



Infant feeding

Artificial baby milks: how safe is soya?



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UK toxicology experts have recently confirmed concerns over the potential health risks of soya-based artificial baby milks. This may come as news to many – especially health professionals who freely recommend it, or parents who can buy it off the shelves (no questions asked) believing it to be a healthy option. Soya is generally viewed as a healthy food, and for adults there are some reported health benefits. However, human infants were 'designed' to drink human milk, and soya-based milk products are a far cry from breast milk.

Concerns

The list of concerns about soya-based artificial baby milks is extensive: the high levels of phytoestrogens, the possible presence of genetically modified (GM) soya, the glucose content and the large quantities of metals such as aluminium, not to mention the fact they do not contain any of the health-protecting immune factors and live cells that breast milk has in abundance (New Zealand Ministry of Health, 1998; Baby Milk Action, 1994).

It is estimated that 2% of all infants in the UK are fed soya-based milks (Ministry of Agriculture, Fisheries and Food (MAFF), 1998; Hamlyn et al, 2002). The soya-based baby milk market in the UK is worth approximately £6 million (the total baby milk market is worth over £150 million (Unsworth, 1998)).

In recent years the possible risks associated with the use of soya products for infants have had much media attention. Headlines have included: 'Is baby food really safe? New GM shock' (*Daily Express* 17 February 1999),

'What your baby's drinking now: genetically altered soya beans, squeezed tuna fish heads?' (*The Observer* 21 December 1998) and 'Warnings on danger of soy formula milk' (*Sunday Herald* 25 August 2002).

It is all health professionals' responsibility to keep up to date in all areas, and infant feeding is no exception. This article aims to outline some of the evidence about the risks involved in using soya – not only when the artificial baby milk is soya-based, but also when soya is used as an ingredient in standard modified cow's milk, usually in the form of soya lecithin (an emulsifier). The two areas of concern addressed here are the presence of GM soya, and high phytoestrogen levels.

Genetically modified soya in baby milks

Advances in biotechnology continue at a fast pace – but at what cost? Are the companies involved (such as Monsanto and Novartis) running before they can walk? The ongoing debate about the use of genetically modified (GM) products in foodstuffs has highlighted the extent to which consumers have been kept largely in the dark.

GM products, especially soya and maize, are now in so many products that it is difficult to avoid eating them, and baby milks and foods are no exception. Infants are particularly vulnerable as they have no choice – their parents choose for them.

Scientists have been debating the safety of GM products for years. Some claim that they cause no harm, others believe that the use of GM foods could create new toxins, damage the immune system and possibly cause cancers and allergies.

Of crucial importance in this debate is the fact that adults have a far more varied diet than infants, so GM soya, or even traces of GM soya, are likely to affect infants to a much greater degree. For infants fed exclusively on soya-based baby milk, soya constitutes practically all of their diet. The effects of this on the development of the child, both in the short and long term, is unknown. However, infants are thought to be more susceptible to harm because their immune systems are immature.

Picture: Charlotte Beniest/VBBB-IBFAN



No formula milk can match the benefits of breast milk



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Under European Union (EU) legislation passed in 1998 it is a legal requirement for producers to state on the label if food contains GM products. However, there are loopholes in the legislation, which means that ingredients such as additives and lecithin are not included. So companies do not have to label their products as containing GM soya if they only contain soya lecithin.

In 1999 Baby Milk Action, a UK-based group campaigning for safer infant feeding, surveyed the leading UK artificial baby milk companies to find out if they claimed their artificial baby milks (both soya-based and modified cow's milk), were GM free or not. This survey was conducted in response to numerous calls from worried parents.

At that time Heinz Farleys, Cow & Gate and Milupa claimed that they did not use soya from GM sources. Mead Johnson failed to respond and SMA admitted that they had used GM soya in 1997, but withdrew it due to consumer concern (Baby Milk Action, 1999).

