

**SOYA INFANT FORMULAS AND THE COT REPORT ON PHYTOESTROGENS****SUMMARY**

- Current Department of Health advice on soya infant formulas is: "Soya infant formulas should only be used on the advice of health professionals and those parents who have been advised by their doctor or health care professional to feed their baby with soya-based infant formula should continue to do so."
- IDFA is reassured by the recent COT report on 'Phytoestrogens and Health' which, having reviewed the scientific evidence on phytoestrogens and soya infant formulas, found no evidence to demonstrate that soya infant formulas are unsafe.
- Despite this lack of evidence both COT and SACN expressed concerns about the usage of soya infant formulas because of 'potential risks'. In addition, SACN have questioned the medical need for, and health benefits of, soya infant formulas. As a result the COT has recommended that the Department of Health should review its current advice on the use of soya infant formulas.
- IDFA believes soya infant formulas are safe and infants thrive on them. They have been used for over 40 years and there is no evidence of adverse effects in human infants, either in the short or long term. The COT report confirms this. The risk to health seems to be hypothetical and the recommendation to review DH advice based on an over-precautionary approach rather than new evidence.
- IDFA is particularly concerned about advice to health professionals and parents which suggests that formulas based on cows' milk protein hydrolysates are always more appropriate than soya infant formulas. Such advice could jeopardize the nutritional health of some infants as well as having financial implications for parents and the NHS.

**Introduction**

A recent report on 'Phytoestrogens and Health' from the Committee on Toxicity in Food, Consumer Products and the Environment (COT) has reviewed the scientific evidence on phytoestrogens and soya infant formulas. IDFA is reassured by the findings of the COT review which found no evidence to demonstrate that soya infant formulas are unsafe.

Despite this lack of evidence the COT expressed concern about the use of soya infant formulas because 'their findings, together with studies on the mechanism of action and biological activity of phytoestrogens reviewed in this report provide evidence of *potential risks*' (emphasis added). The Scientific Advisory Committee for Nutrition (SACN) expressed similar concerns and questioned the medical need for, and health benefits of, soya infant formulas. As a result the COT has recommended that the Department of Health (DH) should review its current advice on the use of soya infant formulas.

IDFA believes that soya infant formulas are safe and infants thrive on them. As responsible manufacturers concerned with infant nutrition and welfare, we continue to monitor research on this topic. The COT confirms that there is no convincing evidence that they cause any adverse effects in humans infants, either short or long term. The risk to health seems to be hypothetical and the recommendation to review DH advice based on an over-precautionary approach rather than new evidence.

## Research

Earlier concerns about phytoestrogens have focused on immune function, thyroid function, reproductive function and fertility. With respect to immune function, the COT considered that current research provided reassurance that phytoestrogens in soya do not have a significant impact on the immune function of children.

On thyroid function, the COT commented that there was little published information to suggest that phytoestrogens affect thyroid function in healthy infants fed soya infant formulas. However, they recommended that health professionals should be advised of the potential interactions between phytoestrogens and thyroid function and that it would be appropriate to monitor those infants with congenital hypothyroidism (a very rare condition) who are fed soya infant formulas to establish susceptibility.

On fertility and reproductive function the COT focused on two studies:

1. Sharpe et al (2002)<sup>1</sup> showed that soya infant formulas suppressed the neonatal testosterone surge suggesting that feeding with soya infant formulas may alter some parameters of reproductive health during the neonatal stage. However, the study has several limitations in that:

- Some of the results were unexpected and need to be repeated to assess whether they are a true effect.
- The study was carried out on marmosets and the same effects in humans cannot be assumed;
- Marmosets exhibit considerable between animal variability. Although the researchers have tried to address this, the study still uses relatively small numbers of animals;
- Other important parameters which were not measured may have been involved;
- There were no naturally fed concurrent controls in the study;
- Although there was no significant difference in weight gain during the study there was a significant difference in the amount of soya infant formula consumed compared to cows' milk based formula. In previous studies this has been found to significantly affect the results.

