentially vulnerable organ systems are likely to have matured by this age, therefore reducing the risk of any long-term harm.

Previous research expressed concerns about soy formula increasing the risk of developing peanut allergy (Lack 2003). However, a subsequent study concluded that the use of a soy formula during the first 2 years of life did not increase the risk for development of peanut-specific IgE antibodies or of clinical peanut allergy at age 4 years (Klemola 2005).

## **In Summary**

Breastfeeding should be strongly encouraged as providing the safest, most nutritionally adequate form of feeding for most infants.

Dietitians should discourage the use of soy protein in children with atopy or cows' milk allergy in the first 6 months of life to avoid sensitisation to soy protein and exposure to phytoestrogens while organ systems remain at their most vulnerable. This would include soy infant formula and soy products such as desserts etc.

When a soy based infant formula is used, parents should be informed of current findings relating to phytoestrogens and health and on the clinical need for soy formula. Any parent choosing to refuse soy for their infant should be supported in their decision.

Soy formulas are not recommended for premature infants

More research into the long-term effects of phytoestrogen exposure in infants is needed and into whether any adverse effects are dose related.

This position statement will be reviewed as further evidence becomes available.

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