In October 2002 the companies were asked once again whether or not they used GM soya. This time Mead Johnson did reply, saying they did not use GM soya in Prosobee (although the Greenpeace True Food Network believes otherwise (see www.truefoodnow.org), but SMA declined to answer.

This is worrying, not only in the light of SMA's past history of using GM soya in artificial baby milks, but also because their parent company Wyeth has sponsored research for a company called PPL Therapeutics in Virginia, US. A PPL spokesperson, David Ayares, said they are aiming to develop 'a completely humanised milk product where you would milk a cow and almost human milk would come out... We now have a mini-herd of transgenic cattle that are making human alphas-lact-albumin... in their milk.' The new GM 'human-cow' milk was due to be on the market midway through 2002 (Baby Milk Action, 2000).

At the dawn of a new millennium it is science fiction at its most scary that such a basic physiological, purely natural function and fluid is being replaced by milk from transgenic cows.

Investigative science writer Moyra Bremner (1999) writes: 'Solving these problems [increasing the number of babies who

receive breastmilk] by engineering a bull to create cows with human milk is like losing your front door key and hiring a Sherman tank to get you in, instead of going to a locksmith. It may be rather fun to use a tank – but is it wise?'

Phytoestrogens in soya in baby milks

Phytoestrogens are naturally-occurring plant chemicals found in a wide variety of edible plants. They are present in high levels in soya beans (the term isoflavone is sometimes used – these are a class of phytoestrogens that occur naturally in soya beans).

Phytoestrogens have oestrogenic properties, similar yet less potent than the female hormone oestrogen.

Infants being fed soya-based artificial baby milks receive the equivalent level of phytoestrogens (per kg body weight) of several contraceptive pills every day (Irvine C et al, 1995).

Research in the US found that soya-based baby milks contained six to eleven times the amount of phytoestrogens known to cause changes to menstrual cycles (Setchell K et al, 1997). This same study also measured the levels of phytoestrogen in the plasma of four-month-old boys; in those babies receiving soya-based baby milk the levels were 200 times higher than those taking breast milk (levels in breast milk were found to be negligible). The authors conclude: 'Long term follow-up studies are needed to assess the potential benefit or adverse effects of phytoestrogens exposure in early life.'

A bibliography of research studies (dated between 1953 and 2002) looking at the effect of phytoestrogens has recently been compiled (Weston et al, 2002). The studies all demonstrate the adverse effects of phytoestrogens, such as increases in cancers, changes in DNA structure, early thelarche (prepubertal development in girls), fertility problems, liver disease – and the list continues. A total of 59 of these studies have been published during or since 1999 – this alone is evidence that the concern about phytoestrogens in the diet is ongoing.

Despite this, a spokesperson for the Infant and Dietetic Foods Association (IDFA), the organisation representing the artificial baby milk and food industry in the UK, claimed that soya-based artificial baby milks are 'safe and that infants thrive well on them' (Jacobs, 1999).

Although the vast majority of the studies included in the bibliography involved rodents and other mammals, there are obvious concerns about the extent of possible health risks to human infants. Dr Tracie Sheehan of the US Food and Drug Administration's National Center for Toxicological Research stated that infants fed soya-based baby milks have been placed at risk in 'a large, uncontrolled and basically unmonitored human infant experiment' (The Food Commission, 1998).

Government action

In the mid-1980s evidence indicated that there was a 'positive statistical association between premature thelarche and the consumption of soy-based formula, various meat products, and a maternal history of ovarian cysts' (Freni-Titulaer L et al, 1986).

By the early 1990s concern about the effect of dangerously high levels of phytoestrogens in soya-based artificial baby milk had escalated, so in 1992 the Department of Health's (DH) committee on toxicity of chemicals in food, consumer products and the environment (CoT) called for monitoring and review of phytoestrogen levels in soya-based baby milks. The resulting report, commissioned by MAFF, was not released until 1998.