The authors themselves state that it is unclear whether these effects would result in untoward consequences in humans and speculate that the effects could also be positive. The COT acknowledged that this work is still in progress and no definitive conclusions can be made about likely health implications. SACN noted that the results were paradoxical and that there were no naturally fed concurrent controls in the study.

2. Strom et al (2001)<sup>2</sup> – This retrospective study was carried out on young adults who as infants had participated in feeding studies carried out by the University of Iowa. This study also has its limitations, in that it was based on recall and did not include any direct measurements of hormone levels or other parameters, but it is the only long term study to have been carried out in humans. The study found only two differences out of 40 outcomes measured, i.e. slightly longer menstrual cycle and a greater discomfort during menstruation in women in the soya group. The researchers felt that the few observed significant differences that were found were probably too small to have clinical significance. They concluded that exposure to soya infant formulas does not lead to different general health or reproductive outcomes and that the findings were very reassuring about the safety of soya infant formulas. Surprisingly, SACN felt that the study raised 'significant concerns' and the COT concluded that it was difficult to draw conclusions from the results of a single study.

## IDFA concerns

IDFA believes soya infant formulas are safe and infants thrive on them. They have been used for over 40 years and there is no evidence of adverse effects in humans. The COT report confirms this. They are only used by a small proportion of UK babies and current advice, which is reflected on product package and information, is that they should only be

used on the advice of a health care professional. Currently around 80% of UK sales are on prescription.

IDFA is concerned that any action taken on the use of soya infant formulas should be proportionate to the risk and is particularly concerned by SACN advice that there is no medical need for, or health benefit from soya infant formulas. Currently SACN and the Food Standards Agency are suggesting that 'more suitable alternatives' to soya infant formulas are those based on cows' milk protein hydrolysates. IDFA believes this advice, is unnecessary and, if translated into practice, could jeopardize the nutritional health of some infants.

Soya infant formulas are currently recommended and used for different reasons including:

- lactose intolerance,
- cows' milk protein intolerance,
- galactosaemia and galactokinase deficiency,
- where there is a family history of cows' milk intolerance, and
- as the only choice for vegans who are not exclusively breastfed.

The alternatives include lactose-free formulas, extensively hydrolysed formulas, partially hydrolysed formulas, and galactose-free formulas. None of these alternatives can directly replace soya infant formulas in all instances. For example partially hydrolysed formulas, by their nature, contain some lactose and cows' milk protein and are recommended only for those at risk of allergy rather than the dietary management of proven food intolerances. They are not suitable for infants who are allergic to cows' milk protein or those with galactosaemia. Infants with proven allergy to cows' milk protein can usually only be fed extensively hydrolysed cows' milk formulas or semi-elemental products. Neither partially nor extensively hydrolysed formulas are very palatable and, therefore, they are not always well tolerated by infants. Any recommendation that encourages the use of less palatable products may have implications for the nutrition of those infants who would otherwise have been fed very successfully on soya infant formulas.

There are also cost implications. Many of these alternative formulas are expensive. Extensively hydrolysed formulas, for example, are two to three times the cost of soya infant formulas. This expense would have to be borne by parents, or by the NHS if the product is prescribed. Fortunately, both the COT and SACN acknowledged that for vegan infants who are not breastfed, there are no other suitable alternatives. However, if faced with expensive, relatively unpalatable alternatives, vegan parents are likely to give their infant ordinary unfortified soya drinks which would not provide adequate nutrition.

As responsible manufacturers concerned with infant nutrition and welfare, we continue to monitor the research on this topic. IDFA remains unconvinced of the need to change current DH advice regarding the use soya infant formulas. Parents and health professionals should continue to follow current DH advice:

*"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 professional to feed their baby with soya-based infant formula should continue to do so."*

#### References

1. Sharpe et al (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' Human Reproduction Vol 17 No 7 pp1692-1703.
2. Strom et al (2001) 'Exposure to soy-based formula in infancy and endocrinological and reproductive outcomes in young adult-hood.' JAMA, 286:807-814.