Meanwhile the CoT had reviewed the existing literature and concluded not only that further research was required, but also that the use of soya in baby milks may be harmful. In response to this, in 1996, the DH issued a press release recommending that:

- Infants already being fed soya-based artificial baby milks on the advice of a health professional should continue to do so
- Infants being fed soya-based milks without the advice of a health professional should continue to do so, but, professional advice should be sought.

The DH also reaffirmed that breastfeeding is the best way to feed an infant and can help prevent allergies, and that if an alternative is required then modified cow's milk is preferable for most infants.

Prior to the press release being issued the DH had sent an urgent 'cascade' circular to all health professionals warning of the risks associated with the use of soya-based baby milks and advising that it should only be used on the advice of a health professional in specific circumstances.



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The research funded by MAFF (released in 1998) had measured levels of phytoestrogens in three major brands of commercially available cow's milk formula and six brands of soya-based baby milk bought in the UK between March 1996 and July 1997. The results were similar to those found in the Setchell et al (1997) study. Once again the DH endorsed the advice given in its 1996 press release.

In April 2000, following new research and continuing concern over the health effects phytoestrogens for infants, the CoT convened a working group to advise on the human health implications of dietary phytoestrogens.

One of the main questions to be addressed was: 'On the basis of current evidence, does ingestion of soy-based infant formula pose any risk for human infants?' (Food Standards Agency (FSA), 2002). The draft report was available for consultation for eight weeks from October 2002 (see the website www.foodstandards.gov.uk).

Regarding the specific question of risk to human infants fed soya-based artificial baby milks, the working group draft report had six key points. These are shown in Table 1.

What needs to be done

The remit of the CoT working group was risk assessment. It is up to the FSA and DH to decide, on the basis of this report, what action needs to be taken.

If the FSA follows the recommendations of the CoT working group by ensuring soya-based artificial baby milks are only used when 'indicated clinically', then changes will have to be made to the way that soya-based artificial baby milks are marketed.

At the moment soya-based artificial baby milks are available in supermarkets and pharmacies and are promoted to health professionals. Parents can feed their babies soya-based artificial milk without ever having consulted a health professional and, as the products carry no appropriate warnings, they will be none the wiser about the possible adverse health effects. Parents at particular risk in this category include vegans, those who drink (adult) soya milk and assume that their baby will also gain health benefits from drinking soya-based artificial baby milk, and the seemingly increasing number of parents who have been told (or who believe) their baby is lactose intolerant and therefore needs a dairy-free

substitute for breast milk.

The incidence of true lactose intolerance is low, although advertising by the artificial baby milk companies suggests otherwise. Companies advocate the use of soya and other artificial baby milks as the answer for 'problem babies', rarely warning about the risks. Advertisements in health professional journals tend to gloss over any potential problems with the use of soya and portray it for use in many circumstances such as diarrhoea, colic and eczema. Breastfeeding, particularly exclusive breastfeeding, is proven to reduce the incidence of atopic disease, but this fact is not widely understood or promoted.

The most obvious change necessary in the marketing of soya-based artificial baby milks is that they should become a prescription-only item. This would prevent off-the-shelf purchases and parents using them without having discussed it first with a health professional.

Because there are still so many unknown factors about the effect of soya on young infants, all infants using it should be monitored – this would be easier if the product was only obtained on prescription.

A weaker option is that soya-based artificial baby milks could become an over-the-counter item in pharmacies, like many painkillers. This would mean that the sale of them would be monitored to some degree by pharmacists.

The DH and FSA should ensure that health professionals are provided with clear guidance and information about the possible risks associated with the use of soya-based artificial baby milks. Such guidance should be continuous rather than one-off, so that health professionals can give up-to-date and correct information to parents.

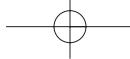
The artificial baby milk companies themselves should ensure that labels and other sources of information highlight both the known and the potential risks of soya products in foods and drinks for infants.

As a precautionary measure the artificial baby milk companies should be required to seek ways of reducing the levels of phytoestrogens in their products – as requested by the MAFF food advisory committee in 1996.

The Food Commission, in their own 1998 investigation, found that companies had failed to respond to this demand and that they 'blocked direct enquiries'. They have

Table 1. CoT working group key points

- Infants fed soya-based artificial baby milks are exposed to the highest concentrations of phytoestrogens (compared to other population groups, e.g. breastfed babies, adults)
- As only one study has specifically examined the long term health effects of soya-based artificial baby milk, it was acknowledged that it was difficult to draw conclusions (particularly as this study relied on recall)
- Health professionals should be made aware of the potential interaction between phytoestrogens in soya-based artificial baby milk and thyroid function. Further, infants with congenital hypothyroidism who are fed soya-based artificial baby milks should have their thyroxin levels monitored
- Human infants fed soya-based artificial baby milks appear to have normal immune function (studies in rodents have shown potentially adverse effects to the immune system)
- The outcomes of an ongoing study looking at the effects of feeding soya-based milks to marmosets (and particularly changes to reproductive health) should be carefully evaluated on its completion
- Finally, and perhaps most importantly, the working group recommended that the advice issued by the DH in 1996 should be amended to state that soya-based artificial baby milks should only be used when 'indicated clinically'. It is also noted that similar advice has already been issued in some countries, eg Australia and New Zealand (in New Zealand the Ministry of Health recommends that soya-based artificial baby milks are only used in very limited circumstances, and always under the direction of a health professional. Even though soya-based baby milks could be used for lactose intolerance, the Ministry states that alternative baby milks exist and their use should be favoured over a soya product. Additionally, infants with hypothyroidism should not be fed soya-based baby milks or foods unless no alternative can be found).



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Picture: Jane Henriques/Baby Milk Action



Breastfeeding is the best option for mother and baby

requested that phytoestrogens are removed immediately from soya-based infant baby milks, as they believe 'it is irresponsible for manufacturers of soya formulas to continue to place infants at unnecessary risk of exposure to phytoestrogens' (The Food Commission, 1998).

In 2002 the Committee on the Convention on the Rights of the Child (the body responsible for ensuring that children can have the highest attainable level of health) specifically recommended that the UK government implemented the WHO International Code of Marketing of Breastmilk Substitutes. If this were done, then parents and health professionals would be spared the potentially misleading information distributed by artificial baby milk companies, and labelling would be improved so as to advise users of the possible health risks of using particular products. This in turn would not prevent genuine scientific and factual information from being given to parents and health professionals.

Midwives are in a key position when it comes to advising parents about infant feeding. This is not an easy task. The journals are full of advertisements – often with scant information, and very little information is available from independent sources.

Midwives need to demand their right to have access to the best available information

and research. Without this, both midwives and parents will remain oblivious to the chemicals and hormones that we are putting into the mouths of our babes.

This is an updated version of an article that appeared in *The Practising Midwife* in June 1999.

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Table 2. Useful websites for further information

- www.soyonlineservice.co.nz
- www.babymilkaction.org
- www.foodcomm.org.uk

UPDATE *** UPDATE *** UPDATE *** UPDATE *** UPDATE ***

Just before this article went to press, the CoT requested that the scientific advisory committee on nutrition (SACN) examine their draft report on phytoestrogens.

The CoT report had stated that soya-based artificial baby milk should only be used 'when clinically indicated'. On this point SACN noted that 'there appears to be no unique clinical indication for soy-based formula' (see the website

www.food.gov.uk/science/ouradvisors/toxicity/cotmeets/cot_2003/107439/agendaTox/2003/03).

This therefore raises the question of whether soya-based artificial baby milks should exist at all, given their potential health risks.

The final report is due out in mid-2003. It will then be up to the FSA and the DH to act on these findings to ensure that parents and infants are protected from an unnecessary health risk.